Slide 1. WELCOME

Slide 2. Advice on NIH SBIR & STTR Grant Applications

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Hello and welcome.

I am Greg Milman and I will share with you some advice on NIH small business programs that may help you succeed with your NIH SBIR or STTR application.

This presentation was updated in April 2005.

You can send your comments, suggestions on topics you would like added, and criticisms by email to gmilman@niaid.nih.gov.

Slide 3. How to Use the Presentation Controls

- Picture of presentation controls as described in text.
- Tutorial on how to use the controls.

Let me first give you a tutorial on how to use the controls.

The names of the main headings and slides under that heading are shown at the left. Clicking on a main heading down arrow hides the slides under that heading. Clicking on a horizontal arrow expands to show all the slides under a heading.

The current slide name is in blue. Clicking on any name brings you to that point in the presentation. Next time, you can skip this slide and jump directly to any other.

The status window shows the number of minutes you are into the presentation and its total length.

There are six control buttons at the bottom. The buttons from left to right enable you to move to the previous slide, back-up in a slide, play a slide, pause a slide, jump-forward in a slide, and move on to the next slide.

The speaker control allows you to adjust the volume level.

The scrolling text displays the script with the current position highlighted in blue.

The search window allows you to find and display occurrences of text in the presentation. For example, if you search for "Intellectual Property," the text window shows all paragraphs that include the phrase "Intellectual Property" with the phrase displayed in capital letters.

Clicking on any displayed paragraph will bring you to that slide in the presentation.

Links to information on the Internet are underlined and in red. First, pause my presentation and then click on a link to open it in a new window. Links to locations within Microsoft Word documents require Word to view. Close the link window and click the play button to continue. OK, we're ready to begin my advice.

Slide 4. 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.

What I will provide is mostly 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, prior to that, as a successful applicant for NIH small business funds. In the last 16 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 representatives.

Caveat emptor applies; follow my advice at your own peril.

Since my opinions are not official, it will not help you to declare that you are following advice that you received from me.

Slide 5. DO I QUALIFY?

Slide 6. NIH Small Business Programs

- Small Business Innovation Research funds support research by business.
- Small Business Technology Transfer Research funds support collaborative research by business and US research institutions.

Congress has mandated that all federal agencies that conduct research designate a percentage of their 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, but I describe some programs specific to the National Institute of Allergy and Infectious Diseases (NIAID).

Slide 7. SBIR/STTR Instructions and Forms

- NIH Small Business Funding Opportunities
- PHS398 Instructions and Fillable Forms
  - SBIR/STTR Instructions
  - SBIR/STTR Fillable Forms
- SBIR/STTR Program Solicitations and Instructions
  - Part I - Program Information, Grant Application Instructions and Preparation Requirements
  - Part II - NIH, CDC and FDA Program Descriptions and Research Topics
  - NIH Guide

In this presentation, 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. Do not depend only on my advice. To learn all the rules and regulations, follow these links to the official NIH small business pages.

The NIH Small Business Funding Opportunities link is to the official NIH SBIR/STTR site. There you will find links to the latest SBIR/STTR solicitation, application forms and instructions for completing your application. Read the News Flashes and archived News Flashes for the latest notices and updates on policies and procedures.

The PHS398 Instructions and Fillable Forms link is to the three part application instructions and forms. Part I contains application instructions. Part II contains human subjects regulations and requirements. Part III contains policies, assurances, definitions, and other information. Each part is available in HTML or Flash for Internet viewing, and in PDF or Microsoft Word for downloading to your computer or printing.

The SBIR/STTR Instructions link is to the HTML version of SBIR/STTR specific instructions. The SBIR/STTR Fillable Forms link is to the PHS398 fillable forms.

The SBIR/STTR Program Solicitations and Instructions link is to the Omnibus Solicitation. It is organized into two parts, each in Microsoft Word or PDF. The PDF versions are best for printing. The link to Part I is to a description of the SBIR/STTR program information, requirements, and application instructions. Instructions in Part I of the Solicitation do not exactly duplicate those in Part I of the PHS398 instructions, so I recommend you read both. The link to Part II is to descriptions of the NIH, CDC and FDA small business programs and lists of research topics.

The link to the NIH Guide creates a search for all small business research topics in the NIH Guide.

Slide 8. 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

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 you can have up to 500 employees. However, if you are affiliated with other companies, their employees are included in your 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.

Slide 9. Awardee Ownership Requirements

- An SBIR awardee at the time of award must be:
  - At least 51% owned and controlled by individuals who are U.S. citizens or permanent resident aliens; or
  - At least 51% owned and controlled by an other small business (e.g. a venture capital or angel investor group) that itself satisfies Paragraph A; or
  - A joint venture in which each entity meets the requirements in either paragraph A or B.
- An STTR awardee can only qualify under paragraph A.
- An SBIR and its affiliates must have no more than 500 employees.
- The 500 employee size limitation makes many investor-controlled small businesses ineligible for SBIR awards.
- Consider submitting an 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 SBA changes the regulations.

An SBIR awardee must meet one of the following three ownership criteria at the time of award:

A. An awardee must be at least 51% owned and controlled by individuals who are citizens or permanent resident aliens of the United States.

B. An SBA rule that went into effect on January 3, 2005, allows an SBIR awardee to be owned and controlled by another small business that meets the requirements in A. For example, a company could qualify if it were owned by a qualifying venture capital or an angel investor group.

C. An SBIR awardee could also be a joint venture if each entity in the venture meets the requirement of either paragraph A or B.

At this time, an STTR awardee can only qualify under paragraph A.

The 500 employee limit applies to the SBIR awardee and its affiliates. Affiliates include a business that controls yours and all other businesses controlled by that business. To meet the small business size requirement, 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. The 500 employee size limitation makes many investor controlled small businesses ineligible for SBIR awards.

You may decide to 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 the SBA change the regulations.

Slide 10. 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.

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 spin a development project into a research proposal.

Slide 11. Research Facility Requirements

- A reasonable portion of the research must be conducted by the company in company controlled facilities.
- You need a lockable door to your research facility.
- You need to control who has the 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."
- Research facility is required at time of award, not necessarily at time of application.

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 a someone else's research laboratory is not "a company controlled facility."

You do not have to let your current lack of research space keep you from writing an SBIR or STTR application. Describe in the resource section of your application the arrangements you have made to occupy and control a research facility and the resources you will have available to you at the time of award.

Slide 12. WHAT FIRST?

Slide 13. 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.

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. The National Human Genome Research Institute would probably be assigned your application 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 directed to a program in 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, you should 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.

Slide 14. 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
  - Analyses you will employ
- Research is not
  - Developing
  - Building
  - Discovering

Academic reviewers are most comfortable with hypothesis-driven research. If your goal is primarily development, I suggest you still focus your proposal on research.

Research is the collection and analyses of data necessary for your product.

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

Slide 15. 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/milestones necessary to bring your product to the point of sales.
- Estimated time and cost to reach each milestone.
- Exit strategy.

You should have a clear vision of your product before you begin 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/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.

Slide 16. 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.

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 the academic institution where the research was done instead of to you, 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.

Slide 17. Provisional Patents Provide Low Cost Protection for One Year

- Provides simplified filing at lower 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 against having the invention stolen.
- Preserves application in confidence without publication.
- Allows filing of multiple provisional applications that can be consolidated into a single non-provisional patent application.
- 2005 Provisional Patent Fee
  - $100 small entity.
  - $200 other than small entity.

Pursuing a full patent application can cost $10,000 and much more. Before spending big bucks on patent costs, you or your academic institution will probably want to be assured that funds will be available to commercialize the invention.

Since June 1995, inventors have been able to file a low-cost provisional patent application that establishes a filing date and allows one year's use of Patent Pending.

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

The provisional application allows up to a one year's 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.

I would like to emphasize that 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.

You or your institution should file a full patent application and not a provisional application if you know that the invention is worth commercializing and if funds are available to pay the cost.

Slide 18. Provisional Patent Cautions

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

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.

Slide 19. Inventions Resulting from U.S. Government Supported Research

- The Bayh-Dole Act specifies invention reporting compliance responsibilities and timelines.
- A grantee institution must report an invention to the U.S. funding agency within 2 months of learning about it from the inventor.
- iEdison (Interagency Edison) is the Internet site that helps you meet these requirements.
- The granting agency (NIH) may pursue a patent application if the grantee institution elects not to.
- The inventor may pursue a patent application if he or she requests it and both the grantee institution and granting agency elect not to pursue it.

The Bayh-Dole Act specifies invention reporting compliance responsibilities and timelines for recipients of research funds from U.S. agencies.

A grantee institution must report an invention to the U.S. funding agency (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 an Internet site that facilitates this required reporting of inventions to all U.S. government agencies.

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

The grantee 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. NIH then has the option of pursing a patent but usually does not. If neither the grantee institution nor NIH elects to pursue a patent, the inventor may request and receive permission to retain ownership and incur the costs of filing the patent application.

Slide 20. CHOICES?

Slide 21. Choices to Consider Before Starting an Application

- SBIR or STTR?
- Academic collaborator, partner, or principal investigator?
- Normal or Fast-Track?
- Which receipt date?
- Which Institute or Center?
- Program Announcement or Unsolicited?
- Requested budget (normal or outside guidelines)?
- Requested time (1 or 2 years)?
- Phase I specific aims and milestones?
- Fee (use of funds)?

The following are some of the choices you should consider before you start your application.

Do you apply for an SBIR or STTR award?

Do you need an academic collaborator, partner, or principal investigator?

Should you submit a normal or Fast-Track application?

Which of the three receipt dates is best?

How should you select which Institute or Center (IC) to target?

Should you respond to a program announcement?

How large a project should you propose?

How much money and time should you request?

What are your specific aims and milestones for Phase I?

Should you ask for a fee?

Slide 22. SBIR OR STTR TRACK?

Slide 23. Comparisons Between SBIR and STTR

		SBIR	STTR
Agency research budget		2.5%	0.3%
Phase 1	Amount	$100,000	$100,000
	Time	6 months	12 months
Phase 2	Amount	$750,000	$750,000
	Time	2 years	2 years
Research institution partner required		No	Yes *
Maximum outsource	Phase 1	33%	60% *
	Phase 2	50%	60% *
Minimum company effort	Phase 1	67%	40% *
	Phase 2	50%	40% *
Minimum research institution effort	Phase 1 and Phase 2	0%	30% *
PI employed by company over 50% time		Yes *	No

**** Mandatory, no wiggle room***

There are some major differences between NIH SBIR and STTR awards. Each type of award has its advantages and disadvantages. Although the pot of money for SBIR awards is about eight times larger than that for STTR awards, SBIR applications have historically outnumbered STTR ones by considerably more than eight-fold. Although the award guidelines appear somewhat different for SBIR and STTR, NIH allows considerable flexibility in both the length and amount of awards.

An SBIR award permits research partners, but an STTR award requires a qualified research partner institution be included in the application.

An SBIR award normally allows only 33% outsourcing in Phase I, and 50% in Phase II. An STTR award permits 60% outsourcing in both Phase I and II. With appropriate justification, the maximum allowed outsourcing is somewhat flexible for SBIR awards, but not for STTR awards.

An SBIR award normally requires a minimum 67% effort by the company in Phase I, and 50% in Phase II, but no minimum effort by a partner. An STTR award requires a minimum 40% percent effort by the company and 30% effort by the research partner in both Phase I and II. With appropriate justification the minimum percent effort by the company is somewhat flexible for SBIR awards, but not for STTR awards.

Perhaps most significant, an SBIR principal investigator, abbreviated as 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 you cannot switch a project between SBIR and STTR. An SBIR Phase I awarded project can only continue as an SBIR Phase II, not an STTR Phase II, and vice versa.

Slide 24. 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.

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 will take that long. And, if you need two or three years for Phase I, ask your IC's staff if your application for more time will be accepted. Reviewers will not trust your judgment if you propose to accomplish a one or two year project in a six-month time-frame. In addition, there is no disadvantage to asking for one year for Phase I. 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.

The reason there is no disadvantage to asking for more time is that 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 as soon as you receive a Phase I award.

Slide 25. 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 consultant may earn consultant fees on top of salary.

SBIR awards have multiple 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.

There no minimum and flexible maximum percent effort requirements for a research institution partner.

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 an investigator has a salary of $100,000 and is employed by an academic institution that allows its faculty to consult one day a week and keep the earnings. In this hypothetical situation, the investigator can accept a $20,000 consulting fee from the business in addition to the $100,000 academic salary.

In contrast, the same faculty member acting as PI on an STTR award can only receive the $100,000 academic salary and cannot accept a consulting fee for the same work.

Slide 26. 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 percent subcontract possible.
- Higher percent of applications funded.

STTR awards have different 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 a demonstrated expertise in the area of science in the application, or perhaps 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; for example, 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 percent of STTR compared to SBIR applications. Although it is not clear if this trend will continue, NIH staff may encourage the STTR route when a choice is possible.

Slide 27. STTR Applications Require Extra Effort

- Both company and research institution partner must sign an intellectual property agreement.
- STTR application must also include a research institution certification on the modular budget, or if non-modular, on a separate form.
- Virtual companies do not qualify – a company's research facilities will be carefully scrutinized.
- Extra care is required to avoid conflict of interest.
- You cannot switch between STTR and SBIR tracks.

STTR applications require extra effort.

Your signature on the budget page of the application certifies that you will sign an intellectual property agreement with your research institution partner prior to an award. The "intellectual property agreement" link takes you to a model agreement which can be revised to meet your needs and those of your research institution partner. Do not include a copy of your agreement in your application. It may be requested by NIH just prior to an award, called "Just-in-Time."

It is likely, and even reasonable, that your research institution partner will 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.

In addition to an intellectual property agreement, STTR applications must include a certification by your research institution partner that a consortium arrangement has been signed or will be signed when you receive an award. Follow the links to the required forms which must be included in your application.

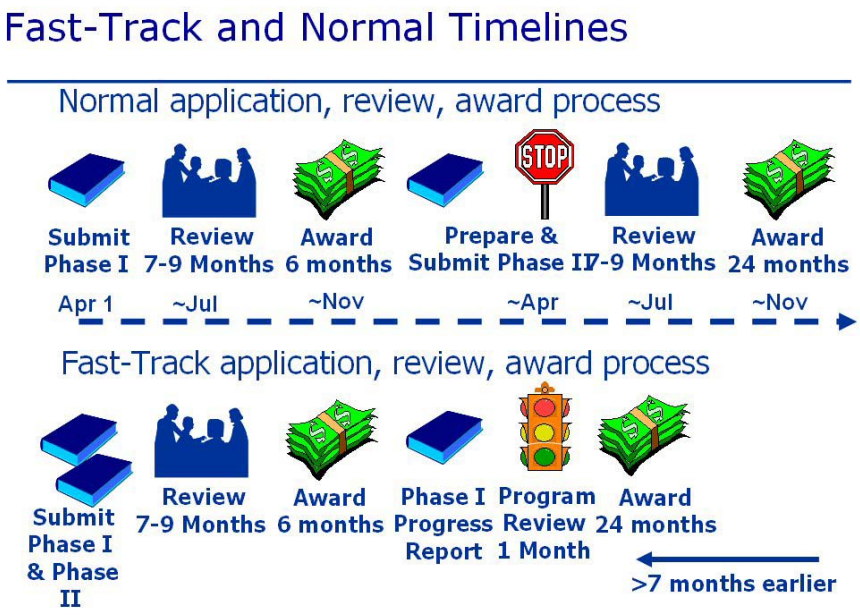
Be aware that virtual companies do not qualify for NIH small business programs, and STTR applications are carefully scrutinized by Grants Management Staff.

You must 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.

Let me again emphasize that you cannot switch a project between STTR and SBIR tracks. An STTR Phase I awarded project can only continue as an STTR Phase II, not an SBIR Phase II, and vice versa.

Slide 28. NORMAL OR FAST-TRACK?

Slide 29. Fast-Track and Normal Timelines



I will describe the NIH Fast-Track process and then 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.

Slide 30. 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.

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 applications are encouraged to have a commercialization partner and your application will compete with applicants that have established good partnerships.

Slide 31. When a Fast-Track Is and Is Not Appropriate

- Develop assay
- Identify lead compound
- Select candidate drug
- Small animal model studies: [pharmacology, toxicology, formulation, bioavailability, etc.]
- Primate studies
- Phase I human safety trial
- Phase II human safety/efficacy trial
- Phase III human efficacy trial

Let me describe a drug development project as an example of when a Fast-Track application is and is not appropriate. Suppose you have selected a drug candidate prior to your SBIR submission. A Fast-Track application is appropriate because you are about to embark on a defined critical path to FDA approval.

In this example, Fast-Track might include small animal models in Phase I and primate studies in Phase II. Each step in the process has criteria for determining if your drug candidate should continue or should be discarded and funding halted. You can write your Phase II application because you know exactly what research results are required.

As the research you propose will probably not be very innovative, the significance of the new drug to public health should be very high. A review committee will most likely not feel the necessity to review your Phase I research decisions if they buy into the significance of your proposal. If your Phase II is funded, you can apply for a competing continuation of your Phase II to continue studies into human safety and efficacy trials.

You should not consider a Fast-Track application if your Phase I results will affect the experimental design of your Phase II application. As an example, suppose during preliminary studies you develop an assay for drug effectiveness. You should propose a regular Phase I to identify a lead compound and maybe select a candidate drug. When you complete Phase I, you will have data to support a Phase II proposal to test the candidate in small animal models studies.

In this case, you should use the regular SBIR route because the review committee will most likely want to evaluate your data from Phase I and your rationale for the choice of a particular candidate drug.

Slide 32. 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.

There are other reasons not to submit a Fast-Track proposal.

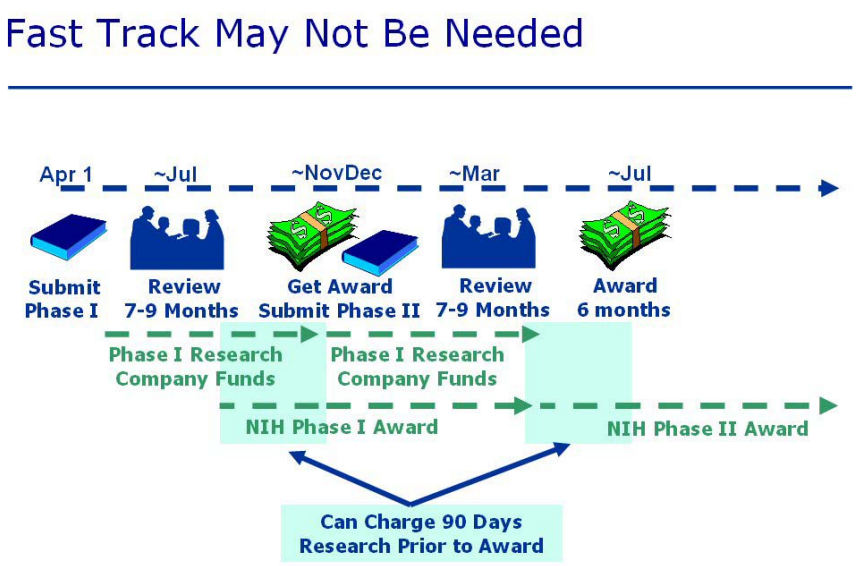
A Fast-Track may not be advantageous to you if it is too early in your product development to get a commercialization partner, of if a partner would demand too much ownership.

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.

Slide 33. Fast Track May Not Be Needed



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

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

Because you have been working on the project, you may complete your Phase I specific aims prior to getting an award. If so, you can submit a Phase II application on the next application receipt date following your Phase I award. You do not have to wait the six months or more that you proposed in your Phase I application.

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

This means that if your Phase I application is successful, some of the company's expenses on the project can be recovered.

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

And again, 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 prior to the Phase II award to recover some of the company's expenses.

Slide 34. FY2004 DATA

These topics will be covered in the following slides.

- Receipt date differences
- Payline and gray zone
- IC award rates
- Program announcements
- Phase I award amounts
- Revised applications
- Phase II award rates and amounts

Slide 35. Interpreting Statistical Data

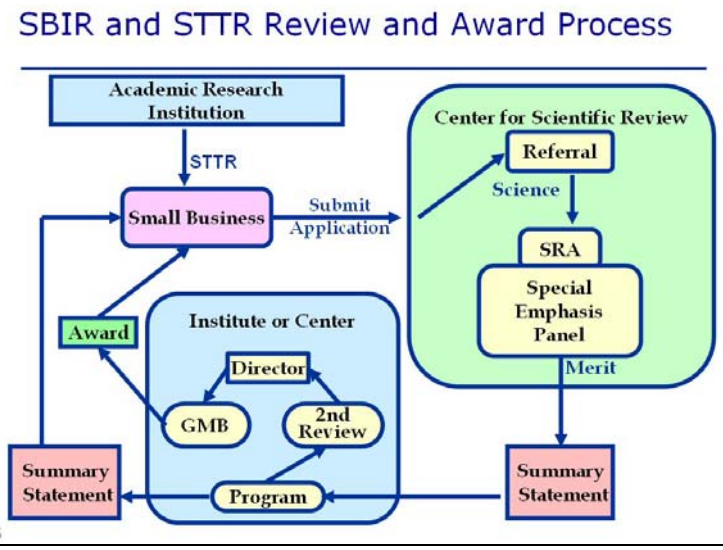
- Data from FY2004 may help you plan your strategy.
- Like the stock market, FY2004's performance is no guarantee that the future will be the same.
- Be careful how you use this information.

I will share with you some data from FY2004 that may help you plan your SBIR/STTR application strategy.

Like the stock market, one year's performance is no guarantee that another year's will be the same.

Be careful how you use this information. Ask NIH staff to describe changes, if any, between FY2004 and today.

Slide 36. SBIR and STTR Review and Award Process



To help you understand the differences in receipt dates, I will briefly describe the review and award process. In "Contact NIH," I will suggest who you should contact at each step. A small business often interacts with an investigator at an academic institution in an informal partnership leading to an SBIR application or a formal partnership in an STTR application. For an STTR application, a small business must first enter into a formal relationship with an academic institution. Both SBIR and STTR applications are always submitted by the small business to the NIH Center for Scientific Review, CSR.

Based on the research proposal, the CSR referral office assigns the application to a Scientific Review Administrator, an SRA. The SRA convenes a Special Emphasis Panel, an SEP, to review applications that have similar science. CSR also assigns the application to a potential funding Institute or Center, an IC. CSR controls the application until the review is complete and then it becomes the responsibility of the assigned IC.

Each application is reviewed in depth by at least two primary reviewers. If an application is considered to be among the top half, or if one of the panel wants the application discussed, it is discussed by the full SEP. By secret ballot, SEP members assign an application a priority score. If the application is not discussed, it does not receive a score.

The SRA averages the priority scores and prepares a summary statement containing the primary reviewers' written comments and a summary of the discussion. The summary statement is transmitted to the assigned IC and the appropriate Program Staff sends the summary statement to the applicant.

A secondary review group in the IC will recommend which applications should be paid if funds are available. If the IC's Director concurs with recommendations and if the budget office determines that funds are available, the application is released to Grants Management Staff who verify that the applicant satisfies all requirements for an award. When all policies and procedures are in order, Grants Management Staff issues a Notice of Grant Award. The entire review and award process takes a minimum of six months and can take up to 18 months depending upon the receipt date on which the application was submitted.

Slide 37. Receipt, Review, and Award Dates

Receipt	1-Apr	1-Aug	1-Dec
Initial Review	~Jul	~Nov	~Mar
Secondary Review	~Oct	~Feb	~Jun
Earliest Award	~Jan	~Feb	~Jun

NIAID Payline

The Receipt Dates link takes you to the official NIH information on receipt, review, and award dates. The award dates in this table differ somewhat from the official table because they are based on the actual FY2004 data shown in the next slide.

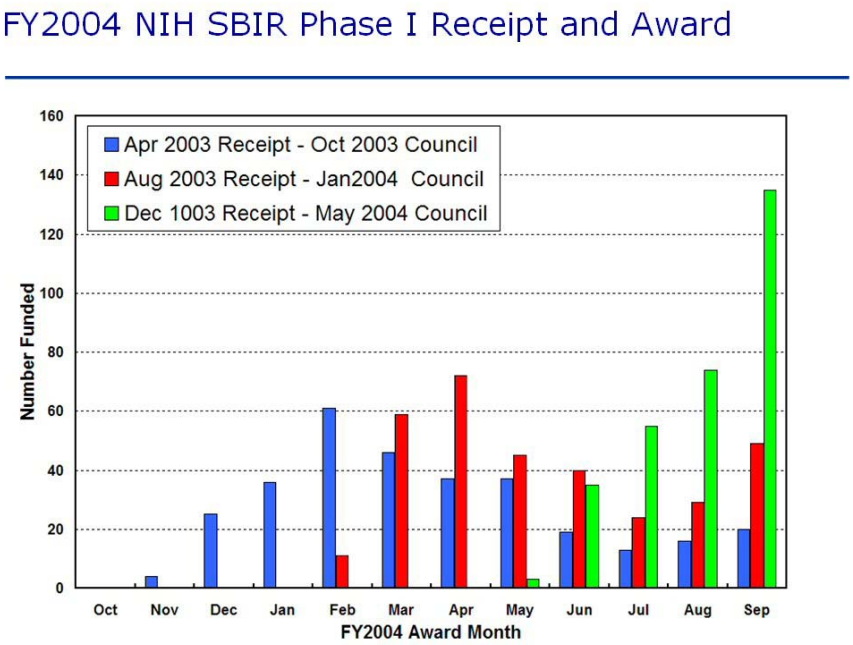
NIH operates on a fiscal year that begins October 1st and ends September 30th. Applications received in April are the first to be funded the following fiscal year. Because our budget is often delayed in Congress, funding of applications received in April is also often delayed.

Review committees assign scored applications a priority from 100 being the best to 500 being the worst. Applications with scores under 200 are likely to be funded and those with scores over 250 are not. Applications with scores between 200 and 250 are in a "Gray Zone" – they may or may not be funded. Based on historical data, the NIAID budget office sets a "payline" and we fund applications with scores up to the payline. A conservative payline around 200 is selected so that applications received later in the fiscal year do not go unfunded because we have already spent our funds on poorer scoring applications. The payline link takes you to public NIAID paylines for all types of grants. Other ICs may not use paylines or may not make their paylines public.

Suppose we spend about 90% of our funds on all the applications with scores within the payline. At the end of the fiscal year, we create a list of unpaid applications in increasing priority score order and use the remaining 10% of our funds to pay the best scoring eligible applications.

As a result of this process, if you receive a score under 200, you are likely to be funded without delay once we have a budget. If you receive a score over 250, you are not likely to be funded at all. Finally, if you receive a score in the Gray Zone, regardless of when your application is received, you probably will wait until the end of the fiscal year in September to learn if it will be funded.

Slide 38. FY2004 NIH SBIR Phase I Receipt and Award



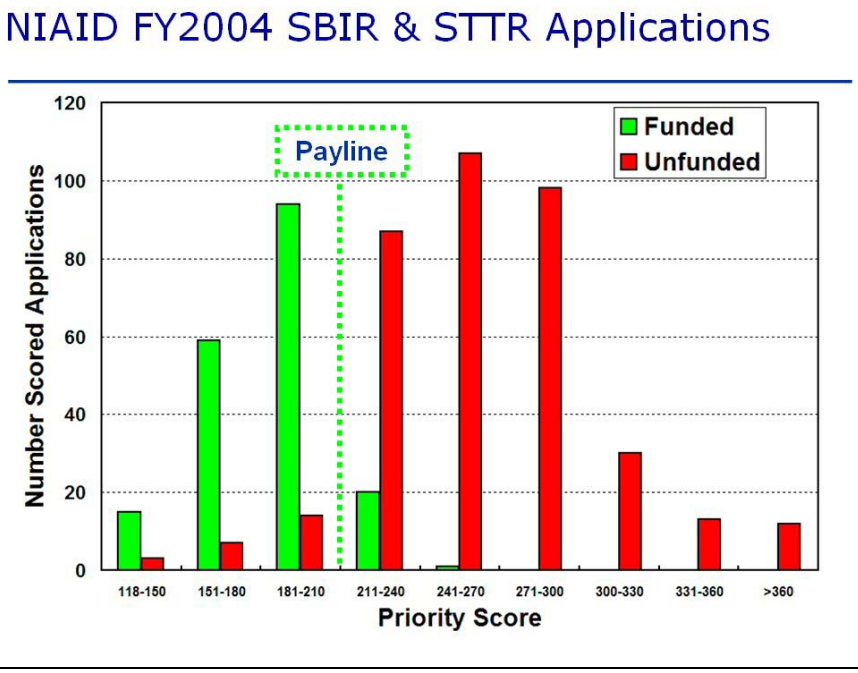
This chart shows the award month for all FY2004 NIH SBIR Phase I applications for all the three receipt dates, April in blue, August in Red and December in Green. The earliest award from the Apr 2003 receipt date was in Nov 2004 with most awards made 10 to 12 months following the April receipt.

Applications from the August and December receipt dates began being awarded about seven months following receipt. Applications in the Gray Zone for all receipt dates were usually awarded in September. Even though April applicants may wait longer to receive an award, there are advantages to the April receipt date.

First, if your application requires revision, you will know early enough to revise it for the August receipt date giving you a second chance at funding in the same fiscal year.

Second, NIH has a number of eligibility requirements that are only examined immediately prior to an award. See my Just-in-Time slide for details. Otherwise fundable applications deficient in any of these requirements may have till the end of the fiscal year to become eligible. April receipt date applications whose awards were delayed until May through August probably had eligibility issues. August and December receipt date applications have less time to meet eligibility requirements before the end of the fiscal year.

Slide 39. NIAID FY2004 SBIR & STTR Applications



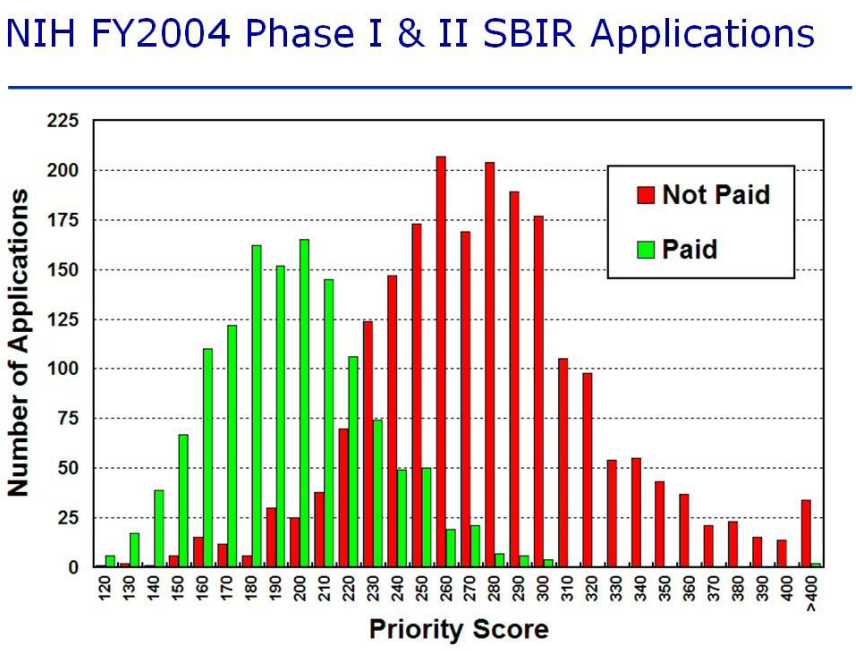
This chart shows the number of NIAID funded and unfunded small business applications within various priority score ranges. Included are all competing NIAID Phase I and Phase II SBIR and STTR applications.

The NIAID payline in FY2004 was 210. Note that there were 24 applications under the payline that did not receive awards because these applications failed to meet eligibility requirements at the time Grants Management Staff contacted them about an award.

All 21 applications with priority scores over the 210 payline were awarded at the end of the fiscal year. In making these end-of-year awards, applications with better scores were passed over if their application did not immediately meet all eligibility requirements.

I cannot over emphasize how important it is for you to meet all eligibility requirements when Grants Management Staff contacts you to offer an award.

Slide 40. NIH FY2004 Phase I & II SBIR Applications

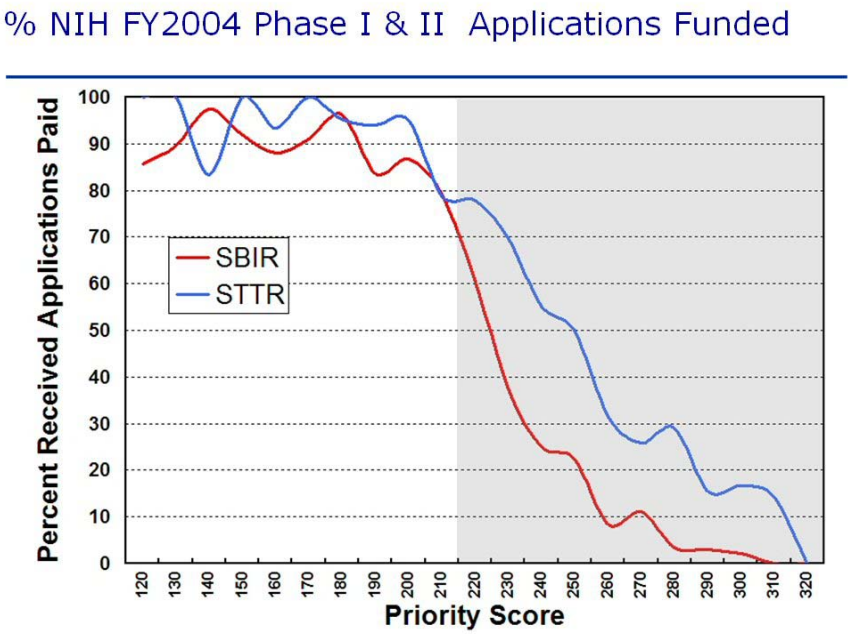


A bell-shaped curve composed of green bars in this chart show the number of FY2004 NIH Phase I and II SBIR applications that were funded within each 10-point priority score range. The center of the green bar curve is a priority score around 190 with tails going from priority scores 120 to 300.

A bell-shaped curve composed red bars show those applications that were not funded. Not shown on this chart are approximately an equal number of applications that were both unscored and unfunded. The center of the red bar curve is a priority score around 280 with tails going from priority scores 150 to greater than 400.

About 90% of applications that had priority scores under 210 were funded. The percentage of funded SBIR applications drops with increasing priority score as shown on the next slide.

Slide 41. % NIH FY2004 Phase I & II Applications Funded



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A red line shows the percentage of FY2004 SBIR Phase I and II applications that were funded in each 10-point priority score range and a blue line shows the data for Phase I and II STTR applications. For priority scores from 120 to about 200, both lines hover at around 90 percent and then fall off almost linearly to zero at a priority score around 300 but the red SBIR line has a steeper slope than the blue STTR line.

About 90% of applications with priority scores under 210 were funded. The unfunded applications with priority scores under 210 most likely failed an eligibility requirement at the time they were offered an award.

Applications with priority scores between 210 and 300 were in the NIH Gray Zone. The percentage of applications funded decreased as the priority score increased but the rate of decrease was less for STTR applications than for SBIR applications. The priority score range within the Gray Zone varies from one IC to another depending upon an IC's award rate as shown on the next slide.

The NIH Gray Zone in FY2004 contained about 25% of funded SBIR applications and 41% of STTR applications. In FY2004, high priority score STTR applications had a better probability of funding than comparably scoring SBIR applications.

Slide 42. FY2004 SBIR Phase I Award Rate by IC

Funded	%	Name
2	3.8	National Library of Medicine
26	8.2	National Institute of Biomedical Imaging and Bioengineering
3	9.4	National Center for Complementary and Alternative Medicine
15	12.1	National Institute of Environmental Health Sciences
1	12.5	National Center on Minority Health and Health Disparities
37	13.3	National Institute of Child Health and Human Development
29	15.1	National Institute of Arthritis and Musculoskeletal and Skin Diseases
59	15.9	National Institute of General Medical Sciences
57	16.2	National Institute of Diabetes and Digestive and Kidney Diseases
136	16.5	National Institute of Allergy and Infectious Diseases
185	17.5	National Cancer Institute
13	17.8	National Institute of Dental and Craniofacial Research
42	18.3	National Center for Research Resources
7	18.9	National Institute of Nursing Research
32	19.9	National Institute of Mental Health
21	20.2	National Institute on Drug Abuse
12	22.6	National Institute on Alcohol Abuse and Alcoholism
115	23.2	National Heart, Lung, and Blood Institute
35	24.1	National Institute on Aging
18	29.0	National Human Genome Research Institute
37	30.3	National Eye Institute
64	30.5	National Institute of Neurological Disorders and Stroke
21	34.4	National Institute on Deafness and Other Communication Disorders

This table shows the data for FY2004 SBIR Phase I applications. The first column shows the number of applications funded by each IC. There are large differences in the numbers of applications funded by each IC. The National Cancer Institute funds the most, and the National Center on Minority Health and Health Disparities, the least. For each IC, the second column shows the percentage of all FY2004 SBIR applications received that were funded. The percentage funded and is not identical to an NIH success rate. The percentage funded ranged from a low of 5% for NLM to a high of 35% for NIDCD. The average award rate for all ICs was 18%.

If your research project is specific to the mission of an Institute or Center (IC), it will be assigned to that IC even if you ask that it to be assigned elsewhere. If you are developing a core technology where you could propose more than one application for your technology, you may be able to select a project which will be directed to an IC that funds a high percentage of its applications. The IC assignment may have influenced funding of those applications whose scores were in the Gray Zone. Use these data cautiously because there is no assurance that a future year's results will be the same.

Slide 43. NIH Awarding Institutes and Centers

Acronym	Code	Name
NCI	CA	National Cancer Institute
NCCAM	AT	National Center for Complementary and Alternative Medicine
NCRR	RR	National Center for Research Resources
NCMHD	MD	National Center on Minority Health and Health Disparities
NEI	EY	National Eye Institute
NHLBI	HL	National Heart, Lung, and Blood Institute
NHGRI	HG	National Human Genome Research Institute
NIAID	AI	National Institute of Allergy and Infectious Diseases
NIAMS	AR	National Institute of Arthritis and Musculoskeletal and Skin Diseases
NIBIB	EB	National Institute of Biomedical Imaging and Bioengineering
NICHD	HD	National Institute of Child Health and Human Development
NIDCR	DE	National Institute of Dental and Craniofacial Research
NIDDK	DK	National Institute of Diabetes and Digestive and Kidney Diseases
NIEHS	ES	National Institute of Environmental Health Sciences
NIGMS	GM	National Institute of General Medical Sciences
NIMH	MH	National Institute of Mental Health
NINDS	NS	National Institute of Neurological Disorders and Stroke
NINR	NR	National Institute of Nursing Research
NIA	AG	National Institute on Aging
NIAAA	AA	National Institute on Alcohol Abuse and Alcoholism
NIDCD	DC	National Institute on Deafness and Other Communication Disorders
NIDA	DA	National Institute on Drug Abuse
NLM	LM	National Library of Medicine

The first column in this chart lists the acronyms for each of the NIH Institutes and Centers (IC) that award grants which are listed in the last column.

The second column lists the two letter grant codes used by each IC.

Slide 44. Program Announcements

- Program Announcements (PAs) are NIH staff "wish lists."
- Review committees usually evaluate an application responding to a PA no differently than any other application.
- You can handicap your application by trying to make it fit a PA.
- Respond to a PA only if the research you want to propose exactly matches the PA request.
- You do not need to respond to PA to request an award over $100 thousand. About 40% of the applicants that did not respond to a PA received awards over $100 thousand.
- Most, but not all FY2004 multi-year awards went to applications in response to PAs.

Program Announcements (PAs) are written by NIH extramural program staff to encourage grant applications that will fill gaps in their portfolios.

Reviewers evaluate an application based on its science and may not even read the PA to which an application responds.

You may handicap your application if you try to "fit a square peg into a round hole."

I suggest you respond to a PA if and only if the research you want supported exactly matches the PA request.

Applicants are attracted to a PA that states that they may request over $100,000 per year and multi-year funding. You do not need to respond to a PA to request an award over $100,0000. All ICs will award over $100,000 per year if the request is well justified and approved by the review committee. In fact, about 40% of the FY2004 applicants who did not respond to a PA received awards over $100,000.

Most, but not all FY2004 multi-year awards went to applications in response to PAs. This could be because few other applicants requested longer time. If you need to apply for a two- or three-year Phase I grant, check first with the appropriate IC staff to learn if your application would be accepted.

Slide 45. NIAID Multi-Year Funding Program Announcements

Program Announcement	Maximum time	Maximum award
SBIR-AT-NIAID		
Phase I	2 years	$300,000 per year
Phase II	3 years	$1 million per year
Fast-Track and STTR not permitted		
BIODEFENSE		
Phase I	2 years	$500,000 per year
Phase II	3 years	$2 million per year
Fast-Track and STTR are permitted		
NIAID high priority biodefense products		

This chart provides information on NIAID advanced technology program announcement, SBIR-AT-NIAID, and SBIR/STTR biodefense program announcement recognize that permit higher than normal award levels and longer times for completion. Check other ICs for their programs and policies.

The SBIR-AT-NIAID is for projects leading to a product or service that requires approval of the FDA. NIAID will consider funding well-justified Phase I SBIR-AT-NIAID applications for up to 2 years, amounts up to $300 thousand per year, and consultant costs exceeding the normal maximum of 33%. The SBIR-AT-NIAID announcement does not permit STTR or Fast-Track applications.

Both normal and SBIR-AT-NIAID Phase I recipients may submit SBIR-AT-NIAID Phase II applications. NIAID will consider funding SBIR-AT-NIAID Phase II applications for up to 3 years, amounts up to $1 million per year, and consultant costs exceeding the normal maximum of 50%.

The NIAID biodefense program announcement permits well-justified small business Phase I applications on high priority biodefense products to request Phase I funds for up to 2 years, amounts up to $500 thousand per year, and consultant costs exceeding the normal maximum of 33%. Fast-Track applications are permitted but the Phase II component is not likely to be funded.

Only Phase I recipients may submit biodefense Phase II applications. NIAID will consider biodefense Phase II applications for up to 3 years, amounts up to $2 million per year, and consultant costs exceeding the normal maximum of 50%. Both Phase I and Phase II applications must include a critical path and scientific milestones for product development.

The NIAID high priority biodefense products link is to a list of products.

Slide 46. FY2004 Phase I Applications Funded

Type	Received	Funded	Award Rate
SBIR All NIH			
No PA	4088	755	18.50%
PA	1276	212	16.60%
STTR All NIH	633	213	33.60%
SBIR NIAID	826	136	16.50%
No PA	426	70	16.40%
SBIR-AT-NIAID	119	28	23.50%
Biodefense	268	34	12.70%
Other	13	4	30.80%

The upper part of this table shows the number of all FY2004 NIH Phase I SBIR applications received and funded and the award rate for applications either responding or not responding to a program announcement. As a group, applicants responding to a PA had a slightly lower award rate than applicants not responding to a PA.

The middle of this table shows the data for all FY2004 NIH STTR applications.

The lower part of this table shows the FY2004 results for NIAID. As a group, NIAID applicants had a slightly lower award rate than the average for applicants to all NIH ICs. Applicants to the SBIR-AT-NIAID PA were more successful than average and applicants to the Biodefense PA were less successful.

The reasons for these differences are unclear, but I will speculate anyway. Reviewer scrutiny of SBIR-AT-NIAID applications is greater than of normal applications so better quality applicants may self-select to apply. Reviewer enthusiasm may be naturally greater because the objective of SBIR-AT-NIAID projects is to produce a product that requires FDA approval. Also, SBIR-AT-NIAID applications often include significant preliminary data, milestones, a product development plan, and commercialization partners that may increase enthusiasm of reviewers.

The lower award rate of biodefense SBIR applications may illustrate what happens when new applicants are attracted by the availability of large-scale funding and propose large-scale projects.

Slide 47. FY2004 NIH Phase I Award Amounts

Type	Number	Average	Average + 1 standard deviation
SBIR No PA	755		
Under $100,000	398	$98,000	$104,000
Over $100,000	357	$168,000	$237,000
SBIR PA	**212**		
Under $100,000	44	$99,000	$103,000
Over $100,000	168	$281,000	$403,000
STTR No PA	**168**		
Under $100,000	79	$99,000	$103,000
Over $100,000	89	$180,000	$261,000
STTR PA	**56**		
Under $100,000	11	$100,000	$101,000
Over $100,000	45	$255,000	$368,000

The top section of this table shows data for all funded FY2004 NIH Phase I SBIR applications that were not received in response to a PA. I have separated the 755 funded applications into two groups: those with funding amounts within normal guidelines and those in excess of normal guidelines.

The first group of 398 awards likely represents applications submitted within normal guidelines, and most of these applications received an award close to $100,000. The second group of 357 awards likely represents applications with budgets exceeding normal guidelines. The average award for the second group was $168,000 with a standard deviation of $69,000 indicating a broad range of funding. There was no significant difference in the percentage of applications funded between these two groups suggesting it may not hurt your chances to request more funds.

The next section of this table shows data for all funded FY2004 NIH Phase I SBIR applications received in response to a PA, many of which permitted higher than normal awards. The 212 funded applications were similarly separated into two groups. The first group of 44 awards likely represents applications funded within normal guidelines. The second group of 168 awards likely represents applications with budgets exceeding normal guidelines. The average award for the second group was $281,000 with a standard deviation of $122,000 indicating a broad range of funding.

The last two sections of the table show essentially the same results for STTR awards.

It is not clear if applications in response to a PA received higher awards because the PA permitted higher awards or because applications in response to a PA were more likely to request higher funding.

Slide 48. Revised FY2004 Phase I Applications

Type	Received	Funded	Award Rate
SBIR All	**5364**	**967**	**18.00%**
Initial	4250	717	16.90%
1st revision	967	206	21.30%
2nd revision	147	44	29.90%
STTR All	**633**	**213**	**33.60%**
Initial	511	158	30.90%
1st revision	106	52	49.10%
2nd revision	16	3	18.80%

This table illustrates that revised applications had a higher probability of funding than initial applications.

The overall award rate for all NIH FY2004 SBIR applications was 18%, but that for initial applications was 17%, increasing to 21% and 30% respectively for first and second revisions. Only about a quarter of unsuccessful applications were revised once, and only about a quarter of unsuccessful revised applications were revised a second time. The higher award rates for revised applications may be attributed to applicants following the reviewers' suggestions.

The overall award rate for all NIH FY2004 STTR applications was 34%, but that for initial applications was 31%, increasing to 49% for the first revision. The number of second revision STTR applications submitted was too small to know if the decrease in award rate is statistically significant.

Slide 49. FY2004 NIH Phase II Applications

Type	Received	Funded	Award Rate
SBIR FY2004	882	285	32.30%
STTR FY2004	71	30	42.30%
FY2001-2003			
Fast-Track	145	114	78.60%

Amount	Number	Average	Average + 1 standard deviation
Under $750K	126	$690,000	$800,000
Over $750K	189	$1270,000	$2,000,000

The top section of the upper table shows the number of FY2004 NIH Phase II SBIR and STTR applications received and funded and the award rate for each type of application. About 32% of the SBIR and 42% of the STTR Phase II applications were funded.

We will not know the Phase II award rate of FY2004 Fast-Track applications until FY2006 because Phase II funding is awarded only after the conclusion of a successful Phase I. Instead, we can examine the Phase II award rate for Fast-Track applications whose Phase I awards occurred in FY2001 to 2003. Of the 145 Fast-Track awards during this period, 114 or about 79% received follow-on Phase II funding.

The lower table shows the number and amount of Phase II awards separated into two pools. SBIR and STTR awards are combined in this table because there was no significant difference between the two groups. Also, there was no significant difference between groups responding or not responding to a PA.

The first pool of 126 awards under $750 thousand likely represents applications submitted within normal guidelines. The average award for this pool was $690,000 and most of these applications received an award close to the $750,000 guideline.

The second pool of 189 awards over $750,000 likely represents applications requesting funding exceeding normal guidelines. The average award for this pool was $1.27 million and awards up to $2.0 million lie with one standard deviation.

Slide 50. GRANTSMANSHIP

Slide 51. William Raub - Past Deputy Director, NIH

“There is no grantsmanship that will turn a bad idea into a good one, but there are many ways to disguise a good one.”

Creating a clear, well planned, and organized grant application plays a major role in winning over peer reviewers.

Slide 52. Know NIH Review Criteria

- **Significance:** Does the study address an important problem and have commercial potential? Will scientific knowledge be advanced and/or enabling technologies created?
- **Approach:** Are design and methods well-developed and appropriate? Are problem areas addressed?
- **Innovation:** Are there novel concepts or approaches? Are the aims original and innovative?
- **Investigator:** Is the investigator appropriately trained and capable of managing the project?
- **Environment**: Does the scientific environment contribute to the probability of success? Are there unique features of the scientific environment?

Peer reviewers are instructed to use five criteria to evaluate your application: significance, approach, innovation, investigator and environment.

These are the same criteria used to judge all NIH applications. Although some are more important than others, none is unimportant. Prepare your application to address each area.

Organize your application to make it easy for reviewers to find information relating to each criteria.

You do not need to excel in all criteria because reviewers do not rate them separately. Instead, reviewers' priority score assignments are a gestalt reflecting your entire application, based on what they read and what they hear from other reviewers.

Slide 53. Phase I Objective

- Establish the technical/scientific merit and feasibility of the proposed R/R&D efforts.
- Not “feasibility” of producing the product.
- Multiple “feasibility” studies may be necessary between the inception of an idea and the sale of a product.
  - The window is open for more than one Phase I and Phase II grant for any product.
  - You should carefully define and limit your proposals.

One of the most common mistakes made by applicants is lack of focus - thinking too big. It may not be likely or even desirable to go from concept to product in a single Phase I/II application.

Your objective for Phase I is to establish the technical, scientific merit, and feasibility of Phase II, not of producing your product.

You may need to test feasibility at many steps along the path from concept to product.

If you are careful and limit the scope of your application, you may be able to have multiple Phase I and Phase II funding to support your voyage from concept to product.

Slide 54. Master the Beginner Slopes First

Cartoon shows a skier as a metaphor where the skier is on mountain with beginner or green, intermediate or blue, and advanced or black slopes.

Our advice skier may help you decide what type of NIAID application you should consider. Small business applications are like most NIH applications: the more time and money you request, the greater the difficulty of writing a successful application.

The “normal” SBIR application, like the beginner green slopes, is the least difficult to master but comes with the least award funds and time.

The SBIR-AT-NIAID, Biodefense and similar multi-year, higher award applications like the intermediate blue slopes are more difficult to master. Successful applications usually include more preliminary data and require better grant-writing proficiency. You are more likely to be successful on the blue slopes after you have received a Phase II award on the green ones.

The Fast-Track application, like the most difficult double diamond black slopes on the top of the mountain should be attempted only by those who have mastered the art of SBIR grantsmanship, have compelling preliminary data, and propose a project with crystal clear go-no-go milestones.

Keep in mind that about half of Phase I awardees receive over $100,000 and thus appear to have mastered the intermediate slopes. Only you can determine on which slope you belong.

Slide 55. Larger Balloons Are More Likely to Be Popped

Cartoon shows an inflating balloon as a metaphor where the balloon is increasing in size with a growing weak spot. Reviewers are shown as sharp needle that breaks the balloon at weak spot. After repair, a new weak spot is detected and the balloon again breaks.

I use a balloon metaphor to illustrate why large applications that exceed normal guidelines are less likely to be funded.

Review committees use a triage process to spend the most time on applications most likely to be funded. They search for any weakness in an application which may quickly eliminate it from further consideration.

Compared to normal applications, SBIR-AT-NIAID, biodefense, and Fast-Track applications are often larger in scope and more likely to have a discernable weakness that leads to their downfall.

Like a balloon, the more you expand your application, the more likely it is to have weak spots.

The review committee's sharp criticism will be directed at the first week spot they detect, and they will pop your balloon.

Once the air is released, your application is no longer considered seriously.

As a result, the criticisms you receive may not fully describe all that is wrong with your application. If you only patch the identified holes and resubmit, you may miss other problems which may be uncovered at the next review.

Your best strategy is to keep your Phase I application as narrow and well-focused as possible, like the smallest balloon. Limit your Phase I goals to only those absolutely necessary to support your application for Phase II.

Do not confuse focus with budget. Ask for no more and no less than the funds required to conduct your Phase I research.

Slide 56. Requesting Multiple Awards for Same Product

A diagram depicts how you can request multiple awards for the same product. The information in the diagram is fully described in the script.

Using a drug development project, I will provide an example of how you might request multiple SBIR Phase I and Phase II grants for the same drug product.

The first Phase I takes the project from lead compound to drug candidate. The Phase I is the feasibility study for the first Phase II which takes the drug candidate through small animal model studies.

The second Phase I follows the investigational new drug application and begins human safety studies. Note that the second Phase I is a feasibility study for further human trials. The second Phase II begins the large scale human safety and efficacy trials. As milestones are met, you can submit multiple competing continuation applications to continue your project.

Slide 57. NIAID Phase II Competing Continuation Awards

- Some ICs offer competing continuation Phase II awards for projects whose product will require approval of a federal regulatory agency, usually the FDA.
- NIAID accepts competing continuation Phase II grant applications for a project period up to three years and a budget not to exceed a total cost of $1 million per year.
- Competing continuation Phase II applications to NIAID may exceed 50% consultant and contractual costs when well justified and necessary to support clinical studies and related expenses.
- Clinical protocols must be approved by NIAID prior to the accrual of subjects.

A number of NIH ICs offer Phase II awardees the opportunity of competing for continued Phase II funding of projects whose product will require approval of a federal regulatory agency, usually the FDA.

NIAID accepts competing continuation Phase II grant applications for a project period up to three years and a budget not to exceed a total cost of $1 million per year.

Also, competing continuation Phase II applications to NIAID may exceed 50% consultant and contractual costs when well justified and necessary to support clinical studies and related expenses.

All clinical protocols must be approved by NIAID prior to the accrual of subjects.

Slide 58. Structure of an Phase I Application

- Use new PHS398 forms and PHS 398 instructions.
- Cover letter
- Page 1* Title, institutional information, eRA users name
- Page 2 Abstract and performance sites
- Page 2 Continued
  - Key personnel (have percent effort)
  - Contributors (zero percent effort)
  - Stem cell use
  - Disclosure permission
- Page 3* Table of Contents
- Page 4 1st Year's Budget (*company pages only)
- Page 5 Budget for all years (if more than one) (*company only)
- Budget and Justification for entire period
- STTR Institution Budget Page
- Biographical Sketches (max 4 pages each person)
- Resources*
- Research Plan (*for sections marked in Research Plan slide)
- Letters from collaborators/consultants
- Checklist and personal data on PI

* Maximum total of 25 pages for these sections

All NIH applications are submitted on the same PHS398 forms. The "one size fits all" nature of the PHS398 means you need to follow the instructions for SBIR/STTR applications and not those for other types of NIH applications.

The sections marked with red asterisks must not exceed 25 pages.

Slide 59. Title and Abstract

- Your title should be as specific and detailed as possible within the 81 character limitation.
- Your abstract should be a concise summary of your entire application. Clearly and succinctly include your project's:
  - Specific aims (milestones)
  - Significance
  - Preliminary studies / background
  - Research design and methods
- Very important – Suggest you write these last.

Your title and abstract are extremely important because they will be used by NIH referral staff to assign your application to a peer review group and to an IC, they will be read by all reviewers, and they will form the basis for decisions within an IC if your priority score is in the gray zone described in the slide on Receipt, Review and Award Dates.

Not only should your title should be as specific and detailed as possible within the length limitations, but if possible it should also convey some of the significance of your proposal.

Do not include confidential information in your abstract because it will become public if you receive an award.

Think of your abstract as an advertisement for your proposal. It should give readers a complete description of what you intend to accomplish and engender enthusiasm for accomplishing it.

You have limited space, so take time to hone your language to convey your message. Make your title and abstract so enticing that even reviewers not assigned to your application will want to read it.

Since research plans evolve as you write them, I suggest that you compose your Title and Abstract after you have completed the rest of your application.

Slide 60. Budget and Fee

- Follow budget instructions.
- Modular budgets are no longer allowed.
- Complete separate budget pages 4 and 5 for company and each contractor.
- If you exceed the annual cap on salaries, you will decrease an award.
- A fee up to 7% can be used for expenses that may not be charged to your grant.

Read the budget instructions carefully as there have been recent changes. For example, modular budgets are no longer allowed.

The simplicity of submitting a modular budget was an incentive to keep the amount you request for Phase I at $100,000 to one year. With modular budgets gone, you should request exactly the amount and time you need because you will have to complete a detailed budget anyway.

If you plan to have a subcontract, each subcontractor must complete budget pages.

Be careful that the annual salaries you request do not exceed the salary cap of $180,100 (effective January 1, 2005) or your award may be administratively decreased.

A fee, if requested, should be used to pay for things related to your grant but not permitted as direct or indirect costs. For example, you could use the fee to pay for patent costs, for market research, or for expenses outside the U.S. Explain how you will use a fee in your justification on form page 5.

Slide 61. Structure of an SBIR/STTR Application Research Plan

- Introduction to revised application
  - A. Specific Aims*#
  - B. Significance and Related R&D*#
  - C. Preliminary Studies*#
  - D. Experimental Design and Methods*#
  - E. Human Subjects*
  - F. Vertebrate Animals*
  - G. Literature Cited*
  - H. Consortium/Contractual Arrangements*
  - I. Resource Sharing*
  - J. Letters from consultants
- Checklist (last page of application)
- Appendix not allowed for Phase I application

* Included in 25 page Phase I limit

\# Maximum of 15 pages for Phase I; 25 for Phase II

The Research Plan of all NIH applications has essentially the same format. Your priority score is determined mostly by what you write in Sections A-D. These sections are limited to 15 pages. Sections E-J have minor impact on your priority score but can cause major delays in funding. Pages marked with a red asterisk are included in the Phase I 25-page limit.

I suggest that you label the sections of your application with the same letters and titles used in the SBIR/STTR solicitation. Include sufficient information to meet requirements and to allow reviewers to judge the quality of your application based on the NIH rating criteria.

Slide 62. Specific Aims - Section A

- Your Specific Aims are the milestones of your research project, driven by your hypothesis or research objective.
- Do not confuse Specific Aims with long-term goals.
- Specific Aims are the criteria by which success of Phase I will be judged.
- Choose Specific Aims that can be easily assessed by the review committee.
- Include concrete Specific Aims that reviewers will expect.

Section A of your research plan is called Specific Aims. Begin this section with your hypothesis or research objective. Then describe your Specific Aims as the milestones for your Phase I research.

Do not confuse specific aims with your project's long-term goals. Specific Aims are what you will accomplish before the end of the first funding period.

When your Phase II application is considered, reviewers will judge your Phase I accomplishments against the Phase I Specific Aims that you proposed. Thus, you want to select Specific Aims you are reasonably confident that you can accomplish. However, the review committee will doubt your judgment if you omit a milestone that they think is essential prior to Phase II funding.

To be easily assessed, a Specific Aim should be an "end point" as opposed to a "best effort."

For example, in a drug development project, instead of a Specific Aim "to evaluate a number of potential drug candidates," which would be a "best effort," make your specific aim "to select the best drug candidate for further study," which is an "end point." In the latter case, you will have reached a conclusion and will be ready to move on to the next phase of your project.

Slide 63. Significance and Related R&D - Section B

- Significant product potential
  - A product-focused application is more likely to have support of business reviewers.
  - A project with sound financial projections is more likely to attract a partner.
- Significant innovative science
  - A scientifically focused application is more likely to have a knowledgeable reviewer.
- Significant to NIH Institute or Center
  - An application that addresses a program's need is more likely to have a champion.
  - Identify and speak with your potential champion.

Section B of your Research Plan, Significance and Related R&D, may have different meanings for different reviewers. To be competitive, applications for NIH small business funds need to show a significant product, significant science, and significant public health need.

Business reviewers will judge your application on its likelihood to lead to a commercially successful product in a reasonable period of time. They are impressed by a project with sound financial projections and partners who will help get your product to the market.

Science reviewers will judge your application on its science innovation and its likelihood to increase knowledge. The more focused the application, the more likely it will be assigned to a knowledgeable reviewer.

Both the product and the science should be targeted to the needs (the mission) of an NIH Institute or Center and to a specific program area administered by a program officer (a champion) who will support funding your project over its competition.

Innovation does not necessarily mean a new paradigm. Either the ends or the means should be innovative, but both do not have to be.

Thus, if the result of the research is critical, it may not be important that your means are not innovative and vice versa.

Slide 64. Illustrate the Significance of Your Research

- Use citations to demonstrate the breadth of your knowledge of both published and unpublished work.
- Describe the state of knowledge in your research area, gaps and roadblocks, and opportunity you have identified.
- Tell why your proposal will increase knowledge and improve public health.
- Identify how the proposed Phase I research milestones will justify Phase II.

The following are my tips to make your significance section better.

Illustrate the significance of your research by describing the state of knowledge in your research area, the gaps as well as the roadblocks, and how your project addresses these.

Show reviewers you know the field by the breadth of your knowledge of both published and unpublished work by others, some of whom could be your reviewers.

Tell reviewers explicitly why your proposal is innovative, how it will increase scientific knowledge, and the way in which it could improve public health.

Show how the Phase I research milestones you outlined in your specific aims will justify your application for a Phase II award.

Slide 65. Preliminary Studies - Section C

- Previous experience (publications, patents, similar products) basis for Investigator evaluation criterion.
- Preliminary data
  - Solicitation states “Preliminary data are not required.”
  - Other applications present preliminary data.
  - Reviewers like to see preliminary data.
  - Preliminary data should support your proposal and the feasibility of the project.
  - Preliminary data may consist of your own publications and unpublished data from your laboratory.
  - Interpret results critically. Evaluate alternative meanings.

Section C of your Research Plan, Preliminary Studies, should convince reviewers that you can do what you propose.

Although the SBIR/STTR solicitation states that “Preliminary data are not required,” most applications present preliminary data. Review committees are likely to have greater enthusiasm for proposals with preliminary data.

Preliminary data may consist of your own publications and those of others, and unpublished data from your laboratory that support your proposal and the feasibility of the project.

Interpret results critically and evaluate alternative meanings. You can be assured that critical members of the review committee will look for explanations other than the ones you propose.

Describe your relevant experience, with an emphasis on work you have accomplished that indicates you can direct the proposed research and achieve the aims of your project.

The Investigator evaluation criterion may be based on this section and on the biographical sketches of key personnel.

Slide 66. Research Design and Methods - Section D

- Describe Research Design and Methods in parallel to your Specific Aims, including for each experiment:
  - Timelines.
  - 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.
  - Collaborators – purpose & letters of agreement.

Section D, Experimental Design and Methods, should spell out in detail what you are going to do, how you are going to do it, and your criteria for success. I suggest you include a timeline chart to convey your entire project quickly to reviewers.

Give a rationale for your choice of experiments. Convince reviewers that your methods are appropriate to your Specific Aims. If your methods are innovative, show how you have changed existing or proven methods while avoiding technical problems. If you are choosing a nonstandard approach, explain why. Provide supporting data and references.

Describe the kinds of results expected and how they would support continuation of your project. Present other possible outcomes and contingency plans.

Define the criteria for evaluating the success or failure of each experiment. Include statistical analysis if possible - reviewers are impressed by statistics. If the review committee does not agree with your criteria for success, your application will probably need revision.

Describe hazards anticipated and precautions you propose. Spell out your sources of important reagents and equipment, and details of any use of animals or human subjects.

Credible collaborators, often academic faculty, can improve your rating on the investigator criteria. Be sure to explain not only who they are but exactly how they will participate in your proposed research. Include letters that describe their agreements with you including their role on the project and hours to be committed.

Slide 67. Other Issues You Must Address

E. Human Subjects.
F. Vertebrate Animals.
G. Literature Cited.
H. Consortium and Contractual Arrangements.
I. Resource Sharing
J. Consultants.

Failure to adhere to regulations on human subjects can easily delay or abort funding for a research project. If your research requires samples from people, try to design your experiments so that you are exempt from human subject regulations.

Failure to adhere to regulations on vertebrate animals can also sidetrack your award. Even if you plan to use animal facilities in a collaborating institution, the company needs to have an approved animal welfare assurance on file prior to an award.

I suggest you try to design experiments that do not require vertebrate animals unless you really need them, and if you need them, get your assurance paper work done early.

The Literature Cited section should include references to significant work but need not be exhaustive. If you fail to cite a reference a reviewer thinks important, that reviewer may not consider you knowledgeable in the field. Cite any reference whose methods you will use but are not described in Section D.

Although absence of some details on Consortium and Contractual Arrangements and Resource Sharing may not affect your priority score, they can delay or even sidetrack your award.

Slide 68. 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 FWA number.
- Institutional review board approval certification date.
- Human subjects education certification.
- Institutional animal care and use committee assurance number and approval date.

Some application information is required Just-in-Time, meaning at the time NIH wants to award you a grant.

At that time you will:

Provide NIH a list of other research support for the PI and all key personnel.

Provide a lease agreement or other documentation showing you control your research space.

Verify that an SBIR PI works over half-time for the company and that the company is eligible for SBIR/STTR funding.

If you are conducting human research, provide an FWA number, IRB approval information, and human subjects education certification.

If you are conducting research using vertebrate animals, provide an IACUC assurance number and protocol approval date.

If any of this information is not available when NIH is ready to fund your application, your award will be delayed and if you do not provide the information within a time specified by the funding IC, your application may be administratively inactivated.

Slide 69. Key to Human Subjects Exemptions

- Investigators who do not have access to subjects' identifiers are usually exempt from human subjects requirements.
- Research involving only coded private information or human biological specimens is generally not considered to be human subjects research with following conditions:
  - Specimens or data are not obtained specifically for the research.
  - Investigators and collaborators cannot readily ascertain a subject's identity through the coded private information or specimen, e.g., a researcher's access to identity is prohibited by a written agreement.
- Investigators who provide coded information or specimens and also collaborate on the research are conducting of human subjects research because they have access to identifiers.
- Review the Human Subject Regulations Decision Charts. If exempt, check "no" in item 4a on Page 1 and provide exemption number, usually number 4.

Many studies using human samples or data can be exempt from human subjects requirements if you follow these three guidelines.

First, the samples or data must be obtained for reasons other than the proposed research, for example as a biopsy for other health reasons.

Second, you sign a written agreement between the provider of the samples and you and your collaborators that specifies that coded private information will not be released.

Third, the provider of the samples cannot be a collaborator on your research.

Review the Human Subject Regulations Decision Charts and if your research is exempt, check "no" in item 4a on Page 1 and list exemption, usually number 4.

Slide 70. Human Subjects – Section E.

- Review PHS398 instructions and the regulations and guidance on the Office of Human Research Protections web site. Contact OHRP for help.
- A Human Subjects Federalwide Assurance (FWA) is required for your company even when studies are contracted out.
- Human subjects assurances are required Just-in-Time, but start early to avoid a delay in funding.
  - You can designate an approved IRB of a partner institution if you obtain a written agreement.
  - Complete IRB-mandated investigator training.
  - Design targeted and planned enrollment.
  - Prepare protocol using human subjects checklist.
  - Obtain IRB approval.
  - File Unaffiliated Investigator Agreement.
  - File FWA form in paper or electronic format at the Office of Human Research Protections website.

If your research proposal includes human specimens or subjects and you are not exempt, you should carefully review the information in the PHS398 instructions and on the Office of Human Research Protections website.

Even if all your human studies will be conducted by a contractor, you will still need to obtain a human subjects FWA and follow all regulations.

Contact OHRP for regulations and guidance. Details of human subjects requirements are too complex to describe here.

Although human subjects assurances are required Just-in-Time, you should allow lots of time, particularly if you are using another institution's IRB.

Slide 71. Using Vertebrate Animals – Section F.

- Consider alternatives to using vertebrate animals.
- If you check yes in item 5 on page 1, you must include in your grant application a protocol and address five points in vertebrate animal section.
- Review NIH Office of Laboratory Animal Welfare (OLAW) tutorial on animals in research.
- You can designate another institution's Institutional Animal Care and Use Committee (IACUC).
- Try to outsource to an institution with an animal welfare assurance on file with the NIH OLAW.
- You must still apply for and receive an Inter-institutional assurance and obtain animal welfare assurance number prior to award.
- The Just-in-Time vertebrate animals requirement can usually be completed between review and funding.

Consider alternatives to using vertebrate animals. If your research requires them, your grant application must include a protocol and address the required five points in Section F, or it may be returned without review. I suggest you take the tutorial on animals in research located on the NIH Office of Laboratory Animal Welfare website. You will need an Institutional Animal Care and Use Committee. You can use that of a partnering institution that has an assurance on file with NIH. You will need to obtain an inter-institutional assurance and an animal welfare assurance number prior to your award. This Just-in-Time requirement can usually be completed between review and funding.

Slide 72. Resource Sharing – Section I.

- Data sharing – Investigators seeking $500,000 or more in direct costs in any year must include a brief one paragraph description of how final research data will be shared, or explain why data-sharing is not possible.
- See NIAID data sharing example and NIAID Data Sharing Policy standard operating procedure (SOP) for guidance.
- Model organisms – All applications where the development of model organisms is anticipated are to include a description of a specific plan for sharing and distributing unique model organism research resources or state appropriate reasons why such sharing is restricted or not possible. Note unlike the data sharing requirement, this requirement is for all applications.
- See NIAID Sharing Model Organisms SOP for guidance.

Investigators seeking $500,000 or more in direct costs in any year must include a brief one-paragraph description of how final research data will be shared, or explain why data-sharing is not possible. Although you must describe data-sharing plans, they are not considered in determining your priority score. Follow the links to view an NIAID data sharing example and the NIAID Data Sharing standard operating procedure (SOP).

If your application includes the development of a model organism for research, you must include a description of a plan for sharing it, or state appropriate reasons why such sharing is restricted or not possible. This NIH policy covers all funded research that could produce model organisms, regardless of the amount of the budget. Follow the link to view the NIAID Sharing Model Organisms SOP.

Slide 73. CONTACT NIH

Slide 74. Prior to Contacting NIH

- Describe core technology and prepare a business plan.
- Explore NIH Internet pages, identify potential NIH support and decide on your NIH product.
- Select PI and explore partnerships.
- Arrange space & resources.

Do your homework before calling NIH.

Identify your core technology and prepare a business plan.

Explore the NIH Internet pages and decide on your likely NIH product and your likely NIH source of support.

Select a Principal Investigator, explore strategic partnerships and arrange for space and resources.

Now you are ready to contact NIH Staff.

Slide 75. Prior to Submission

- Talk with Program Staff to obtain science advice.
- Identify and talk with other scientists.
- Talk with Grants Management Staff to discuss regulatory and policy issues.
- Talk with CSR Staff to identify likely Institute/Center and review committee assignments.

Early in the planning stages of your application, you will want to obtain science advice from Program Staff. The more knowledgeable you are the more productive your conversation is likely to be. You may learn that your technology is more relevant to a different program or Institute.

Ask who you could contact both in and outside NIH to get additional information on your proposed research. Bounce your ideas off as many scientists as possible. Refine your ideas and proposal based on your conversations.

If there are regulatory or policy issues that may affect your application, you should begin conversations with Grants Management Staff.

You could also start communications with the Center for Scientific Review Staff to identify likely review committee assignments for your proposal.

Slide 76. Program Staff

- Discuss the state-of-the-art, research trends, gaps and roadblocks.
- Identify your competition.
- Identify resources to help you.
- Identify other funding opportunities.
- Provide informal and sometimes more blunt feedback from the review.
- Be your advocate in the process.

Ask Program Staff to help you better understand the state-of-the-art in your research area. Talk about research trends, gaps and roadblocks, and your competition.

Also, ask program staff to identify resources you might use and other funding opportunities.

Although they do not participate in the review process, Program Staff often attend application review meetings.

When they do attend, they can provide you with informal and sometimes more blunt feedback from the review than you will read in the summary statement.

If a Program Staff person believes in the value of your proposal, she or he may be your advocate for funding if your application is in the Gray Zone I described previously.

Slide 77. Grants Management Staff

- Administrative matters
- Budget
- Rules and regulations
- Policy issues

You will mainly interact with Grants Management Staff during and after preparation of a Notice of Grant Award. However, you may want to contact Grants Management Staff prior to submitting an application if you have questions on administrative matters. These include budgets outside the normal levels, rules and regulations, and policy issues on human subjects and vertebrate animals.

Slide 78. Learn About Your Review Committee

- CSR Review Staff
- Information on review assignment
- Pub Med Central
- CRISP - Computer Retrieval of Information on Scientific Projects

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Many applicants for NIH grants make the big mistake of believing they should please the NIH Institute or Center to which their application will be assigned. Instead, I suggest you think of the review committee as the "primary customer" for your application. Your chance of getting funded is almost totally dependent on their judgment that your application is better than someone else's.

Due diligence requires that you learn as much as possible about your reviewers. Before you send NIH your application, communicate with CSR staff to identify which SRA and review group is likely to receive it. Ask for a list of committee members who would have reviewed your application if you had submitted it for an earlier receipt date. Many of these same reviewers may be on the committee that will review your application.

I encourage you to conduct a literature search on potential reviewers to learn their areas of expertise. Pay particular attention to the publications of those reviewers likely to receive primary assignment of your application. It is not a good idea to say something in your application that they would disagree with. You can use the National Library of Medicine's Pub Med Central site to search for publications by author.

I also encourage you to use the NIH CRISP database. CRISP stands for Computer Retrieval of Information on Scientific Projects. You can search CRISP to learn if potential reviewers of your application have NIH funded projects. If they do, you can read an abstract about their work. Be particularly cautious if the hypotheses in your application differs from one they espouse.

Slide 79. Application Submission

- Include cover letter to
  - Suggest IC and review committee.
  - Explain expertise necessary for review.
  - Ask that some people be excluded as reviewers.
  - Never suggest reviewers.

When you submit your application you can include a cover letter requesting its assignment to an Institute or Center. Be sure to explain your reasons.

Also, describe the expertise necessary to review your application.

You can request the exclusion of particular reviewers, with your reasons for exclusion. Be careful though! If you exclude too many reviewers, your application may be placed in a panel with little expertise in your scientific area.

Reviewers who know little about your research area may not appreciate its significance and this can lessen enthusiasm for your proposal. Do not suggest reviewers for your application because your suggestion will almost certainly guarantee that they will not be asked to serve on the committee.

Slide 80. eRA Commons (Electronic Research Administration)

- Small business concerns are invited to register with the NIH eRA Commons.
- Registered principal investigators can check assignment and contact information, review outcome, and other important information.
- In the future, grant applications will be submitted electronically.

I suggest that your company and you register with the NIH Electronic Research Administration Commons. Once registered, you can quickly check review assignments, review outcomes, and other important information such as your Just-in-Time requirements. In the not too distant future, grant applications will be submitted electronically.

Slide 81. Application Deadline + 10 Days

- Review CSR letter listing review date, committee, and IC assignment.
- Contact CSR referral office if letter not received or if you are concerned about your application's assignment.

About ten working days after the receipt deadline, you should receive a letter from CSR listing your application's assignment to a review panel, the date the panel meets, and the primary assignment to an NIH Institute or Center.

Call the CSR referral office if you do not receive this letter within three weeks of the receipt deadline, or if you receive the letter but are concerned about your application's assignment.

Slide 82. At Least 7 Weeks Prior to Review

- Call or email SRA to ask if updated or supplementary material can be provided, and if so, its latest submission date.
- You can check the CSR Roster site for a list of members on your review panel.

There is a limited time window after submission, up to seven weeks prior to review, when you may be able to provide additional information or correct or update some information in your application. If you discover such a need, don't wait – contact the SRA as early as possible with your request.

Also, check the CSR Internet site to see who will be on your application's review panel. This is the time for you to request the exclusion of specific reviewers but you will have to provide good reasons for their exclusion. Be aware that the SRA is under no obligation to agree to any of your requests.

Slide 83. Special Emphasis Panels (SEP) Composition

- Approximately 75% same reviewers from one meeting to the next.
- Many members also serve on standing Initial Review Groups (IRG).
- Some members ad-hoc with special expertise in science or business.
- CSR Small Business Applications information

Although the special emphasis panel, may have different reviewers for each review meeting, approximately 75% of the panel members remain constant.

Many of the SEP members also serve on standing Initial Review Groups, known as IRGs.

Others may have special expertise in a science or business area for that particular set of applications.

The Internet site for the Center for Scientific Review Small Business Applications publishes SBIR/STTR review guidelines, a list of current review committees and their SRA managers, and a roster for upcoming review meetings.

Slide 84. Review Date + 7 to 10 Days

- Call or email Program Staff to ask for Priority Score if not received by mail.
- Ask about payline and probability of being funded.
- If a revision is necessary, ask for advice.
- Contact Grants Management Staff if funding likely to review required Just-in-Time information.

About ten working days after the review meeting, you should receive a priority score in the mail. You can call or email your program staff (but not the SRA) for the score if you haven't received it within three weeks following the review.

Ask your Program Staff about the current payline and the probability of your application being funded.

If you are told that your application is not likely to be funded, ask for advice on preparing a revised application even though you will probably not receive a summary statement for another five to seven weeks.

If you are told that you are likely to be funded, contact Grants Management Staff to review the Just-in-Time information that you will need to provide prior to our issuing an award.

Slide 85. Advice for Applications in the Gray Zone

- Program staff is your best source of information about your assigned IC. Ask:
  - If the IC award rate will be similar to FY2004?
  - If the IC funds Gray Zone applications in priority order or selects by IC priorities?
  - If by IC priorities, will your program staff champion payment of your application over others with better scores?
  - If your STTR application (usually not an SBIR application) could be transferred to another IC for funding?
- If you submitted for the April or August receipt dates, consider revising and resubmitting your application at the next receipt date for funding in the same fiscal year because revised applications have a higher award rate than initial applications.
- If you are going to wait for end-of-year funding, complete your Just-in-Time information for Grants Management.
- If your SBIR priority score is over 240, or your STTR priority score is over 270, you should probably revise your application responding to reviewer suggestions and resubmit.

Program staff is your best source of information about your assigned IC. Ask:

If the IC award rate will be similar to FY2004?

If the IC funds Gray Zone applications in priority order or selects by IC priorities?

If the IC selects by IC priorities, will your program staff champion payment of your application over others with better scores?

If your STTR application (usually not an SBIR application) could be transferred to another IC for funding?

If you submitted for the April or August receipt dates, consider revising and resubmitting your application at the next receipt date for funding in the same fiscal year because revised applications have a higher award rate than initial applications.

If you are going to wait for end-of-year funding, complete your Just-in-Time information for Grants Management.

If your SBIR priority score is over 240, or your STTR priority score is over 270, you should probably revise your application responding to reviewer suggestions and resubmit.

Slide 86. Review Date + 6 to 8 Weeks

- Call or email Program Staff to ask for Summary Statement if not received by mail.
- Ask about probability of funding.
- Discuss revisions if funding unlikely.
- Contact Grants Management Staff if funding likely to review required Just-in-Time information.

About six to eight weeks after the review meeting you should receive a summary statement.

If after eight weeks you haven't received the summary statement, you can contact your program staff to request a copy.

Again, inquire about the probability of funding.

Discuss revising your application if funding is unlikely.

On the other hand, if funding is likely, I want to emphasize again that you should contact Grants Management Staff to review the Just-in-Time information that you will need to provide prior to NIH issuing an award.

Slide 87. Common Reasons for Poor Priority Scores

- Lack of new or original ideas.
- Absence of an acceptable scientific rationale.
- Lack of experience in the essential methodology.
- Questionable reasoning in experimental approach.
- Diffuse, superficial, or unfocused research plan.
- Lack of sufficient experimental detail.
- Lack of knowledge of published relevant work.
- Unrealistically large amount of work.
- Uncertainty concerning future directions.
- If any of these reasons appear in reviewers comments, you need to rethink, reorganize and rewrite your application.

Slide 88. Council Date + 1 to 2 Weeks

- Call or email Program Staff to ask if your application has received secondary review and, if yes, is it in line for funding.
- Call Grants Management Staff to discuss Just-in-Time information and to provide any other information necessary prior to approval of a Notice of Grant Award.

Although you will probably have a pretty good idea if your application is in line to be funded based on its priority score and your communication with program staff, there are additional gates your application must pass through before receiving an award. I described these in the slide on the SBIR/STTR Review and Award process. Call your program staff to learn if your application has received secondary review and if it is in line for funding.

The Grants Management Office must verify that you meet all the requirements for funding. This gate is the one where many SBIR or STTR applications are delayed or blocked. If you haven't been contacted by Grants Management Staff by now, this is likely to be your fate too. Call the Grants Management Office to be sure they are satisfied that you meet all requirements for funding and ask when they can issue a Notice of Grant Award.

Slide 89. My CONTACT INFORMATION

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Thank you for watching this presentation. I hope it improves the success of your SBIR or STTR application. My full contact information is included here. The best method to reach me is by email to which I try to respond within 48 hours.