



The NCI SBIR Program



How to Apply

Tips for Preparing and Submitting an Application



- SBIR/STTRs are highly competitive
- There is a big gap between being “funded” and being “almost funded”
- **Solution:** Prepare a strong application
- Get an advantage in every possible dimension

- **Start-up**

- Entrepreneur-founder with experience in the field
- Highly innovative technical solution to meet significant clinical need
- Significant commercial potential
- **Need feasibility data**
- Too risky for private investors

- **Established small company**

- Innovative new product leveraging company's expertise
- Significant commercial potential
- **Need feasibility data**
- No resources to try a new approach, but board supports SBIR

- **Chasing solicitations**
 - See an NIH funding opportunity: why not apply?
 - Result: distraction, lack of focus, long-term reliance on SBIRs, waste of energy
- **Chasing “cool” technologies**
- **Need cash urgently**
 - SBIRs take 8 -14 months or more to get
- **Incremental upgrade to existing product**
- **“Me too” product, matching competitor’s capabilities**
- **Product is at the stage where it needs investment significantly exceeding SBIR funding levels**

- **Significant, highly innovative, sound, and focused science**
- **Well-designed studies**
 - Phase I: Key feasibility question
 - Phase II: Proceed to eliminate technology risks
- **Significant product and/or commercial 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
- **Translational research/clinical applications projects should have a strong team and involve the appropriate collaborators**
 - Appropriate for the problem
 - Have clinicians involved: Oncologists, Pathologists, Statisticians
 - Other relevant scientists/professionals involved, e.g., Biostatisticians

Omnibus Solicitation

<http://grants.nih.gov/grants/guide/pa-files/PA-11-096.html>

Funding Opportunity Title	PHS 2011-02 Omnibus Solicitation of the NIH, CDC, FDA and ACF for Small Business Innovation Research Grant Applications (Parent SBIR [R43/R44])
Activity Code	R43/R44 Small Business Innovation Research (SBIR) Grant - Phase I, Phase II, and Fast-Track
Announcement Type	Reissue of PA-10-050
Related Notices	<ul style="list-style-type: none">• February 8, 2011 - See Notice NOT-AI-11-030 The purpose of this Notice is to highlight NIAID's interest in receiving grant applications to develop strategies, methods and/or tools to optimize influenza vaccine production.
Funding Opportunity Announcement (FOA) Number	PA-11-096

SF 424 Application Instructions

<http://grants.nih.gov/grants/funding/424/index.htm>



U.S. Department of Health and Human Services
Public Health Service

**SF424 (R&R)
SBIR/STTR
Application Guide for NIH
and Other PHS Agencies**

A guide developed and maintained by NIH for preparing and submitting SBIR/STTR applications via Grants.gov to NIH and other PHS agencies using the SF424 (R&R)

Significance

- Does the study address an important problem and have commercial potential?

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? Is the environment unique?

Commercialization

- Is the company's business strategy one that has a high potential for success?

Key #1

Start Application Process Early!



- **Start developing your application as early as possible. You need time to develop a strong proposal.**
- **Seek help of experienced applicants early in process:**
 - SBIR Program Staff
 - Experienced SBIR applicants
 - Academic collaborators with grant experience
 - Professional grant writers
- **Assemble a strong scientific team and allow time to fill in the gaps**
 - If you have a weakness or gap in expertise, fill it early
 - Secure access to equipment and other resources
 - Obtain letters of support

- **Start informal discussions to clarify the product vision**
 - Potential customers
 - Technical experts
 - Potential investors & commercialization partners
- **Identify the most important technical risks**
 - Identify approaches to address those risks
 - Study design is critical

Key #3 Build the Proposal Team



- **Choose the Principal Investigator (PI)**
- **Consider building a multi-PI team**
 - Allows for multidisciplinary proposals
 - Beneficial when PI lacks certain types of necessary expertise
 - Must appoint Contact PI (SBIR, > 50% of time w/ business)
- **Identify personnel who will carry out the actual work**
- **Partner to fill the gaps**
 - Academic collaborations
 - Consultants
 - Other companies
- **Use the SBIR application as engagement tool**
 - Academic researchers understand grants
 - Offer to include them on proposals as consultants/collaborators

Key #4

Consider Your Company's Strengths and Weaknesses



SBIR & STTR

- **Consider your company's strengths**
 - Try to exploit those strengths to address a specific NIH Program initiative
- **Consider your weaknesses too**
 - It is rare that a small company will have all the necessary expertise for a strong application
 - If you have no track record of commercialization, consider getting a partner who does
- **Partner with other companies or academics to fill gaps**
- **Contact NIH Program Director in advance to discuss your proposal and receive feedback**
- **Review similar currently funded projects using the [NIH Research Portfolio Online Reporting Tool \(RePORT\)](#)**



- **Specific Aims (1 page)**
 - Focal point of the application
 - Describes the goals of the application
 - Accompanied by quantitative performance milestones
- **Research Strategy (Phase I: 6 pages, Phase II: 12 pages)**
 - Provide background information
 - Provide detailed technical plan to achieve the Specific Aims
 - Propose realistic scope/budget/timeline
 - Preliminary data is not required... but often powerful
 - Describe potential pitfalls and alternative angles of attack
- **Introduction (for resubmissions only, 1 page)**
 - Your response to reviewers' critiques

Key #5 Reviewers Only See the Application (cont'd)



- **Other application components**
 - Biosketches for all senior and key personnel (<4pages each)
 - Budgets for each project period
 - Separate budgets for each subcontract
 - **Phase II Commercialization Plan (Phase II, 12 pages)**
 - Descriptions of facilities and equipment
 - Letters of support
 - Human subject research section (if applicable)
 - Vertebrate animals section (if applicable)
 - Other information, as required
- **Grants: SF424 R&R SBIR/STTR Application Guide**
 - Excellent source of administrative information
 - http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_SBIR_STTR_Adobe_VerB.pdf
- **Contracts: see respective Request for Proposals (RFP)**
 - E.g., <http://grants.nih.gov/grants/funding/SBIRContract/PHS2012-1.pdf>

- **Strongly worded letters of support from:**
 - ALL consultants and collaborators
 - Those who provide access to facilities / administrators
 - KOLs (Key Opinion Leaders) who think highly of your project
 - Customers who will buy the product once it is available
 - Current or potential industry partners
 - Current or potential investors
 - Suppliers of critical technology
- **A good letter of support:**
 - Explains who the writer is and why s/he is excited about the proposed project
 - Explains the writer's role in the proposal
 - Contains specific support of your story/approach

- **Who is going to review your application?**
 - Primary reviewers (2-4 people) read your application and lead the discussion. These primary reviewers have appropriate expertise and are assembled by SRA (Scientific Review Administrator)
 - All members of the Review Panel will score your application
 - Combination of academic and business professionals, as well as industry reviewers
- **Identify the most appropriate study section BEFORE you submit your application**
 - See CSR (Center for Scientific Review) website for study section descriptions
 - Discuss study section selection with NCI SBIR Program Staff

Key #7 Always Consider the Reviewers (cont'd)



- **What are they looking for?**
 - Readable and understandable application
 - Do not assume they will know everything you know
 - You understand your application best so convey it to them
 - Clear and concise language, “lay summary”
 - Clear plan for Phase I, II and commercialization
 - Feasible, standard methods
 - Appropriate objective tests of success for each Specific Aim
 - Promising preliminary data are very influential
 - Solid letters of support for commercialization

Key #7 Always Consider the Reviewers (cont'd)



- **Read your material critically as if you were the Reviewer**
 - What are the weaknesses?
 - Point out potential difficulties, do not hide them
 - Suggest ways to address them or provide rationale
 - Recruit an independent reader
- **Provide alternative methods if a particular approach is not successful**
- **Be realistic about your goals**
 - Provide a feasible timetable for key objectives
- **Be realistic about your budget**
 - Ask Program Director for early guidance

Help the Reviewer write his analysis

Key #8 Run “your own” peer review



- ... before you submit
- **Ask all consultants/collaborators to review the application**
 - Act on their feedback
- **Recruit independent, technically trained ‘laymen’ as readers**
 - Do they understand it?
 - Are they excited?

- **Have you honestly assessed the commercial viability of your technology?**
- **Do you have a talented professional to be a PI?**
- **Is the PI supported by the right team? Does he or she have the time?**
- **Do you have the resources to write the grant application or contract proposal?**
- **Do you have the resources and capabilities to execute?**
- **Do you have the business resources needed for a successful launch?**

If you aren't funded the first time...



- **Use peer review to improve your technology and presentation**
 - Reviewers often spot errors in the proposal
 - Reviewers will let you know if what you are proposing has been done before
- **If peer reviewers “didn’t get your proposal”**
 - Customers, investors, and employees may not get it either
 - Fix errors, improve your presentation
- **It’s always painful not to be funded, but at least you get the feedback**
 - Respond to the Summary Statement carefully
- **Explore opportunities to serve on NIH peer review panels**
 - Exposure to grantsmanship & insight into the review process
 - Meet bright colleagues
- **Learn more about SBIR/STTR Programs**
 - Talk to successful applicants
 - Explore opportunities to serve on NIH peer review panels
 - Understand the review process and dynamics
- **Revise and resubmit**

- **Reviewers did not understand your proposal**
 - Reason #1: Proposal is not sufficiently clearly written
 - Solution: Improve your presentation
- Reason #2: Proposal is in the wrong study section
- Solutions:
 - Can you find a better study section on NIH/CSR website?
 - http://www.csr.nih.gov/Roster_proto/sbir_section.asp
 - Discuss study section selection with the assigned NCI Program Director

- **Reviewers say the proposal is 'not innovative'**
 - Reason #1: Technology is not clearly differentiated
 - Solution: Position the technology relative to available alternatives

 - Reason #2: Technology is a novel combination of existing approaches
 - Solution: Emphasize novelty AND clinical need

- **Reviewers feel the team is not qualified to handle the problem**
 - Strengthen your team by adding collaborators and consultants
 - If the PI has experience gaps: put together a multi-PI team
 - Have ALL collaborators review the proposal

- **Reviewers do not think you are working on significant problem**
 - Sell them on the importance of the problem
 - Be specific and quantitative
 - Get a letter of support confirming the problem
- **Reviewers are critical of the approach**
 - Respond to specific criticisms
 - Revise your approach
 - Have your approach reviewed by professionals similar to the reviewers

More Information on the NCI SBIR & STTR Website



The screenshot shows the homepage of the NCI SBIR & STTR website. At the top, there is a red header with the National Cancer Institute logo and name, and the text "U.S. National Institutes of Health | www.cancer.gov". Below this is a dark blue navigation bar with the SBIR & STTR logo, a search bar, and links for "Sign Up for Updates", "Follow us on Twitter", "Contact Us", and "Site Map". A light green navigation bar contains the main menu items: "About", "Funding Opportunities", "Resource Center", "News & Events", and "Success Stories". The main content area features a large banner image of a scientist in a lab coat and safety glasses, with the text "Leading small business innovation and commercialization in the fight against cancer". Below the banner are two columns of content. The left column has a section titled "What are the NCI SBIR & STTR Programs?" with two paragraphs of text and a "[Learn More]" link. The right column has a section titled "Latest Announcements" with two sub-sections: "** \$8M in New Contract Funding Available **" and "SBIR & STTR Omnibus Solicitation Funding Available", each with a brief description and a list of links.

National Cancer Institute U.S. National Institutes of Health | www.cancer.gov

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About Funding Opportunities Resource Center News & Events Success Stories

Leading small business innovation and commercialization in the fight against cancer

What are the NCI SBIR & STTR Programs?

The goal of the NCI is to eliminate the suffering and death due to cancer. The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs are NCI's engine of innovation for developing and commercializing novel technologies and products to prevent, diagnose, and treat cancer.

The SBIR & STTR Programs are one of the largest sources of early-stage technology financing in the United States. We welcome entrepreneurs and small business leaders to this website to explore grant and contract funding opportunities and a new spirit of collaboration with the NCI.

[\[Learn More\]](#)

Stay Connected

Sign up to receive updates and news about the NCI SBIR & STTR Programs and upcoming funding opportunities

Latest Announcements

**** \$8M in New Contract Funding Available ****

The NCI SBIR Program announced 12 new contract funding opportunities. [Learn more about the new contract topics.](#)

Receipt Date: November 7, 2011

SBIR & STTR Omnibus Solicitation Funding Available

The NCI SBIR & STTR 2011 Omnibus Solicitation has been issued:

- [PA-11-097, PHS 2011-02 Omnibus Solicitation of the NIH for Small Business Technology Transfer Grant Applications \(Parent STTR \[R41/R42\]\)](#)

<http://sbir.cancer.gov>

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**Register on web site for funding
opportunity updates**