

Advice on NIH SBIR & STTR Grant Applications
Basic Information



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July 2009

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Hello, I am Gregory Milman. In these presentations I provide advice on the of NIH Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR) programs. This module is titled Basic Information. It was updated in July 2009. Send your comments, suggestions, and criticisms to gmilman@niaid.nih.gov.

Why Is This Site Different From All Other Sites? Don't Pass Over These Qs & As



- Why does this site begin with a disclaimer?
 - Opinions are not official.
 - My opinions are not universally shared.
- Why does this site have cartoons?
 - I emphasize concepts.
 - Humor and metaphor are effective communication.
- Why does this site have FY2008 award data?
 - Official sites have instructions.
 - Data indicate what has been successful.
- Why does this site give entrepreneurial information?
 - Academic science faculty are entrepreneurial.
 - Collaboration with companies provides resources.
 - Some faculty may even want to start a company.

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Why is this site different from all other NIH sites?

All other sites provide instructions and helpful hints. I provide advice - guidance and suggestions that are opinions and not facts. In the last 20 years, I have provided advice to hundreds of companies. These presentations enable me to convey this same advice to you.


Why does this site begin with a disclaimer? My opinions are not necessarily shared by everyone including those who may be your reviewers or NIH staff. Since my opinions are not official, it will not help you to declare that you are following advice that you received from me. You can choose to follow my advice or not.

Why does this site have cartoons? I include cartoons on slides to emphasize concepts and to entertain you because humor and metaphor are effective means of communication. Think of the bald cartoon character with glasses as your mentor. Any resemblance between your mentor's appearance and me may or may not be coincidental.

Why does this site have FY2008 award data? Official instructions tell you what to do. Data indicate what was successful in the past but not necessarily the future.

Why does this small business site provide entrepreneurial information for academic faculty? Science faculty, like small businesses, compete for funds and manage laboratory personnel. Collaboration with companies on small business grants can help faculty pursue these goals. Once bitten by the entrepreneurial bug, some faculty want to start their own companies and learn how to begin.

Agenda
Basic Information



- Official source of NIH information
- Innovation and research definitions
- Phase I, II and III descriptions
- Details
 - Small Business Innovation Research (SBIR)
 - Small Business Technology Transfer Research (STTR)
- SBIR and STTR Comparisons

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Agenda - Basic Information

Each module begins with an agenda of the module's topics. The next slide gives a link to basic information covered by NIH.

Definitions of innovation and research are my interpretations. I show that the average Phase I and II length and amount of award differ from the "normal" values described in the official solicitation. I describe flexibility in the NIH SBIR and STTR programs and the advantages and disadvantages of each.

[NIH Small Business Research Funding Opportunities](#)



- 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

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NIH Small Business Research Funding Opportunities

Follow the title link on this slide to the official site for the NIH Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR) programs. There you will find information on eligibility, receipt dates, program descriptions, electronic submission, application review, policy, grant preparation resources, and presentations at NIH small business conferences.

For the most part, I will not reiterate official NIH instructions and guides. Instead, I focus on strategies that may make a difference between your application being funded or not funded. I also focus on Phase I applications with only a few comments on Phase II and Phase II renewals.

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
- See "Writing for Reviewers" module for advice on
 - Significance
 - Innovation

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Innovation and Research Definitions

Your SBIR or STTR project must show innovation and should emphasize research and not development.

"Innovation" could be new technologies, significant improvement of existing technologies, or new applications for existing technologies. Applications showing little innovation will probably not engender much enthusiasm from a review committee.

I emphasize "research" because most reviewers feel that NIH funds should be used for research and not for development. In fact, I would avoid using the word "development" in your application. I define research as the collection and analysis of data necessary to commercialize your product. Research does not necessarily have to be innovative if the product is innovative. For example, safety and efficacy studies for an AIDS vaccine are not necessarily innovative but a vaccine would be.

The "Writing for Reviewers" module contains advice on describing significance and innovation.

SBIR and STTR Phase I and Phase II



- 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 (Experts only)
- 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



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SBIR and STTR Funds Phase I and Phase II

The NIH SBIR/STTR Application Guide states "SBIR Phase I awards normally may not exceed \$100,000 total cost for a period normally not to exceed 6 months, and STTR Phase I awards normally may not exceed \$100,000 total for a period of 1 year. Phase II awards normally may not exceed \$750,000 total (direct costs, F&A/indirect costs, and fee) for a period normally not to exceed 2 years." Congress may revise these guidelines or set statutory limits during SBIR reauthorization.

You should know that in FY2008 the average NIH Phase I award was \$160K per year for one or two years, and the average NIH Phase II award was \$375K per year for two or three years.

Unless Congress changes the statutory limits, I suggest requesting one or two years' funding at no more than \$300K per year. But, do not use this opportunity for higher funding to propose too much work. The purpose of Phase I is to demonstrate the feasibility of Phase II funding. Propose only those milestones whose accomplishment will convince reviewers to award you Phase II funds.

In FY2008 I suggest requesting three years' funding at no more than \$1M per year.

Fast-Track applications, combined Phase I and II, are loads of work to prepare. I suggest you avoid them, particularly in institutes where they are rarely funded.

If your product will require FDA approval, you can apply for a competing renewal, i.e., a second Phase II award. I suggest requesting two or three years of additional funding at no more than \$1M per year.

Commercialization Plan in Phase II



- Remaining steps of commercialization – Phase III
- Commercialization Plan in Phase II or Fast-Track
 - a. Value of project
 - b. Company objectives
 - c. Market, customer, competition
 - d. Intellectual property (IP) protection
 - e. Finance plan for additional funding
 - f. Production and marketing plan
 - g. Revenue stream
- License, merger or acquisition in place of revenue stream, marketing and production
- Brief commercialization plan information in Phase I Background and Significance section

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Commercialization Plan in Phase II

The Omnibus Solicitation describes Phase III as the commercialization steps remaining when government funding ends.

Describe these steps in the Commercialization Plan of your Phase II or Fast-Track application. The Application Guide's seven headings for a Commercialization Plan are: value of project, company, market, intellectual property (IP) protection, finance plan, production and marketing plan, and revenue stream.

Describe your plans to lasso additional funding under Finance Plan.

If your exit strategy for further product development is to sell or license it to another company or merge or be acquired by another company, you should describe the stage in project development when this could occur and any substantiation that your strategy will succeed. Include this information in place of the production and marketing and revenue stream headings.

Although a Phase I application does not have a Commercialization Plan section, I suggest you include one or two paragraphs on commercialization in your Background and Significance section. For example, you could include a sentence each on the value of your project, how it affects your company, the market for your product, your customers and competition, how you will protect your intellectual property, and the financial resources necessary to commercialize your product.

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

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Small Business Innovation Research

There are major differences between SBIR and STTR awards. See the "FY2008 Data" module for details on the number of applications, award rates, and funding.

SBIR awards receive 2.5% of NIH's extramural research budget or about \$550M in FY2008.

In an application with a single principal investigator (PI), the PI must be employed over 50% time by the company.

NIH allow multiple PIs on all grants, usually with different but not necessarily hierarchical responsibilities. A leadership plan defining the responsibilities of each PI is required in multiple PI applications. One PI, designated the Contact PI, is in charge of communication with NIH. The Contact PI on an SBIR grant must be employed over 50% time by the company. An academic investigator can be an SBIR PI on a multiple PI application but not the Contact PI.

SBIR awards normally allow up to 33% subcontracting in Phase I and 50% in Phase II. However, the maximum allowed subcontracting is flexible with appropriate 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
- FY2008 success rates for SBIR better than for STTR
- Cannot switch Phase II applications between SBIR and STTR

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Small Business Technology Transfer Research

STTR applications must include a qualified research partner that conducts a minimum of 30% of the work, measured by percent of total grant funds.

The business must conduct a minimum of 40% of the work in its facilities.

Remaining funds if any may be used for consultants and other subcontracts.

The business and partner must have an intellectual property agreement.

The business applies for and receives the award.

An STTR Contact PI must commit 10% effort, need not be employed by the business, may be an academic employee, and need not receive salary from the award.

STTRs receive 0.3% of NIH's extramural research budget or about \$72M in FY2008.

The funding for SBIRs is about eight times larger than that for STTRs. In FY2008, the number of Phase I SBIR applications was about four times larger than the number of STTR applications. As a result, the success rate for SBIRs was considerably better than that for STTRs.

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

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STTR applications require extra effort

Signatures on the budget page of the application certify that the business will sign an intellectual property (IP) agreement and cooperative R&D arrangement (CRADA) with its research institution partner before an award.

NIH provides a model intellectual property agreement. You should obtain legal advice to edit the model agreement before you sign it.

Research institution partners often demand ownership of the intellectual property developed through STTR funding. I suggest that you include an exclusive license at a reasonable rate in your intellectual property agreement. Also, I suggest that you describe in the agreement any intellectual property that the company brings to the partnership so that its future ownership will not be in doubt.

Be aware that virtual companies do not qualify for NIH small business programs, and grants management staff carefully scrutinize STTR applications.

Be particularly careful to avoid conflict of interest issues if you are the STTR faculty component and also have a financial interest such as equity ownership in the company.

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
- 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 currently not permitted from Phase I to Phase II.

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Advantages of SBIR and STTR Awards

SBIRs have some advantages over STTRs. SBIRs do not require a research institution partner, meaning you have fewer agreements, fewer lawyers, less cost and the company controls all the funds. Past years' success rates are higher for SBIR applications than for STTR applications. SBIRs have flexibility to increase or decrease amount subcontracted. An academic scientist could be better off financially as a consultant on an SBIR award than as a PI on an STTR award.

On the other hand, STTR awards have some advantages over SBIR awards. If a company lacks a credible PI, an academic PI may provide the credibility for funding. An independent PI role may be essential to the academic scientist for tenure or promotion. An academic PI may give the company access to academic facilities, intellectual property, and support. An STTR award allows you to pay a higher percent of a Phase I award to a research institution without special justification.

Changes are currently not permitted from Phase I to Phase II.

Be aware that an SBIR Phase I project can continue only as an SBIR Phase II and not as an STTR Phase II, and vice versa.

More Presentations



TOPICS

- Basic Information
- Managing the NIH Timeline
- Writing for Reviewers
- FY2008 Data
- Tips and Tricks
- More than SBIR/STTR Funds
- Small Business Funds for Academic Investigators

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Thank you for watching this module. Close this window to select another topic.