

Advice on NIH SBIR & STTR Grant Applications – Grantsmanship



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Hello, I am Gregory Milman. In this presentation I provide advice on grantsmanship to help you prepare an NIH SBIR or STTR grant application. This presentation was updated in May 2007. Send your comments, suggestions, and criticisms to gmilman@niaid.nih.gov.

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?

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Peer reviewers 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.

Phase I Objective



- Establish the technical and scientific merit, and feasibility of 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.

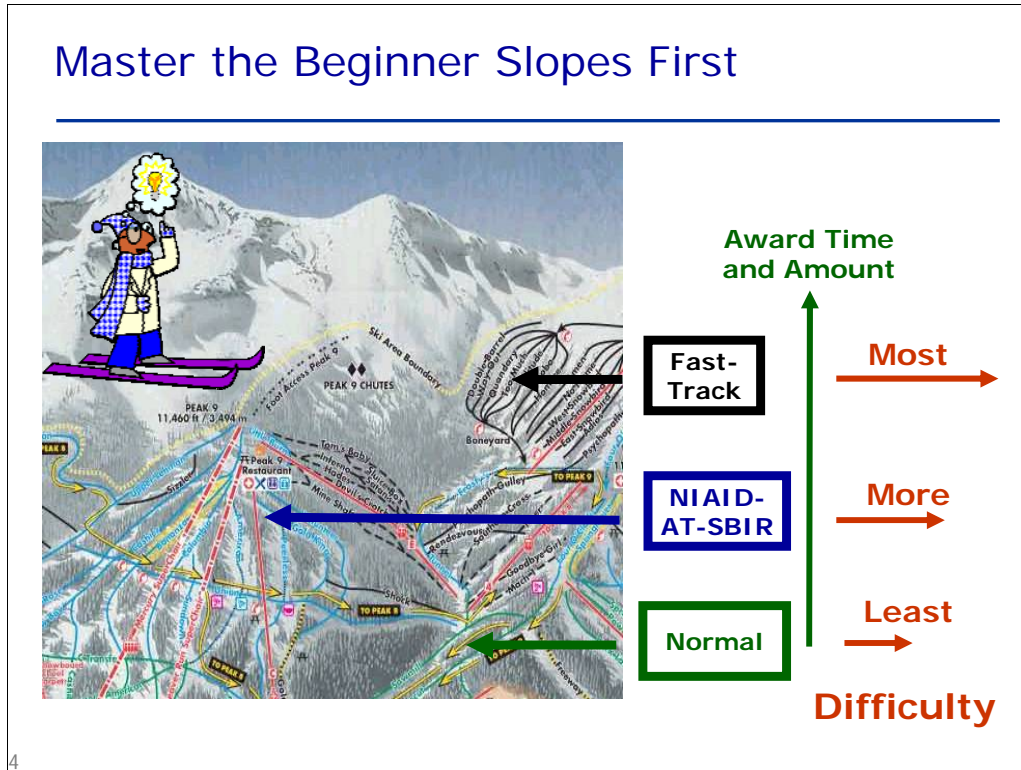
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One of the most common mistakes made by applicants is lack of focus - thinking too big. It may not be likely or even desirable to go from concept to product in a single Phase I/Phase II application.

Your objective for Phase I is to establish the technical and 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.



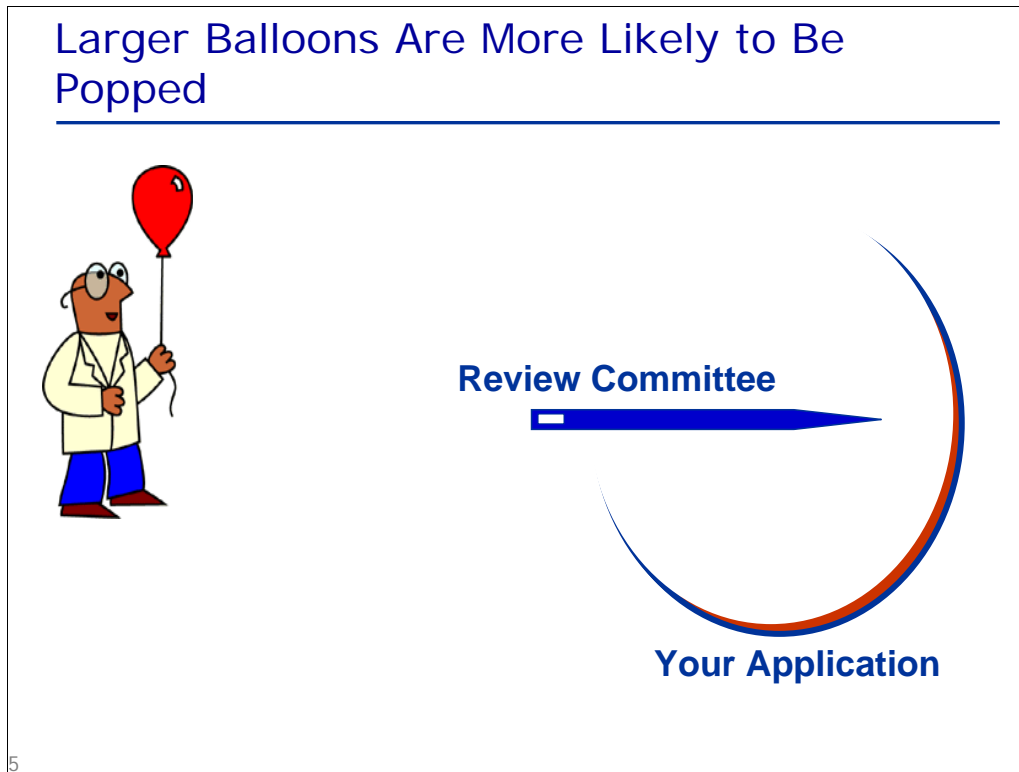
Our advice skier may help you decide what type of NIAID application you should consider. Small business applications are like most NIH applications: the more time and money you request, the greater the difficulty of writing an application that gets funded.

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

The NIAID-AT-SBIR, and similar multi-year, higher award applications are more difficult to master, like the intermediate blue slopes. 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.



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

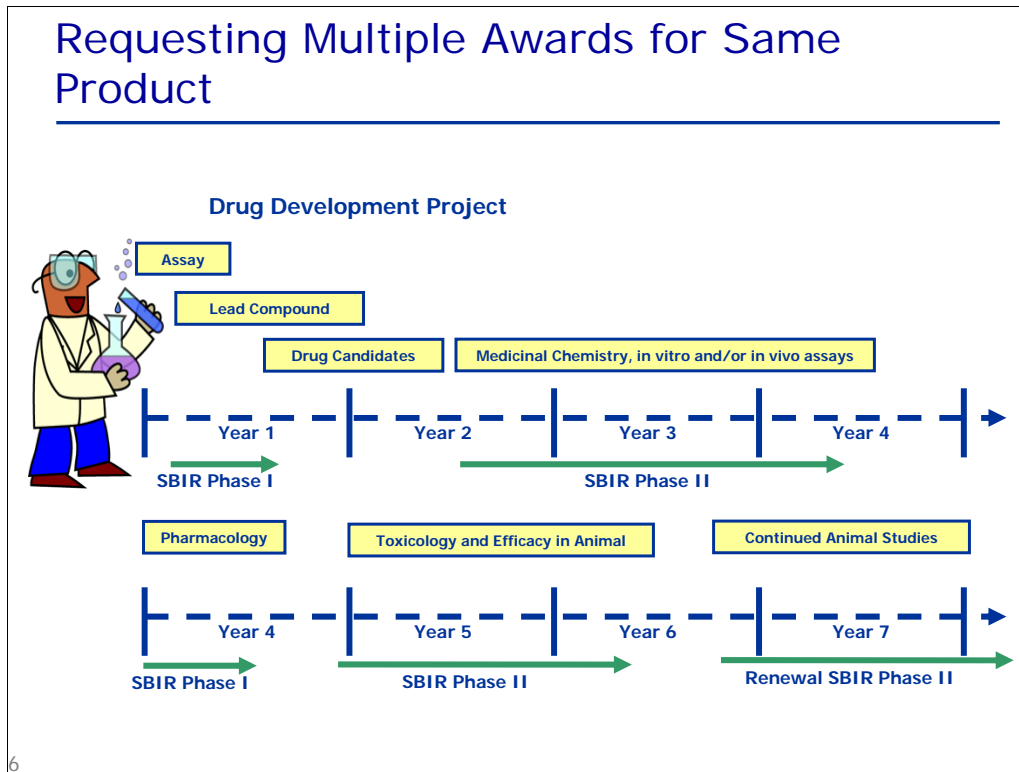
Review committees use a triage process to spend the most time on applications most likely to be funded. They search for any weakness in an application which may quickly eliminate it from further consideration.

Compared to normal applications, NIAID-AT-SBIR 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 weak 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 patch only 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 small 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. Then, ask for no more and no less than the funds required to conduct your Phase I research.



Using a drug development project, I provide an example of how you might request multiple SBIR Phase I and Phase II grants for the studies leading to an investigational new drug FDA application, an IND.

The first Phase I takes the project from assay to lead compounds. This Phase I is the feasibility study for the first Phase II which conducts medicinal chemistry to move from lead compound to drug candidate using in vitro and/or cell culture assays.

The second Phase I begins the critical path to drug development following the selection of a drug candidate. Phase I studies could include formulation and animal model studies on pharmacology. A follow-on Phase II might continue with animal model studies of toxicology and efficacy. If additional pre-IND studies are required, you could apply for a competing renewal of your Phase II grant as I describe in the next slide.

NIAID Phase II Competing Renewals



- Many ICs offer competing renewal Phase II grants for products that require approval of the FDA.
- NIAID accepts competing renewal 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 renewal Phase II applications to NIAID may exceed 50% consultant and contractual costs when well justified and necessary to support well-justified studies and related expenses.
- NIAID supports SBIR/STTR clinical trials only through the NIAID R34 – U01 application process.

A number of NIH ICs allow Phase II grantees to apply for Phase II renewal funding for projects whose products require FDA approval.

NIAID accepts Phase II renewal applications for grants up to three years and a budget not to exceed a total cost of \$1 million per year.

Also, NIAID Phase II renewal applications may request in excess of 50% consultant and contractual costs when well justified and necessary to support studies and related expenses.

Note that NIAID supports SBIR and STTR clinical trials only through NIAID's R34 – U01 application process.

Electronic Applications



- Bookmark and follow the NIH step by step [Electronic Application Process](#).
- Print the [Electronic Application Flow Chart](#) to track your progress.
- Open and print the official "SBIR/STTR Application Guide SF424 (R&R)" from the link on the [SF424 \(R&R\) Application and Electronic Submission Information](#) page.
- Grants.gov may switch from Pure Edge to Adobe Forms by the August or December 2007 receipt dates.
- Register for application submission:
 - Company and company official must be registered in [Grants.gov](#).
 - PI and company official must be registered in the [eRA Commons](#).

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All NIH SBIR and STTR applications are submitted electronically. I suggest you bookmark and follow the NIH step by step Electronic Application Process. You can track your progress using the Electronic Application Flow Chart. Application instructions change frequently. Always print the most recent official "SBIR/STTR Application Guide SF424 (R&R)" from the link on the SF424 (R&R) Application and Electronic Submission Information page. Be aware that Grants.gov may switch from Pure Edge to Adobe Forms by the August or December 2007 receipt dates.

To submit an application, a company must be registered in both Grants.gov and the eRA Commons, and the PI must be registered and associated with the company in the Commons. Allow at least a month to complete these registrations. Also, I suggest you submit your application two or more weeks before an application receipt date to give you plenty of time to correct errors and resubmit.

