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## SBIR/STTR Grants: Application Guidance

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# SBIR/STTR Grants: Application Guidance

## Summary

- Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) grants provide a valuable opportunity to receive non-diluting capital.
- The process of applying for an SBIR/STTR grant has several steps and can take months to complete.
- SBIR/STTR proposals take the form of typical grant proposals, except the former are shorter and have a lower requirement for preliminary data.
- An academic entrepreneur should not expect to receive SBIR/STTR funding on their first attempt at a proposal.
- There are several common pitfalls during the application process, and careful consideration of these issues can substantially improve an application.

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# SBIR/STTR Grants: Application Guidance

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## Topic Relevance by Timeline

### Summary

- Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) grants provide a valuable opportunity to receive non-diluting capital.
- The process of applying for an SBIR/STTR grant has several steps and can take months to complete.
- SBIR/STTR proposals take the form of typical grant proposals, except the former are shorter and have a lower requirement for preliminary data.
- An academic entrepreneur should not expect to receive SBIR/STTR funding on their first attempt at a proposal.
- There are several common pitfalls during the application process, and careful consideration of these issues can substantially improve an application.

### Introduction

This chapter provides a more detailed review of the preparation and application process for an SBIR/STTR grant. There are multiple steps in this process, many of which may be unfamiliar to a startup team or an academic entrepreneur. These center around registering the company, the grant preparation process, and the formal review at the National Institutes of Health (NIH). The content of this chapter complements that in the preceding chapter “SBIR/STTR Grants: Introduction and Overview.” Some key points are repeated in both chapters in case a reader is starting with this chapter and has not read the preceding one.

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# Determining Whether to Apply

## *Advantages*

The upside to an SBIR grant is significant for a small company (National Academies of Sciences, Engineering, and Medicine). First, the investment is non-diluting, which means that the government does not take any share of ownership in the awardee at any time in exchange for the award. This makes a small business very attractive to future venture capital investment because the seed funding round will have already taken place without exchange of equity or dilution. Second, the award does not require board seats or decision-making authority, which means that the founders retain full autonomy over the company decisions. Third, the award comes with some advisory support. Fourth, this competitive award may act as a catalyst to spur future investment later on. Fifth, indirect overhead costs—usually 40% to 70%, as set by the principal investigator (PI)—go directly to the company instead of being absorbed by the institution.

## *Disadvantages*

There are not any significant disadvantages to receiving an SBIR/STTR grant; however, there are some potential disadvantages to applying. Indeed, the main factors involved in making the decision to apply for an SBIR/STTR grant center often center around the time and effort required to prepare an application, which can be considerable. However, the research plan for a Phase I proposal is limited to 6 pages, while Phase II research plans are limited to 12 pages. Phase II applications also require a 12-page commercialization plan, which is a typical business plan. In total, a Phase II application may fall somewhere between 100 and 200 pages in length. The Phase I commercialization plan is typically only one paragraph in length. These limits result in relatively short applications for awards of this size. Further, the preparation to make a pitch to an angel investor or venture capital firm also requires time, and a large portion of an SBIR/STTR application can later be repurposed for a pitch or a Food and Drug Administration (FDA) marketing application. Another disadvantage of applying is the time required for a decision to be made. In some cases, the decision may be delivered in excess of one year from the submission date. This timescale may be unacceptable for the growth of a new startup company, especially in an active field that requires rapid development. On the other hand, obtaining angel investment may improve the likelihood of success of a future resubmission or an SBIR/STTR application. However, this strategy will mitigate some of the advantages mentioned in the previous section, as taking angel investments can be relatively costly (in terms of equity) (see the chapter “Angel Investors”). Much of the advance time needed to apply for the SBIR/STTR grant is spent obtaining the proper credentials to create an application. There are at least seven credentials that must be obtained sequentially, and while they each require little effort, some can take weeks to process.

The considerable time and energy invested in preparing a small business for an SBIR/STTR application necessitates careful consideration of the benefits and costs of receiving an SBIR/STTR

grant in the specific context of the applicant. Moreover, the benefits and cost considerations can differ significantly when viewed from either the academic or the company perspective (Table 1).

**Table 1: Comparison of SBIR/STTR Pros and Cons from Academic and Company Perspectives.**

	Academic Perspective	Company Perspective
Pros	<ul style="list-style-type: none"> <li>• Opportunity to commercialize research activities</li> <li>• Improved funding success rate compared to traditional grant mechanisms</li> <li>• SBIR/STTR application is a natural extension of academic grant writing; relies on many of the same skills</li> </ul>	<ul style="list-style-type: none"> <li>• No loss of equity or control in return for funding</li> <li>• Opportunity to further develop business model and access to consultants</li> <li>• Prestige accompanying successful receipt of the award, which may lead to other funding opportunities</li> </ul>
Cons	<ul style="list-style-type: none"> <li>• Limited grant funds in relation to time invested compared to NIH R01 funding mechanisms</li> <li>• Challenges of bridging cultural gaps between corporate and academic cultures in the review process</li> </ul>	<ul style="list-style-type: none"> <li>• Significant paperwork required for SBIR/STTR grant application</li> <li>• Significant effort undertaken for available funding</li> <li>• Uncertain funding prospects</li> <li>• Delay in receiving funding (minimum of 1 year, up to 2 years to receive funding, including preparation time)</li> </ul>

Given the considerable time investment and expertise required to prepare a successful SBIR/STTR application, the business entity for which this time investment represents a worthwhile endeavor will typically be smaller and have the flexibility of waiting months between their application, award notification, and actually receiving the allocated funding. Notably, NIH grants may require up to 100–200 hours of work in total to prepare. This time investment is worth considering, as the opportunity cost of preparing a strong application includes the time that could have been spent seeking other, more substantial sources of funding. Additionally, the particular restrictions placed on SBIR/STTR funding make certain businesses more suitable to one mechanism of funding compared to the other. For example, the greater flexibility in fund allocation in the SBIR program makes it more appropriate for relatively more established small businesses that can operate without an academic partner. The STTR program can be more attractive to a new company that lacks a credible principal investigator or may rely more heavily on access and close collaboration with available academic resources (see the chapter “SBIR/STTR Grants: Introduction and Overview”).

From the academic entrepreneur’s perspective, SBIR/STTR grants can be worth the time and effort investment if a company partner can be identified easily, or if there is a desire to create a company de novo. The structures and timelines of SBIR/STTR grants are particularly useful for exploring the practical applications of technologies, which might be a natural extension of an academic entrepreneur’s ongoing research, in addition to surveying market potential. Additionally,

SBIR/STTR grants can be submitted in conjunction with other federal grants, including a mechanism-focused R21 or R01 grant, allowing academic entrepreneurs to leverage existing work that has been done in preparing such grant applications for an SBIR/STTR application.

With these costs and benefits in mind, the *ideal* project proposal for an SBIR/STTR funding application has some combination of the following four components, depending on whether it is a Phase I or Phase II application: a strong scientific basis (Phases I and II), team members with expertise in the area of the proposed development (Phases I and II), preliminary data (Phase II), and a working prototype of the technology (Phase II). For Phase I, although helpful, neither preliminary data or a working prototype are necessary components to a successful application; the amount of preliminary data included in an SBIR/STTR Phase I application is often much smaller than what is expected for an R01/R21 application. Ultimately, having a strong team and compelling scientific basis are the key foundation for a Phase I grant, even in the absence of robust preliminary data or a working prototype. Additionally, generating preliminary data or making a working prototype is frequently used as one of the aims of an SBIR/STTR Phase I proposal. If an academic entrepreneur is thinking of applying for an internal university pilot award, for example, this may also be a good time to apply for a Phase I SBIR/STTR grant, since neither require preliminary data. That being said, if possible, it is still helpful to have preliminary data or a basic prototype to support the Phase I application; however, if the preliminary data already answer the research question proposed in the Phase I application, or the prototype is too far developed, that will be grounds for rejecting the application. For Phase II applications, on the other hand, preliminary data and a working prototype are often necessary, in addition to a strong scientific basis and team expertise.

## Overview of the Application Process

There are generally two categories of SBIR/STTR applications: (1) investigator-initiated applications and (2) responses to a funding opportunity announcement (FOA), which include requests for applications (RFA) and requests for proposals (RFP). The recommended approach is to identify an RFA or RFP that corresponds to an academic entrepreneur's interest area—typically, federal agencies offering SBIR/STTR funding will have information outlining their emerging interests and areas of high priority on their corresponding websites. A compilation of current FOAs can be found under “Funding Topics” on the SBIR/STTR government-sponsored website (*SBIR.gov*).

An important preliminary consideration when preparing an SBIR/STTR application is to define the degree of involvement of research partners, particularly the laboratory principal investigator if the applicant is themselves not the lead investigator behind the research being proposed. Agreement from the laboratory PI should be solicited before proceeding, and receiving this agreement from the PI may involve negotiating intellectual property and equity issues. Negotiations with PIs

are frequently a balancing act between offering enough IP/equity to maintain their engagement and not being too generous so that the rest of the team is undermined. Defining clear expectations from PIs and the academic entrepreneur can often be a challenging conversation, and obtaining an outside second or third opinion is fundamental to ensuring that both parties are satisfied with any agreements that may result from the negotiation process.

In general, the structure of SBIR/STTR grants closely resembles other research grant applications, with some important differences (Garland). SBIR/STTR applications will have a “Specific Aims” section that is similar to an NIH R03 or R21 application, with the addition of one–two paragraphs discussing commercialization potential and market size. Writing the “Specific Aims” is often the most time-consuming part of the application, and applicants should plan approximately four weeks to prepare in order to get the input of all the members of the team; once this is agreed upon, the “Research Plan” can flow naturally from this framework. In the “Grant Budget” section of the application, a key difference from more traditional grant budgets is the requirement of sharing 30%–60% of the budget with the corporate entity, depending upon the type of grant. University indirect costs come directly out of the budget, rather than added on top as with traditional grants. Notably, companies are permitted to include 7% of the costs outlined in the grant budget as profit. In some cases, universities will allow academics to receive a salary both from the university sub-contract (to do the research at the university) and also as an employee of the company; this can be an additional \$10,000–\$20,000. Specific policies will vary depending on the university, and time should be allotted accordingly during the application process (approximately one–two months) with the potential for these discussions in mind. For more information on preparing an application, refer to the additional chapter on SBIR/STTR grants.

## Requirements for Applying

### *Credentials*

One of the most challenging parts of the SBIR applications is the extensive credentialing process required before submission of an application (*Guide to SBIR/STTR Program Eligibility*). The credentials that must be obtained are contained in Table 2. It is important to retain the PDF generated by the SBA registration as it must be uploaded with the grant application.

This portion of the application process can take several months. It is best practice to start obtaining credentials even if the academic entrepreneur is still just considering applying; this way the application can be expedited once the decision is made. At a minimum, credentials should be obtained two months before submitting an application. The applicant should also be prepared to answer verification phone calls from Dun and Bradstreet and from the System for Award Management (SAM). In addition, the NIH has specific guidelines about the criteria for qualifying as an eligible small business concern (these are reviewed in the chapter “SBIR/STTR Grants: Introduction and Overview”), including percent of effort devoted to the small business by the principal investigator;

these should be carefully reviewed on the NIH website at <https://sbir.nih.gov/about/eligibility-criteria> (“Small Business Eligibility Criteria | NIH SBIR/STTR”; *Guide to SBIR/STTR Program Eligibility*). Much like the FDA, the NIH encourages informal emails and calls regarding SBIR/STTR submissions.

**Table 2: Steps Involved in Preparing a Small Business for Filing SBIR/STTR Grant Applications.**

	<b>Time to complete form</b>	<b>Time to obtain credential</b>
<b>Dun and Bradstreet Data Universal Numbering</b>	20 minutes	2 days
<b>System for Award Management (SAM)</b>	30 minutes	Up to several weeks (depending on verification process)
<b>Commercial and Government Entity</b>	5 minutes	10 days from the SAM submission
<b>Grants.gov</b>	20 minutes	1 day
<b>SBIR.gov</b>	15 minutes	Same day
<b>NIH eRA Commons</b>	30 minutes	Up to 10 days
<b>Small Business Administration (SBA)</b>	30 minutes	2 days

### *Proposal*

Investigators may solicit pre-submission feedback at the [seedfund.nsf.gov](http://seedfund.nsf.gov) website. A pre-submission may help an investigator determine if their project meets the requirements and goals of the SBIR/STTR program before applying. However, a pre-submission is not required and does not directly improve the chances of receiving an award.

There are two routes to making a proposal for an SBIR/STTR grant. The first is to identify an NIH institute that already has an objective in line with the research or technology enterprise of the principal investigator. The other—much more common—route is simply to apply during a request



for proposals period as determined by the NIH. All submissions are electronic, and the SBIR/STTR program uses the “SF 424 Research and Related” document form.

A proposal for a Phase I award must demonstrate *proof of concept* and *feasibility*. Phase I should be outlined sufficiently to lead to a Phase II award, even if the investigator does not intend on submitting a Phase II application. The review committee prefers to see applications with future objectives in mind. This requires having milestones to measure successful completion of Phase I; these milestones should have very specific outcomes and measurable, numeric thresholds for success/failure. Investigators are often reluctant to do this because they worry this will limit their ability to apply for a Phase II grant in the future, but the review committee members are asked to search for these criteria, thus they need to be included. It is crucial that a proposed technology be novel and that funds not be purposed for marketing or minor improvements to existing products.

It is also imperative that the proposed budget and study plan be within the time and financial limits of Phase I and Phase II. The five axes upon which a proposal will be judged include “significance, approach, innovation, instigators (team), and environment” (Ford et al.). The submission of a proposal does not formally constitute a public disclosure. This consideration is especially salient if the investigator has not yet made a public disclosure and intends to obtain intellectual property protection in the future. However, the abstract of the grant application *will* be made public, so any information in the abstract should not be privileged. Applicants can also request that elements of the grant application be kept confidential for a limited period of time. However, the grant may be requested under the Freedom of Information Act, with some information redacted (Freedom of Information Act Office).

Readers should refer to the NIH guidelines (see the Resources section of this chapter) for a crucial list of elements that should and should not be included in the proposal. If a proposal is successful, the investigator must enter into a funding agreement with the federal government to receive funding.

The project summary is critically important because it will determine which study section will review the SBIR application; however, the applicant may request a particular study section on the cover page of the proposal. The summary should be interpretable by a reader outside the pertinent field, so it should be the most scrutinized and heavily edited part of the application. A poorly written project summary is often grounds for dismissal of the whole application. A cover letter may also be submitted with the application that requests a specific study section; this can be helpful to ensure that the application is reviewed in a timely manner by a section with sufficient expertise. Study sections have assigned Scientific Review Officers (SROs), who are often able to provide guidance prior to submission; after the review, however, it is best for the principal investigator to communicate with the NIH Program Officer (PO).

While preliminary data are required for a Phase II application, they are not required for a Phase I application; however, they can vastly improve the competitiveness of a Phase I proposal. If preliminary data are included, then they must be presented as if they were in a peer-reviewed journal article: they must contain statistical analysis that can be replicated, and be presented in a cogent, unbiased fashion. However, as noted earlier, excessive preliminary data in a Phase I application may lead to rejection, as the reviewers may feel that a Phase II application is warranted instead, or that the project was already completed as evidenced by the preliminary data.

## SBIR/STTR Grant Review Process

Once applications are submitted, they are initially assessed on their scientific and technical merit by a specific study section tasked with evaluating their significance and potential for commercialization. Study sections are usually composed of 20 or more scientists from the broad community related to an applicant's topic of focus, although specific expertise in the area of the proposed research is not guaranteed. Applications are scored on six broad categories, the first five of which are used to derive a funding priority score: significance, approach, innovation, investigator or investigators, environment, and other—which includes consideration of whether or not the research involves human subjects, or the representation of the applicant, among other factors ([https://grants.nih.gov/grants/policy/review/rev\\_prep/scoring.htm](https://grants.nih.gov/grants/policy/review/rev_prep/scoring.htm)). Each specific grant is assigned to three–four reviewers drawn from a mix of academia and industry experts. Reviewers typically receive ten applications and are given four–six weeks to evaluate applicants.

A survey of NIH reviewers showed that the most common reasons applications are rejected include: (1) the application was not convincingly realistic in its goals, (2) the project was overly ambitious, which raised feasibility questions, (3) the follow-up terms were unclear, and (4) the significance of the research was not convincing or clearly communicated (Ford et al.). Other common pitfalls include: the method for evaluation of the results was lacking; the research protocol was underdeveloped; and lack of commercial expertise or commercialization plan.

### *Review and response*

The NIH strives to make recommendations on a proposal, affirmative or negative, within six months of submission, but in practice it can take longer to receive the actual funding.

About 80% of SBIR/STTR proposals are reviewed at the NIH Center for Scientific Review (CSR), and the rest are reviewed at the specific NIH institute (i.e., National Cancer Institute (NCI)) as appropriate. Updates on the proposal will be posted to the eRA Commons page. The top 50% of all proposals will be discussed and receive a quantitative score. Scores range from 10 to 90; lower scores are better, thus 10 is the best score. In general, higher (worse) scores are not discussed, and if an application is not discussed, no formal score is provided (applications in the lower 50% are considered triaged). Regardless of the score, the submitter will receive reviewer feedback.

If a proposal is rejected, it is not eligible for resubmission until the next call for submissions. However, a resubmission must be made within 37 months of the rejection. Approximately one-third of all successful applications had a resubmission. Notably, resubmissions are ordinarily not permitted if the initial proposal was made in response to a request for applications (RFA) that has expired, but investigators are advised to check the details of the RFA; it may be possible to submit as a “new” application under the Omnibus SBIR/STTR solicitation or a different RFA. Before a resubmission, applicants are highly encouraged to contact the NIH to receive additional feedback.

## Deliverables

The main deliverables required for SBIR/STTR grants, aside from the research itself, are final summary reports, due no later than 120 days from the end of the award. These reports are submitted through eRA Commons. For Phase II, or other multi-year awards, an annual progress report must be submitted in addition to the final report at the conclusion of the grant. A form for report submissions is included in the Resources section.

## The Funding Gap Between Phases

The NIH acknowledges that there is the possibility of a significant gap between Phase I and Phase II funding. The following strategies are recommended to reduce the duration and impact of this gap:

- Instead of applying for Phase I and Phase II grants sequentially, an investigator may elect to apply for a “fast-track” combined Phase I and Phase II application. In essence, this requires the submission of a Phase II application while planning for receiving both a Phase I and a Phase II award with a single application. This, however, is only suitable if the company can demonstrate a high likelihood of having a successful Phase I. For this reason, only 5.8% of funded SBIR applications were on the fast track.
- Another option is to apply directly for a Phase II grant. This can be done if a company already has sufficient preliminary data to support a Phase II application and would rather skip to the more substantial funding and time allocation of Phase II.
- A bridge award (of \$1 million) is also available for up to three years from some NIH institutes, like the NCI, to bridge the gap between Phase II and Phase III.
- Apply for Phase II during Phase I. In this scenario, the Phase II application is prepared while the Phase I study is being conducted, and once the Phase I tasks are accomplished (which may occur before the formal end date of the Phase I grant if the team is efficient and successful), the Phase II application is immediately submitted. However, this can still lead to delays for the review process, or if a resubmission is required. Submitting a Phase II grant before the stated tasks of the Phase I are completed is not recommended, though,

since successful completion of the Phase I tasks are a criteria for awarding a Phase II grant in many cases.

## Special Considerations

- Submitting a successful SBIR/STTR proposal is not just about the quality of the proposal. It is also about timing. Congressional research support may wax and wane depending on the political climate, and funding for specific NIH institutes may also increase or decrease compared to others.
- Intellectual property rights can prove challenging to manage for small businesses that emerge from a university-sponsored project (see the chapter “Intellectual Property: Ownership and Protection in a University Setting”). The technology transfer office ordinarily does not relinquish its ownership of a patent for development by the small business. Instead, it reaches some compromise wherein the small business can continue the development of a technology for a limited term in exchange for a fee or royalties (see the chapter “Working with the University Technology Transfer Office”). This process is called “licensing” and is increasingly common; it is described in more detail in the chapters on IP. For STTR grants in particular, negotiating the licensing framework between the company and the academic partner is usually required.
- A university may have confidentiality standards divergent from those of a small business. In general, universities encourage public dissemination of information, while small businesses keep information confidential as long as possible. This can become especially complicated if academic research investigators participating in the SBIR/STTR programs need to publish for their career advancement. Ordinarily, however, this complication can be ameliorated by clarifying intellectual property guidelines and establishing reasonable common ground with the university to protect both parties’ interests.
- Some amount of customer discovery data should be established prior to applying. These data are very useful for demonstrating the commercialization potential of the technology and for guiding its development toward a useful product. Market research and customer discovery may take one–two months. Commercialization plans should demonstrate an interest in the technology, a well thought-out cost and pricing plan, and a marketing plan. A university may have a number of resources, such as I-Corps or a business school, to assist in the performance of market research or the creation of a business plan (see the chapter “I-Corps as a Training Tool for New Technology Development”).
- On average it requires about 100 to 150 hours of sustained effort to complete a proposal, which is usually spread over 2 to 3 months.
- In comparison to an R21 or R01 grant, the SBIR/STTR pathway has a stronger emphasis on the composition of the team and the letters of recommendation from investors or stakeholders.

## Conclusion

The SBIR/STTR award is a low-risk, high-reward federally funded grant opportunity for small business entities working on a new technology. These small businesses are typically spun out of universities, but this is not a requirement for funding. While obtaining an SBIR/STTR award often takes over one year from start to finish, some of the benefits are that it is non-diluting and does not require any equity or board control to be granted to an outside party.

## Resources

1. A guide on obtaining all the necessary credentials for application to SBIR/STTR: <https://sbir.nih.gov/apply/electronic-submission>.
2. An essential guide for the submission of an SBIR/STTR grant to the NIH: <https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/sbir-sttr-forms-e.pdf>
3. A guide containing proposal style tips: <https://files.eric.ed.gov/fulltext/EJ888519.pdf> (p.64 and onward).
4. The listing of terms and conditions for award acceptance: [https://www.nsf.gov/pubs/policydocs/sbir/sbiri\\_117.pdf](https://www.nsf.gov/pubs/policydocs/sbir/sbiri_117.pdf).
5. A guide for determining if an investigator and their small business concern are eligible for an SBIR or STTR award: [https://www.sbir.gov/sites/default/files/elig\\_size\\_compliance\\_guide.pdf](https://www.sbir.gov/sites/default/files/elig_size_compliance_guide.pdf).
6. A very helpful step-by-step guide to writing SBIR/STTR Phase I and II grant applications is *Winning SBIR/STTR Grants: A Ten Week Plan for Preparing Your NIH Phase I Application* and *Winning SBIR/STTR Grants: A Twelve-Week Plan for Preparing Your NIH Phase II Application* (Garland).
7. Additional details on the NIH review process (to learn about how a proposal will be scored) can be found on the NIH Center for Scientific Review site: <https://public.csr.nih.gov/>.
8. A sample SBIR application: <http://www.niaid.nih.gov/ncn/sbir/app/default.htm>.
9. The form for the final report submission: <https://grants.nih.gov/grants/funding/finalprogressreport.pdf>.

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