SMALL BUSINESS AWARDS

. What is the Small Business Innovation Research Program?

The Small Business Innovation Research (SBIR) program is a set-aside program (2.5% of an agency's extramural budget) for domestic small business concerns to engage in Research/Research and Development (R/R&D) that has the potential for commercialization and public benefit.

The Small Business Technology Transfer Program (STTR) was established in 1992 with as setaside program of 0.3% of the agency's extramural budget. The unique feature of the STTR program is the requirement for the small business concern applicant organization to formally collaborate with a research institution in Phase I and Phase II.

Where can I find basic information on small business awards?

Basic information on SBIR and STTR awards is located on the NCI <u>Small Business Grants</u> page, which includes videos from recent <u>SBIR and STTR forums</u> and <u>News and Events</u>. Additional information including information on upcoming SBIR/STTR conferences is available on the NIH <u>Small Business Research Funding Opportunities page</u>.

How do I apply for a small business award?

SBIR and STTR applications are now submitted electronically through <u>Grants.gov</u> by scrolling down the <u>SBIR funding opportunity announcement</u> or the <u>STTR funding opportunity announcement</u> and selecting the button that says "Apply for Grants Electronically." Remember to read the full announcement and before beginning your application. Examples of applications are provided on the NCI <u>Small Business Resource Center site</u>.

What constitutes a small business?

A <u>small business</u> is independently owned and operated and not dominant in its field. It has no more than 500 employees and it controls the facilities in which it conducts a major part of NIH-supported research. See <u>Eligibility Criteria</u> for more information.

Can a foreign business own an SBIR-funded company?

No. According to the <u>Omnibus Solicitation for SBIR/STTR Grant Applications</u>, a company or subsidiary must have majority ownership by U.S. citizens and a principal place of business in the U.S.. It must also conduct all grant-funded research in the U.S.

• What's the difference between an SBIR and an STTR?

Under SBIR Program, the <u>Principal Investigator</u> must have his/her primary employment with the small business concern at the time of award and for the duration of the project period; however, under the STTR Program, primary employment is not stipulated. The STTR Program requires research partners at universities and other non-profit research institutions to have a formal collaborative relationship with the small business concern. At least 40 percent of the STTR research project is to be conducted by the small business concern and at least 30 percent of the work is to be conducted by the single, "partnering" research institution.

What is the difference between a small business grant and contract?

Small business concerns are invited to submit Phase I grant applications in any area within the NCI mission identified in the <u>SBIR/STTR Omnibus Solicitation</u>. Contract proposals are accepted only if they respond specifically to a research topic within the <u>Contract Solicitation</u>. The topics are not the same as those in a grant solicitation. They are much more focused and specific. Contracts are only solicited one time each year versus three receipt dates per year for grants.

Are there other funding opportunities besides NIH Omnibus Solicitation for SBIR/STTR Grant Applications?

Search the NCI Funding Announcement List for additional Program Announcements and Requests for Applications open to small business concerns. Links to SBIR/STTR Funding Opportunity Announcements is provided on the SBIR/STTR Funding Opportunities page, including the Innovative Molecular Analysis Technologies initiatives. Note that you will face strong competition with funding opportunities that are open to large companies and academic investigators.

Should I apply for a small business award if my goal is to patent a product?

Yes. You can pay for patent costs out of a fee that you request for your SBIR or STTR grant.

• Do I own the intellectual property from my STTR award?

In general, grantees own the rights to data and inventions resulting from any grant-supported project. Read the NIH Grants Policy Statement (12/03) for more information on intellectual property rights.

. Does NIH often use its march-in rights to take away intellectual property?

No. NIH may use march-in rights only if an awardee fails to achieve practical application of an invention. Furthermore, NIH has never exercised this right because of the lengthy administrative process. For more information, see Appendix D of the June 4, 1998, Research Tools.

· How much of my small business research project may I outsource?

You may outsource up to 33 percent of your project for a phase I SBIR award or 50 percent for a phase II SBIR. For an STTR award, you may outsource no more than 60 percent of your project.

While you may have some leeway with this requirement in an SBIR grant, the maximum outsource level for STTR grants is not negotiable.

Even though the normal phase I for STTRs is six months, can I ask for 12 months of funding?

You can, and it is recommended that you do.

What is a Fast Track application?

The <u>SBIR Fast Track</u> process requires phase I and phase II proposals in the initial application. In contrast, a normal SBIR application includes only a phase I proposal, and an applicant sends a

phase II proposal only if a phase I award is made. The success rate of Fast Track applications is lower than phase I applications. Contact NCI SBIR/STTR program staff to discuss further.

Are reviewers more likely to find problems with bigger applications?

The more you expand the research goals of your application, the more likely you are to include specific aims that are subject to criticism. Your best strategy is to limit your phase I goals to those necessary to support your phase II application. For more advice, contact the NCI SBIR/STTR program staff.

· Can small business award funds be spent on research in a foreign country?

No. Although funds can not be spent directly, in your application, you can request and justify a <u>fee</u> of up to 7 percent of your total grant. The fee belongs to the company, so you may use it to pay for costs outside the U.S.

Can I use small business award funding to analyze patient-derived samples collected in a foreign country?

You may use SBIR/STTR funding to analyze samples from a foreign country, but the analysis must be performed in the U.S.

Are there special programs to assist small business awardees in commercialization of their research project?

To help NIH SBIR phase I and phase II awardees move their products into the marketplace, NIH has developed a "menu" of technical assistance programs (see below) that will provide technical and/or commercialization assistance specific to the companies' individual needs. Programs are pilot tested prior to offering to all SBIR awardees.

Niche Assessment Program (NAP): Assesses if there are other applications or niches for the SBIR-developed technology and evaluates the market opportunities, needs and concerns of the end-users, and helps to discover new markets for possible entry.

<u>Commercialization Assistance Program (CAP):</u> Provides assistance with developing and implementing an appropriate business strategy that will help commercialize the products that have resulted from federally funded SBIR research projects.

Manufacturing Assistance Program (MAP): In partnership with the NIST Manufacturing Extension Partnership (MEP) program, participants will have access to MEP's nationwide network of non-profit manufacturing centers.

Are there any funding opportunities to bridge the gap between the completion of the phase II award and commercialization?

The <u>SBIR Phase II Bridge Award</u> is intended to augment previously funded NIH-wide SBIR Phase II projects that require additional funding in order to achieve key technical and regulatory milestones along the path toward commercialization. This funding opportunity focuses on the continued development of cancer therapies and cancer imaging technologies, which require clinical evaluation and approval by a Federal regulatory agency.