

Secrets of NIH Small Business Grant Applications

Gregory Milman
National Institute of Allergy
and Infectious Diseases
gmilman@niaid.nih.gov
July 22, 2010





1

Agenda

- Description of NIH SBIR and STTR Grant Programs
- Beware of secrets
- Ways academic investigators can tap into SBIR and STTR grants
- Comparison of award data – SBIR, STTR, and R01
- Budget and fee advice
- Writing for reviewers
- More tips
- Expect award in last quarter fiscal year
- Expect payline 30 to 35
- Shift your career with SBIR SHIFT Award



Particularly important information is highlighted in red



2

SBIR
Small Business Innovation Research

- Business applies for and receives award
- 2.5% of NIH extramural research budget
- About \$575M in FY2009 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



3

STTR
Small Business Technology Transfer Research



- Business applies for and receives award
- 0.3% of NIH extramural research budget
- About \$75M in FY2009 NIH awards
- 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
- Contact PI
 - Must commit 10% effort
 - Need not be employed by business
 - Full-time academic employee allowed
 - Need not receive salary from award



4

STTR Applications Require Extra Effort



- Prior to award but not at time of application both business and research institution partner must sign:
 - An intellectual property agreement (IP)
 - A cooperative R&D arrangement (CRADA)
- Model intellectual property agreement.
 - Obtain legal advice to edit before you sign
 - Obtain exclusive license
 - Agree on IP business brings to partnership
- Virtual companies ineligible
- Conflict of interest concerns associated with equity



5

SBIR and STTR Are Multiphase Programs

- Phase I Awards
 - SBIR Phase I "normally" \$150K for 6 months
 - STTR Phase I "normally" \$100K for 1 year
- Phase II Awards (renewal?)
 - SBIR Phase II "normally" \$1000K for 2 year
 - STTR Phase II "normally" \$750K for 2 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 \$1000K 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.



6

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 (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




7

Revealing Secrets Levels the Playing Field







8

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.

9

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
- Shift careers with NIH SHIFT Award

10

Paradigm SHIFT in Culture



UNIVERSITY	COMPANY
<ul style="list-style-type: none"> ■ Open Ended ■ Basic Research <ul style="list-style-type: none"> – Unpredictable – Can change directions – No promises ■ Long Term Oriented ■ Individual controls ■ Individualistic (investigator) ■ Publication ■ Societal Responsibility 	<ul style="list-style-type: none"> ■ Goal Oriented ■ Develop Product <ul style="list-style-type: none"> – Specific objectives – Specific tasks – Specific endpoints ■ Short Term Oriented ■ Institution controls ■ Hierarchical (team) ■ Confidentiality ■ Proprietary Responsibility

11

FY2009 NIH Phase I Applications




Type	Received	Funded	Award Rate
SBIR All	3361	654	19.5%
Initial	2476	443	17.9%
Revisions	885	211	23.8%
Median Award		\$180K	
STTR All	615	105	17.1%
Initial	392	42	10.7%
Revisions	223	63	28.3%
Median Award		\$172K	
R01 New	22540	3598	16.0%
Median Award		\$370K	







12

FY2009 NIH Phase II Applications

Type	Received	Funded	Award Rate
SBIR All	720	256	35.6%
Initial	471	161	36.7%
Revisions	249	84	33.7%
Median Award		\$491K	
STTR All	106	33	31.1%
Initial	69	21	30.4%
Revisions	37	12	32.4%
Median Award		\$420K	
R01 Competing	6925	2099	30.3%
Median Award		\$366K	




 Oregon Bioscience Association  13 




- ### Budget and Fee Advice
- 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 during 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.
-  Oregon Bioscience Association  14 

Potential NIAID SBIR Funds per Project (Total Cost) SBIR Collaboration for Academic Investigators

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	3	\$1.0M	\$3.0M	\$1.5M
Total	8		\$6.6M	\$3.3M
Average			\$825K	\$413K




* Subcontract could be to an academic investigator
Median competing R01 = \$381K/year (Total Cost)




 Oregon Bioscience Association  15 

- ### 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!
-  Oregon Bioscience Association  16 

Application Components Relating to Review Criteria

Pages	Section
N/A	Title (Significance and Innovation in 81 characters)
N/A	Project Summary/Abstract (All Criteria)
1	Introduction – Resubmitted or New Applications Only
1	Specific Aims (Significance, Innovation, Approach)
6	Research Strategy <ul style="list-style-type: none"> Significance Innovation 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	Facilities and Other Resources – Environment. Explain how resources contribute to the project.
4	Biographical Sketch – Investigators, Environment <ul style="list-style-type: none"> Personal Statement –Qualifications for the Project Publications – No More than 15 Relevant to the Project

 Oregon Bioscience Association  17 

- ### 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.)
-  Oregon Bioscience Association  18 

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.



19

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?



20

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.






21

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



22

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 the 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."



23

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



24

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



25

Approach – Research Design



- Describe your research design and methods in parallel to your Specific Aims and include a timeline in table or diagram format. (**Innovation**)
- Include for each set of experiments:
 - 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



26

**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.



27

**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?



28

**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**



29

More Tips

- Propose just enough work in Phase I
- Select project best for your company
 - Usually 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



30

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

Review Committee

Your Application

NATIONAL INSTITUTES OF HEALTH

Oregon Bioscience Association

31

Stick to the Omnibus Solicitation
Master the Beginner Slopes First

Fast-Track

Other FOAs

Omnibus Solicitation

NATIONAL INSTITUTES OF HEALTH

Oregon Bioscience Association

32

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

NATIONAL INSTITUTES OF HEALTH

Oregon Bioscience Association

33

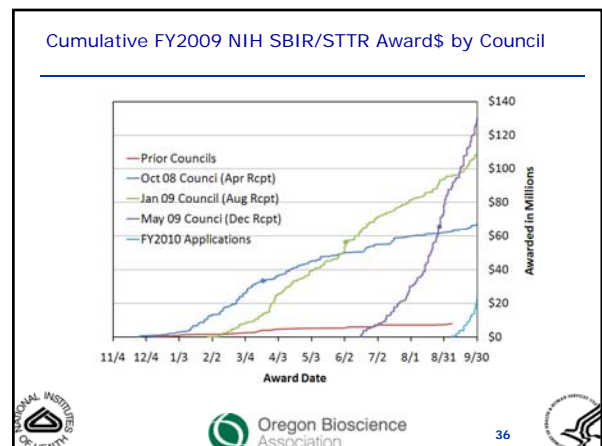
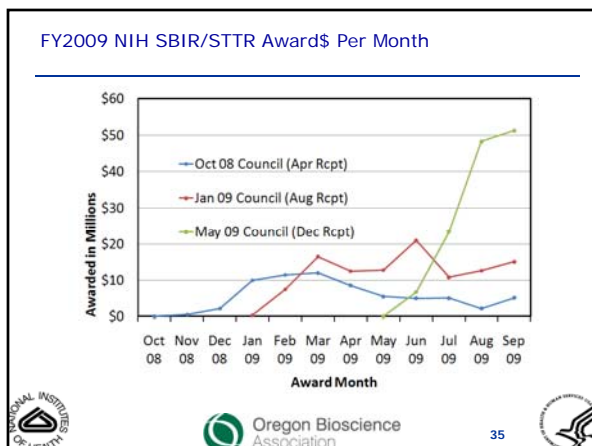
Just-in-Time – Our Time, Not Yours

- 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

NATIONAL INSTITUTES OF HEALTH

Oregon Bioscience Association

34



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

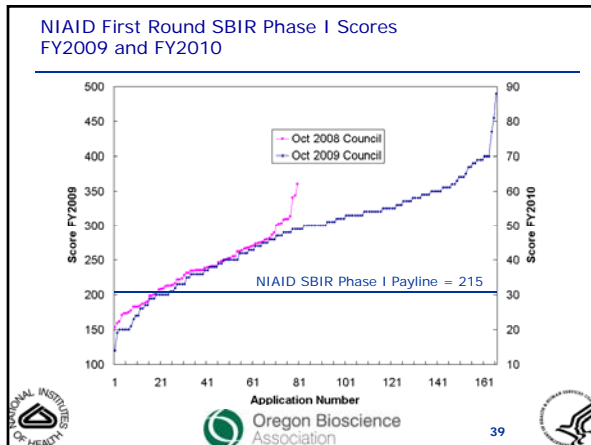
Oregon Bioscience Association 37

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

	<u>FY2009 1st Round</u>	<u>FY2010 1st Round</u>
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

Oregon Bioscience Association 38



SHIFT Award: Small Businesses Helping Investigators to Fuel the Translation of Scientific Discoveries (R43/R44)

- <http://grants.nih.gov/grants/guide/pa-files/PA-10-122.html>
- PI SHIFT requirement
 - At time of application, contact PI must be primarily employed by research institution.
 - At time of award, contact PI must be primarily employed by small business.
 - No new investigator advantage or disadvantage.
- Budget – Higher than "Normal"
 - Phase I up to \$200K/year for 1 or 2 years
 - Phase II up to \$750K/year for 2 or 3 years
- Topics – Any within the mission of the twelve participating Institutes and Centers

Oregon Bioscience Association 40

Eleven NIH Institutes and Centers Participating in SHIFT

NHLBI	National Heart, Lung, and Blood Institute
NIA	National Institute on Aging
NIAAA	National Institute on Alcohol Abuse and Alcoholism
NIAID	National Institute of Allergy and Infectious Diseases
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Diseases
NICHD	National Institute of Child Health and Human Development
NIDA	National Institute on Drug Abuse
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIGMS	National Institute of General Medical Sciences
NCCAM	National Center for Complementary and Alternative Medicine
NCRRT	National Center for Research Resources

Oregon Bioscience Association 41

SHIFT Connector: Bringing Academic Investigators and Companies Together

- <http://funding.niaid.nih.gov/ncn/sbir/shift>
- NIAID hosts pilot SHIFT Connector site to help investigators and businesses connect for SHIFT award applications.
 - Academic investigators post product-oriented research topics
 - Businesses post their diseases and products
 - Networking sponsors post network contact information


Oregon Bioscience Association 42

SHIFT Connector: Academic Investigators

- <http://funding.niaid.nih.gov/ncn/sbir/shift/reslist.htm>
- Site for academic investigators who are interested in working in business to post proposed project titles. They can use unidentifiable email addresses to protect their identity.

Email Address*	Proposed Project Titles*	Areas of Expertise
Example: greatPI@gmail.com	Example: Antigen Detection Assay for the Diagnosis of Visceral Leishmaniasis	Example: Parasitology, immunology, bioengineering


*Required field



SHIFT Connector: Businesses

- <http://funding.niaid.nih.gov/ncn/sbir/shift/bizlist.htm>
- Site lists diseases and products of interest to businesses who are looking to recruit a scientist from academia.


Business Name, Link	Diseases and Products	Contact Email
Celadon Laboratories , Hyattsville, MD	Products: • Primer and probe design genotyping software • Immunoassay software	Raymond J. Peterson, peterson@celadonlabs.com
QuantaSpec Inc. , Burlington, VT	Diseases: • Malaria • Nosocomial infection • Tuberculosis • Chlamydia • Cancer Product: • Automated reagentless diagnostics	Kenneth A. Puzey, kpuzey@quantaspec.com



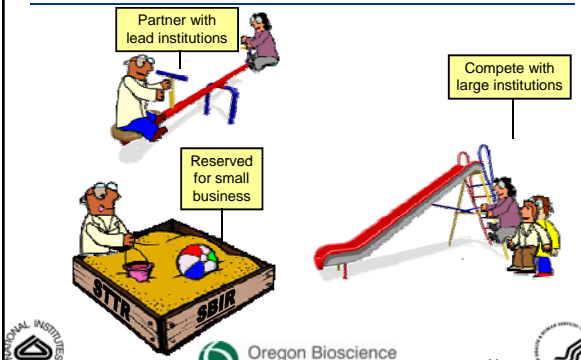

SHIFT Connector: Networking Sponsors

- <http://funding.niaid.nih.gov/ncn/sbir/shift/network.htm>
- Site that lists organizations that help academic investigators and businesses connect and posts networking events.

Networking Sponsor and Link	Location	Contact Email
BioForward	Wisconsin	brenk@bioforward.org
MichBio	Michigan	info@michbio.org
Tennessee Biotechnology Association	Tennessee	rolwing@tnbio.org
Oregon Bioscience Association	Oregon	john@oregonbio.org
Southern California Biomedical Council	So. California	scbc@socalbio.org




Think Outside the SBIR & STTR Sandbox


Consider Other Award Mechanisms

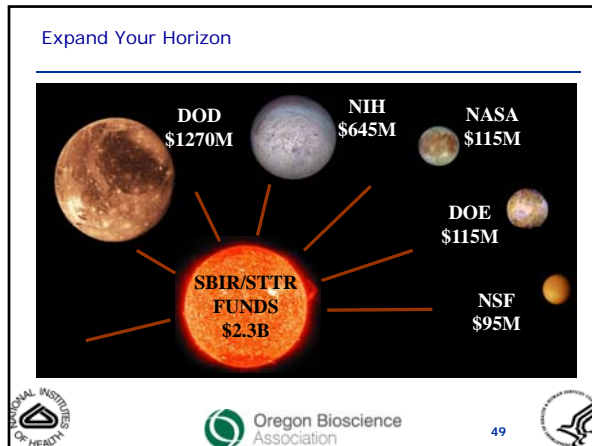
- Small Grant Program (R03)
 - \$50K/year for up to 2 years.
 - Check participation by NIH Institute/Center.
 - Check Funding Opportunity Announcements.
- Basic Research Grant (R01)
- Exploratory/Developmental Grants Phase I (R21)
 - ~\$275K/2years.
 - Check Funding Opportunity Announcements, e.g., NIAID 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.



Qualifying Therapeutic Discovery Project Program

- Tax credit or grant of up to 50% of qualified private investment, up to \$5M per firm.
- Applications had to be postmarked by July 21, 2010.
- IRS will issue certifications by October 29, 2010.
- http://grants.nih.gov/grants/funding/QTDP_PIM/index.htm





Links to More Information

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

Advice on SBIR and STTR Applications
<http://funding.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

NATIONAL INSTITUTES OF HEALTH

Oregon Bioscience Association

50