Advice on NIH SBIR & STTR Grant Applications – Basics

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Hello, I am Gregory Milman. In these presentation modules I provide information on NIH SBIR and STTR programs that may help you prepare your application. This presentation module covers the basics of NIH small business programs and was updated in May 2007. Send your comments, suggestions, and criticisms to gmilman@niaid.nih.gov.

Advice - Opinion About a Course of Action

- Opinions are not facts.
- Based on experience.
- My opinions are not shared by everyone including reviewers and NIH staff.
- Caveat emptor.
- Advice not official - don't quote.

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I provide advice - information and guidance that are opinions and not facts, and certainly not official.

My opinions are based on experience both as an NIH branch chief and, before that, as a successful applicant for NIH small business funds. In the last 18 years, I have provided advice to hundreds of companies. This presentation enables me to convey this same advice to you.

Please remember that my opinions are not necessarily shared by everyone including those who may be your reviewers or your 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.

Caveat emptor applies; chose to follow my advice or not.

I have included cartoons on my slides to help you remember take-home messages.

Any resemblance between my appearance and that of the bald cartoon character with glasses is purely coincidental.

NIH Small Business Programs

- **S**mall **B**usiness **I**nnovation **R**esearch funds support research by business.
- **S**mall Business **T**echnology **T**ransfer **R**esearch funds support collaborative research by business and U.S. research institutions.

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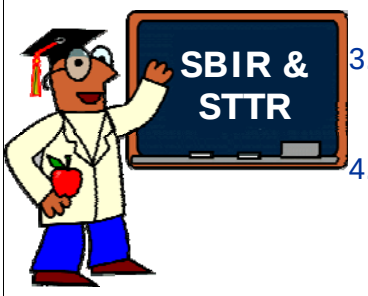
Congress requires that all federal agencies that support outsource research designate a percentage of their extramural research funds for small businesses. Follow the slide title link to learn about the legislation.

Small Business Innovation Research, SBIR funds, support research by a business with or without an academic partner.

Small Business Technology Transfer Research, STTR funds, are also awarded to a business. However, STTR recipients must have a U.S. research institution as a collaborative research partner. Both SBIR and STTR funds may be awarded as grants, contracts, or cooperative agreements.

The advice in my presentation is intended for applicants to the NIH small business grants programs only. My advice is generally applicable for applicants to all NIH Institutes and Centers, called ICs, but I describe some programs specific to the National Institute of Allergy and Infectious Diseases, abbreviated as NIAID or as AI.

SBIR and STTR Instructions



1. NIH Small Business Funding Opportunities.
2. NIH, CDC, and FDA Program Descriptions and Research Topics.
3. Preparing for Electronic Submission.
   A. Grants.gov.
   B. eRA Commons.
4. NIH, CDC, and FDA Omnibus SBIR and STTR Solicitations.
   A. SBIR Program Announcement (PA-07-280).
   B. STTR Program Announcement (PA-07-281).
5. SF424 Application and Electronic Submission Information.
6. NIH Guide Advanced Search (for R41 or R43).
7. Search in Grants.gov (for R41 or R43).

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In my presentations, I focus on topics where my advice may make a difference between your application's being funded or not funded. I also focus on Phase I applications with only a few comments on Phase II. Follow these links for more information.

Link 1 is the official NIH SBIR/STTR site. There you will find links to the latest SBIR/STTR solicitations and instructions for preparing your application. Read the News Flashes and archived News Flashes for the latest notices and updates on policies and procedures.

Link 2 gives official descriptions of NIH, CDC, and FDA small business programs and lists of research topics.

Link 3 provides official advice to help you prepare for electronic submission of your application. You need to register with both Grants.gov and the eRA Commons.

Links 4A and 4B are the parent solicitations for all SBIR and STTR applications.

Link 5 takes you to the official application and electronic submission information.

Link 6 goes to the *NIH Guide* advanced funding opportunities and notices search. Select small business activity codes R41 for STTR and R43 for SBIR.

Link 7 leads to the Grants.gov "Search Grant Opportunities" site for all agencies. Enter R41 as a keyword to search for NIH Phase I STTR opportunities, and R43 to search for NIH Phase I SBIR opportunities.

Small Business Requirements

- Business = For-Profit.
- Principal place of business in U.S.
- SBIR/STTR funded research must be conducted entirely in the U.S.
- Control research facilities where SBIR/STTR research will be conducted.
- Small = 500 or fewer employees in the small business and its affiliates.
- Satisfy U.S. ownership requirement.

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Let me describe what is meant by "small," by "business," by "innovation," and by "research."

The Small Business Administration (SBA) specifies requirements for a small business to qualify for SBIR or STTR funds.

The "business" criterion means you must be "for-profit."

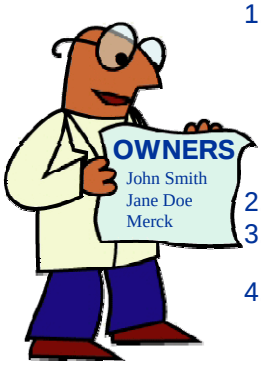
The principal location of the small business must be in the U.S., and all the research supported by NIH SBIR or STTR funds usually must be conducted in the U.S.

The small business must conduct a significant part of the NIH-funded research in facilities that it controls. Failure to demonstrate this requirement is a common reason for not getting funded or for a delay in receiving an award.

Most independent biotechnology companies easily meet the "small" criterion since they can have up to 500 employees. However, if they are affiliated with other companies, their employees are included in the 500 employee limit.

Finally, the small business must have a majority ownership by U.S. citizens or by another qualifying small business, as I describe in the next slide.

Awardee Ownership Requirements



1. An SBIR awardee at the time of award must be:
   - A. Over 50% owned and controlled by U.S. citizens or permanent resident aliens, or
   - B. Over 50% owned and controlled by another small business that satisfies A, or
   - C. A joint venture in which each entity meets the requirements in either A or B.
2. An STTR awardee can only qualify under paragraph A.
3. An SBIR or STTR awardee and its affiliates must have no more than 500 employees.
4. You can submit an SBIR or STTR application even if your company is ineligible. It could become eligible during the seven or more months between application and award if your company's ownership changes or if the regulations change.

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1. At the time this presentation was recorded, an SBIR awardee organization had to meet one of the following three ownership criteria at the time of award:
   A. It is over 50% owned and controlled by U.S. citizens or permanent resident aliens.
   B. Or, it is over 50% owned and controlled by another small business that meets the requirements in A.
   C. Or, it is a joint venture where all parties satisfy A or B.
2. At this time, an STTR awardee can only qualify under A.
3. The total number of employees for an SBIR or STTR awardee and all its affiliates is limited to 500. This means that the sum of your employees, your investment firm's employees, and the employees of all other companies controlled by the investment firm must be under 500.
4. You can submit an SBIR/STTR application even if your company is currently ineligible because it could become eligible during the seven or more months between the time of application and time of award if your company ownership changes or regulations change.

Innovation and Research Requirements

- Innovation
  - New technologies.
  - Significant improvement of existing technologies.
  - New applications for existing technologies.
- Research
  - Collection and analysis of data.
  - Validation of product, e.g., safety and efficacy.

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Your SBIR/STTR project must be innovative 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. I define research as the collection and analysis of data necessary to commercialize your product, for example, safety and efficacy studies.

In the Grantsmanship section, I will illustrate how you might present a development project as a research proposal.

Research Facility Requirements

- Companies must conduct research in facilities it controls.
- You need a lockable door to your research facility.
- You need to control who has a key and when they can enter.
- Space may be located in a collaborating institution's facility but you will need a written agreement, a lease.
- Bench space in another's research laboratory is not "a controlled facility."
- A research facility is required at time of award, not necessarily at time of application.

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A reasonable portion of the research must be conducted by the company in company controlled facilities. Controlling a research facility means that you have the same rights you would have if you were renting an apartment.

Control means you have both the authority and ability to limit access to your facility by closing and locking a door.

Business research facilities can be located in a collaborating institution provided they meet the "control" requirements. A sign on your door can demonstrate it is your space.

In contrast, bench space in someone else's research laboratory is not "a company controlled facility."

If your company currently lacks the required research facilities, describe how you will have them at the time of award.

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.
- Describe the public health and financial significance of your product.

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There is a big difference between business strategy and grant writing strategy. Building core technology that can be used to create many different products is outstanding business strategy but a flawed approach for an SBIR/STTR application. I believe a better strategy is to focus on a single use of your core technology.

For example, imagine that your technology enables inexpensive rapid genetic tests for susceptibility to cancer, heart disease, infectious diseases and other health problems. Your application would probably be assigned to the National Human Genome Research Institute based on this technology but would Genome program staff be supportive? Would scientific reviewers be supportive? How would business reviewers evaluate the product when it is not clear what the product will be?

Consider instead an application focused on applying your technology to breast cancer. The application would be assigned to the National Cancer Institute. Cancer reviewers are likely to be enthusiastic about an impact in their area. Business reviewers are likely to be enthusiastic about product sales.

Because you focused on a single use, you could submit additional SBIR/STTR applications for other uses based on the same core technology. For example, an application on cardiac screening could be directed to the National Heart, Lung, and Blood Institute and one on asthma to NIAID.

In each application, it is critical to focus on the public health significance of the product in that specific area and the financial impact of the product in the market and to your company.

Application Focus Should Be Research

- NIH reviewers are most comfortable with hypothesis-driven research.
- If your proposal is primarily development, you should still focus on research.
- Research is:
  - The data you will collect.
  - The analyses you will use.
- Research is not
  - Developing.
  - Building.
  - Exploring.

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Academic reviewers are most comfortable with hypothesis-driven research. Business reviewers are comfortable with goal-directed research, but NIH SBIR/STTR panels usually have more academic than business reviewers. If your goal is primarily development, I suggest you still focus your proposal on research.

You may recall that I define research as the collection and analysis of data necessary for your product.

Research is not developing something, building something, or exploring something. You can use grant funds to develop, build, and explore but only as necessary to collect and analyze data.

Write a Business Plan to Define Your Product

- Describe the market.
  - What is your product?
  - Why is it needed?
  - What are the requirements to sell it?
  - When will it be ready to be sold?
  - How will it be sold?
  - Who will buy it?
  - What are estimated sales and price?
  - What is the competition and why is your product better?
- Steps or milestones necessary to bring your product to the point of sales.
- Estimated time and cost to reach each milestone.
- Exit strategy.

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You should have a clear vision of your product before you begin writing an NIH application.

Write a business plan to help you describe the product potential of your application. If you have not created a business plan, your state or local economic development organizations may be able to help. Your business plan and the significance section of your application should answer the following questions:

What is the market? What is your product? Why is it needed? What are the requirements to sell it? When will it be ready to be sold? How will it be sold? Who will buy it? What are estimated sales and price? What is the competition and why is your product better?

What are the steps or milestones necessary to bring your product to the point of sales?

What is the estimated time and cost to reach each milestone?

What is your "exit strategy"? How far does your company plan to take the product towards sales? Describing your exit strategy will demonstrate to business reviewers that you are not naïve. For example, reviewers are not likely to believe that a small business can take a drug or vaccine through clinical trials, or a diagnostic test or device requiring FDA approval to the market.

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.
- Core technology must be protected (patented, patent pending, or provisional patent pending).
- Company must own title to patent or have exclusive license to it.

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I strongly recommend that you protect your intellectual property before you describe it in a grant application. I would not depend upon confidentiality agreements signed by reviewers or the fact that grant applications are not public documents.

Patent protection is an absolute requirement to obtain private funds for commercialization. Although it can take considerable time for a patent to be issued, at a minimum your inventions should be protected by Patent Pending or Provisional Patent Pending.

If the intellectual property belongs to an academic institution, you should insist that the institution file the patent application before you submit your grant application.

Also, if the intellectual property is owned by an academic institution, it is important that you have a signed exclusive license to commercialize it before developing it further. This is not an SBIR/STTR requirement. It is just good business sense.

Provisional Patents Provide Low Cost Protection for One Year

- Provisional Patent Application
  - Provides simplified filing at low cost with one year to assess commercial potential.
  - Establishes a U.S. patent application filing date.
  - Permits one year's authorization to use "Patent Pending" notice.
  - Enables promotion of the invention with greater security. Should not be used when value of invention is known and funds are available for a formal patent application.
- 2007 Provisional Patent Fee
  - $100 small entity.
  - $200 other than small entity.

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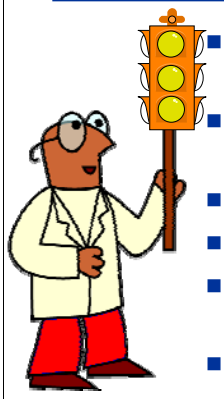
Pursuing a full patent application can cost $10,000 and much more.

A low-cost provisional patent application allows up to a one year delay in the cost and effort of pursuing a formal patent application. During this year, you can disclose the invention to investors and seek funding through grant applications with little risk that the invention will be stolen. The provisional patent application also establishes a patent filing date and allows one year's use of Patent Pending notice.

The provisional filing fee is only $100 for a small entity or $200 otherwise.

A provisional application's major use is to protect your invention while you seek funds necessary to show that the invention is worth commercializing and thus worth the cost of a full patent application. File a full patent application and not a provisional one if you know that the invention is worth commercializing and if funds are available to pay the formal patent costs.

Provisional Patent Cautions



- Provisional applications are not examined on their merits.
- The disclosure of the invention must be as complete as possible to support full application.
- Full patent application must be filed within one year.
- Each inventor must be named.
- Amendments are not permitted after filing other than those to comply with regulations.
- The formal full patent application must have one inventor in common with the inventor(s) in the provisional application.

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Because provisional patent applications are not examined for merit, inventors often believe that they can prepare and file their own applications without help.

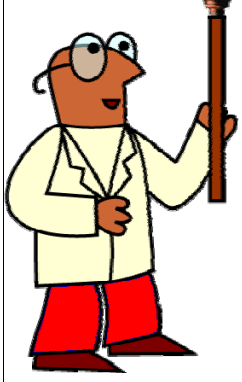
Inventor-prepared applications often provide incomplete disclosure, which can lead to a variety of problems including total loss of rights.

The provisional application should contain the full and complete disclosure of the invention at the same quality level found in a full application.

I suggest engaging a professional to write the detailed description that will be used without alteration in a subsequently filed full application.

Remember, the clock is running once the provisional application is filed – the full application must be filed within one year.

Inventions Resulting from U.S. Government Supported Research



- The Bayh-Dole Act specifies invention reporting compliance responsibilities and timelines.
- Your institution must report an invention to the U.S. funding agency within two months of learning about it from the inventor.
- iEdison (Interagency Edison) is the Internet site that helps you meet these requirements.
- NIH may pursue a patent application if your institution elects not to.
- You may pursue a patent application if you request it and both your institution and NIH elect not to pursue it.

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The Bayh-Dole Act specifies compliance responsibilities and timelines for invention reporting.

Your institution must report an invention to the NIH within two months of learning about it from the inventor. You should report any potential inventions to your institution as soon as possible to start the clock. Reporting does not constitute public disclosure and does not invalidate a future patent application.

iEdison is the Internet site for this required reporting.

Your institution has a maximum of two years to elect either to pursue a patent application or not. Appeal to your institution to make this decision promptly, particularly if you plan to describe your invention in a public presentation or publication.

Your institution may elect not to retain title if commercialization seems unlikely or if a licensee is not found that is willing to cover legal and patent costs. Then NIH has the option of pursing the patent but usually does not. If neither your institution or NIH elects to pursue a patent, you may request and receive permission to retain ownership.

Comparisons Between SBIR and STTR

		SBIR	STTR
Agency research budget		2.5%	0.3%
Award guidelines	Phase I	$100K	$100K
		6 mo.	12 mo.
	Phase II	$750K	$750K
		2 yr.	2 yr.
Research institution partner required		no	yes*
Max. outsource	Phase I	33%	60%*
	Phase II	50%	60%*
Min. company effort	Phase I	67%	40%*
	Phase II	50%	40%*
Min. research inst. effort	Phase I & II	0%	30%*
PI Company employed over 50% time		yes*	no
* Mandatory, no wiggle room			

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There are major differences between NIH SBIR and STTR awards. Each has advantages and disadvantages.

Although the pot of money for SBIRs is about eight times larger than that for STTR awards, SBIR applications have historically outnumbered STTR applications by considerably more than eight-fold causing the success rate for SBIRs to be lower than that for STTRs.

An STTR application must include a qualified research partner that gets between 30% and 60% of the grant funds. There is no flexibility on these values for STTR awards.

An SBIR application normally allows up to 33% outsourcing in Phase I and 50% in Phase II. However, the maximum allowed outsourcing is flexible with appropriate justification.

Perhaps most significant, an SBIR principal investigator, that is the PI, must be employed over half-time by the business during the award period. In contrast, an STTR PI may be an academic employee and need not receive any salary from the business.

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

Ask for One Year for Phase I Awards

- Unless you are positive you can complete the Phase I in 6 months.
- Reviewers will know if what you propose will take longer.
- You can apply for Phase II funding when you complete your Phase I objectives.

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Although the guidelines list six months as the normal time for an SBIR Phase I, I suggest that you always ask for at least one year because most projects take that long. And, if you need more than one year for Phase I, ask if a two year Phase I application would be accepted by the IC most likely to receive your application.

Reviewers will not trust your judgment if you propose to accomplish a one or two year project in a six-month time-frame. However, if you only ask for six months and later discover that you need more time, you will have to get approval for a no-cost extension.

There is no downside to asking for more time because you are not required to wait till the end of Phase I to apply for Phase II. If your Phase I research has been ongoing following your Phase I application, and you have completed your Phase I objectives, you can apply for Phase II funding on the next receipt date after you receive a Phase I award.

Advantages of SBIR over STTR

- No research institution partner necessary.
  - Fewer agreements, fewer lawyers, less cost.
  - Company controls all funds.
  - Less or no academic overhead.
- More flexible percent effort than STTR.
- Academic scientist may earn consultant fees on top of salary.

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SBIR awards have advantages over STTR awards.

SBIR awards do not require a research institution partner, meaning fewer agreements, fewer lawyers, and less cost. The company controls all the funds, and SBIR research dollars are not used to support overhead in an academic institution.

As an academic scientist, you may be better off financially in a consultant role on an SBIR award compared to a PI role on an STTR award.

For example, suppose you have a salary of $100,000 and your academic institution allows you to consult one day a week and keep the earnings. In this hypothetical situation, you could accept a $20,000 consulting fee from the business in addition to your $100,000 academic salary.

In contrast, if you were the PI on an STTR award, you would only receive the $100,000 academic salary and could not accept a consulting fee for the same work.

Advantages of STTR over SBIR

- Company may lack credible PI, e.g.,
  - Scientist with expertise in area of application.
  - Clinician with access to medical setting.
- PI role essential to academic scientist.
  - Promotion, etc.
  - May be easier to avoid conflict of interest.
- Potentially better access to academic facilities, intellectual property, support, e.g., IRB and animal welfare committee.
- Higher percentage subcontract possible.
- Higher percentage of applications may be funded.

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STTR awards have advantages over SBIR awards.

If a company lacks a credible PI, an academic PI may provide the credibility for funding.

For example, you might require a PI with certain expertise, e.g., a clinician who could monitor a clinical trial.

A PI role may be essential to the academic scientist for promotion, to avoid conflict of interest, or for other reasons.

In addition, an academic PI may give the company better access to academic facilities, intellectual property, and support; e.g., institutional review boards and animal welfare committees.

An STTR award allows you to pay a higher percentage of the award to a research institution without special justification. This may be particularly important for clinical trials.

Historically, NIH has funded a higher percentage of STTR compared to SBIR applications. This may change as NIH staff encourage the STTR route when a choice is possible. I recommend you choose an SBIR or STTR mechanism based on your requirements and not on the probability of funding.

STTR Applications Require Extra Effort

- Both company and research institution partner must sign an intellectual property agreement.
- Certification of cooperative R&D arrangement between business and research institution is required before award.
- Virtual companies do not qualify – a company's research facilities will be carefully scrutinized.
- Extra care is required to avoid conflict of interest.

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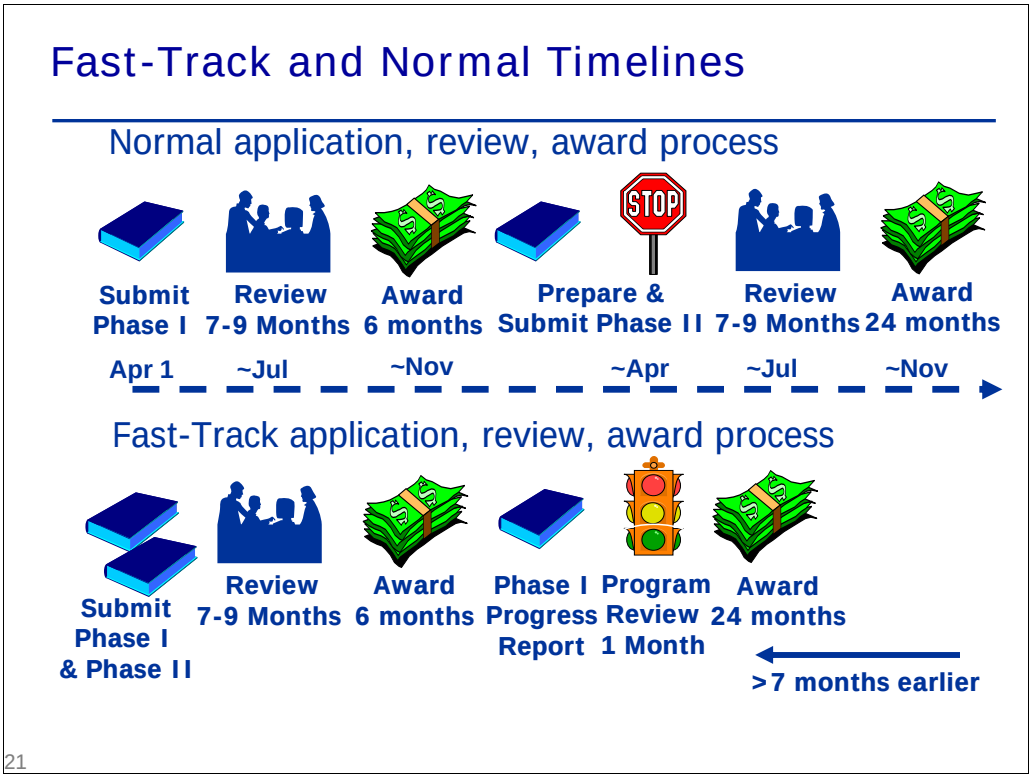
STTR applications require extra effort.

Your signature on the budget page of the application certifies that you will sign an intellectual property agreement and cooperative R&D arrangement with your research institution partner before an award. The "intellectual property agreement" link takes you to a model agreement which you can revise. Do not include a copy of your agreement in your application.

Research institution partners usually 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.



I will describe the NIH fast-track process and explain why I discourage fast-track applications.

Fast-track reduces the gap in funding that can occur between the completion of Phase I and the start of Phase II.

For the normal process, you submit a Phase I application, wait seven to nine months for an award, work six months on the project, prepare and submit a Phase II application, and then stop work during the seven to nine month period while your Phase II application is reviewed and awarded.

The fast-track application contains both your Phase I and Phase II proposals which undergo concurrent review.

If you receive a fast-track award, you can proceed normally through Phase I and then submit a progress report to receive approval for Phase II funds.

Program review of your progress may be completed in a short time, and Phase II funding may commence seven months or more earlier than applications following the normal process.

Fast-Track Requirements

- Phase I and II applications submitted at same time.
- Clear, measurable milestones for Phase I that are easily assessed.
- Commercialization plan (business plan).
- Commercialization partner.

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Although fast-track provides a potential opportunity to avoid the funding gap between Phase I and Phase II awards, fast-track applications have some daunting additional requirements.

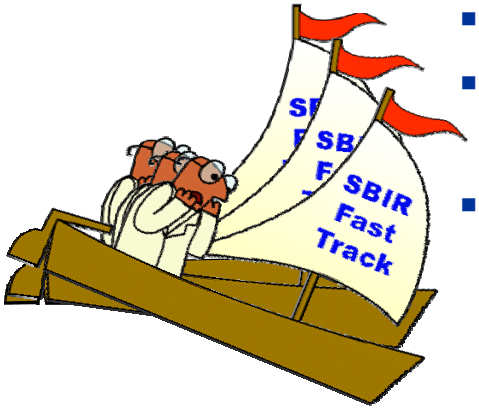
You have to submit both Phase I and Phase II applications at the same time. It is very difficult to write an outstanding Phase II application when you do not know the results of Phase I.

To be successful, the specific aims (milestones) for Phase I must be clear, measurable, and easily assessed.

Fast-track applications must also include a detailed commercialization plan up to 15 pages in length, in other words, a detailed business plan for the product.

Finally, fast-track applicants are encouraged to have a commercialization partner. Your application will compete with applicants that have established good partnerships.

Reasons Not to Submit a Fast-Track Proposal



- It is too early in your product development to get a commercialization partner.
- A fast-track proposal requires at least four times the effort of a Phase I.
- You lack experience writing SBIR applications.
- You may not need a fast-track award to avoid a funding gap. You may be able to request more than one year's funding for Phase I.
- Review committees cannot disassociate and score the Phase I component from a fast-track application.

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There are many reasons not to submit a fast-track proposal.

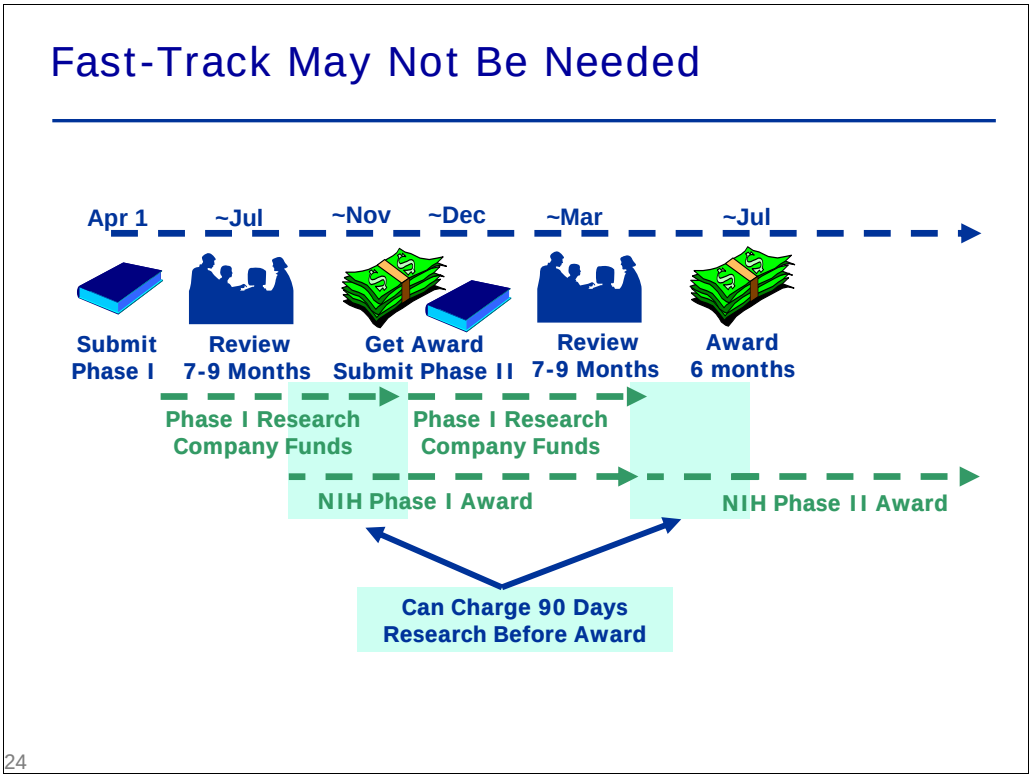
A fast-track may not be advantageous to you if it is too early in your product development to get a commercialization partner, of if a partner would demand too much ownership.

Preparing a fast-track application is at least four-times the effort of preparing a Phase I application. Your efforts might be better employed writing more Phase I applications on different concepts.

If you lack experience writing SBIR applications, you probably do not want to prepare a complex fast-track application.

On the next slide, I will explain why you may not need a fast-track award to avoid a funding gap. Also, you can consider requesting more than one year's funding for Phase I, which may enable you to submit a Phase II application before the end of Phase I funding.

A review committee that likes the Phase I component but not the Phase II component cannot recommend only the Phase I be funded and give a score for only the Phase I. This means an outstanding fundable Phase I application may be torpedoed when attached in a fast-track to a Phase II application reviewers don’t like.



If your project is important to your company and you have the resources to pursue it while you wait for NIH funding, the disadvantages of a fast-track application may outweigh the advantages.

For example, let's say you submit a Phase I application and use company funds to continue research while review proceeds. Now, suppose you receive a Phase I award.

Because you have been working on the project, you may already have completed your Phase I specific aims. If so, you can submit a Phase II application on the next application receipt date. You do not have to wait for the Phase I grant to end.

Also, if you receive a Phase I award, you are allowed to charge the cost of the research on the project during the 90 days before the award.

While you wait for review and award of Phase II, you can continue working on the project using the Phase I and company funds.

Similarly, if you receive a Phase II award, you are allowed to charge the cost of your research on the project completed during the 90 days before the Phase II award.

More Presentations

TOPICS

- Basics
- Choices and FY2006 Data
- Grantsmanship
- Electronic Application
- NIH Timeline

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