

*This guide is for potential applicants to the Small Business Innovation Research (SBIR) program within the U.S. National Institutes of Health (NIH). The document identifies unique aspects of the NIH SBIR program, describes the nature of its interests, and links readers to additional agency resources. When used in conjunction with MTIP's Profile of a Good Candidate, this guide will help prospective applicants determine quickly whether to pursue funding under the NIH SBIR program and how best to approach a proposal.*



## THE SBIR/STTR PROGRAMS

*The federal SBIR program is a source of early-stage R&D seed capital exclusively for small, tech-based U.S. companies engaged in serious R&D and commercialization of technologies of interest both to the government and to the company. Applicants submit proposals in response to specific topics released by each of the 11 participating agencies. Within each agency, the rules and requirements frequently change from one solicitation to the next. Prospective applicants must monitor closely each targeted agency's solicitations.*

SBIR funding is provided as either grants or contracts, and does not have to be matched or repaid by the small business. The award monies can be used to fund most costs associated with the R&D project and up to a 7% profit margin. The company maintains ownership of any new intellectual property, and the government retains certain rights to use the technology.

SBIR is a three phase program starting with Phase I to establish the technical feasibility of the proposed technology. Phase I awards vary, but can be as high as \$225,000 for periods ranging from 6 to 12 months. Phase II is to perform more in-depth R&D on the technology, ideally moving toward prototyping and demonstration. Phase II awards range as high as \$1.5 million, generally for a period of up to two years. The objective of Phase III is commercialization of the technology. This phase is non-funded though some agencies offer extra assistance in the form of commercialization support programs.

In SBIR Phase I, up to 33% of the total budget may go to outside services, including consultants and subcontractors. In Phase II, this figure rises to 50%. In addition, for both Phase I and II, the Principal Investigator (PI) must be employed by the company for greater than 50% of ordinary work hours for the duration of the project.

Overall, agencies report that the chance of winning a Phase I award ranges from ~7% to ~15%. Well-qualified Montana applicants can substantially improve these odds by working closely with the no-cost services offered by the Montana Technology Innovation Partnership (MTIP). If not currently enrolled for MTIP services, see the information box at the end of this Guide.

## NIH SBIR PROGRAM

*Falling under the Department of Health and Human Services (HHS), the NIH SBIR program also includes the Centers for Disease Control and Prevention (CDC), the Food & Drug Administration (FDA), and the Administration for Children and Families (ACF). The National Institute on Disability and Rehabilitation Research (NIDRR) transferred from the Department of Education (Mar 2015), and will now be included in NIH solicitations as the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR). Within these components are nearly 40 separate research institutes, centers, and offices offering SBIR funding opportunities. Program information can be viewed at: <https://sbir.nih.gov>.*

The NIH offers a broad array of research funding opportunities, many of which are not related to the SBIR program. The different types of research programs are coded, and SBIR opportunities are identified as Activity Codes R43 for SBIR Phase I and R44 for SBIR Phase II. To help simplify the process, applicants should watch for the *SBIR Omnibus Grant Solicitation of the NIH* which includes the *SBIR Parent Funding Opportunity Announcement*. This is the primary source of NIH SBIR funding opportunities and is typically released annually in January. Proposals to non-AIDS-related topics under this solicitation may then be submitted in response to three deadlines each year on April 5th, September 5th and January 5th. Proposals on AIDS-related topics are typically due May 7, September 7 and January 7. Listed at the same site as the *SBIR Omnibus Grant Solicitation* is a table representing other SBIR R43/R44 Special Announcements targeting specific agency needs. While the *Omnibus*

*Solicitation* substantially renews annually, the Special Funding Opportunities may be offered on a one-time basis only.

NIH offers several program options that may allow enhanced project opportunities and funding. For example, its FastTrack option allows Phase I and Phase II to be submitted at the same time to expedite worthy projects. Phase IIB opportunities allow applicants to apply for a second Phase II round of funding on selected topics. Applicants also may switch between the STTR and SBIR programs for Phase II or Phase IIB (e.g. perform a Phase I STTR and pursue the Phase II as an SBIR, without the research institute partner). NIH also has piloted an SBIR Direct-to-Phase II solicitation, permitting small businesses to receive a Phase II award even without doing an SBIR Phase I (though having met that standard of research from other funding sources). All of these special options should be discussed in detail with the program officers.

## IDENTIFYING AN APPROPRIATE TOPIC

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*Each Program Announcement or Funding Opportunity Announcement references the participating Institutes and Centers (the program sponsors), closing dates, the opportunity or purpose, and awards allowed. These also provide a link to the detailed topics of interest and additional program information. For 2015, that topics document is located with all other forms and guides at: <http://grants.nih.gov/grants/forms.htm>.*

All prospective applicants engaged in medically- and/or health- related R&D will be able to identify at least one topic relevant to their technology. In the event a specific topic cannot be found, most NIH institutes and centers include language that invites applicants to contact the sponsor if a proposed technology fits well with the mission of the targeted organization. Online utilities that permit NIH topics to be searched by using key words can be found at: <http://www.zyn.com/sbir> and <http://grants.nih.gov/grants/guide/index.html>.

## CONTACTING THE AGENCY

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*Having identified a promising topic, potential applicants are strongly encouraged to communicate with the assigned point-of-contact (POC). Contact information for these POCs is provided with each topic. The primary purpose of this communication is for the applicant to fully understand what the program sponsor is seeking under a particular topic and to explore how well the proposed technology is likely to meet that need.*

Though not required, a good way to approach the POC is by sending a 1-2 page write-up on the technology and scheduling a follow-up phone discussion. This write-up should begin with a clear, concise statement of the problem to be addressed and then describe: (a) the company, (b) the team and its credentials, (c) the technology being proposed as a solution and an explicit statement of its innovation, (d) the market in terms of what the end product will be and who will buy it and why, and (e) the competition. Through a phone communication with the POC, the applicant will achieve a better understanding of whether the technology is of interest and any nuances that will enhance the sponsors' interest in the proposed project.

## PREPARING/SUBMITTING THE PROPOSAL

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*Registration and application process instructions are found in Parts I & 2 of the NIH SF424 SBIR/STTR Application Guide found at: [http://grants.nih.gov/grants/funding/424/SF424\\_RR\\_Guide\\_SBIR\\_STTR\\_VerC.pdf](http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_SBIR_STTR_VerC.pdf).*

NIH proposal submissions require multiple electronic registration efforts that can require 6 to 8 weeks for completion. These include: 1. One-time registrations to obtain a DUNS number and an Employers' Identification Number (EIN); 2. A government contractor registration on the System for Awards Management (SAM); 3. An SBA Company Registry, or an update of the Registry for the new application; 4. A one-time only, registration at Grants.gov for access to the application forms package and to enable proposal submission; and, 5. A registration on NIH's eRA Commons for the company and the project Program Director and/or PI.

Information necessary to preparing a submission begins with the Program Announcement, which links to the topics document and the *NIH SF424 SBIR Application Guide*, both referenced above. If additional program guidance is needed, the HHS maintains its overarching guide, *Public Health Service Grant Applications (PHS398)* at: <http://grants.nih.gov/grants/forms.htm>.

The NIH SBIR proposal permits very few pages to achieve substantial information requirements. Accordingly, plan the document carefully and allow time for revisions to stay within the allowed constraints. The purpose of the proposal is to provide sufficient information to persuade the review team the proposed technology is a unique and sound solution to the need expressed in the topic. The proposal should be written at a level suitable for publication – that is, with no typos, poor word usage, editorial errors, etc. There are many ways applicants can enhance their chances of success:

- **Start early.** NIH has an *SBIR/STTR Application Process* page at: <https://sbir.nih.gov/infographic>. Find a Funding Opportunity Announcement or Program Announcement - a complete list of active SBIR/STTR opportunities can be located through the NIH site at: <http://grants.nih.gov/grants/guide/index.html>. Become familiar with the Institute sponsoring the topic under consideration. Make contact with the program POC to determine project suitability under the selected topic. Initiate the required registrations.
- **Dive into planning.** Applicants can discuss their project and proposal approaches with an MTIP counselor. The project must be vetted against any special considerations identified under the targeted topic area, as well as against the agency's review criteria. Give careful thought to any outside consultants or subcontractors, with the understanding that these individuals should strengthen the team's credentials. Identify necessary letters of support and set a plan for securing them.
- **Read the entire solicitation.** All SBIR agencies have specific requirements for font size and style, page limits, marking of confidential information, and other aspects of the proposal. Agencies routinely reject proposals that don't comply with these instructions. One person on the proposal team must be responsible for reading the instructions thoroughly, noting all requirements. Initiate a properly-formatted proposal template that puts key guidance for each section into comment boxes for easy reference while writing. Use the agency website to find instructional webinars or other guidance specific to its process.
- **Develop a project plan that envisions both the Phase I and the Phase II R&D activities.** Start the writing effort by developing well-defined Technical Objectives (for NIH, the Specific Aims). Follow the instructions carefully in writing this piece that is the backbone of the technical proposal. Outline a work plan for achieving the objectives, giving consideration to what must be performed in Phase I to create a good foundation for Phase II. Review these pieces to determine whether the project matches well with the topic and agency guidelines. Conduct a team meeting to get full buy-in on the proposed work plan AND on the proposal-writing efforts. Develop a schedule and assign responsibilities for completion of the proposal. Immediately start the process of collecting team Curriculum Vitae and letters of support.
- **Obtain an outside, third-party review.** Regardless of the applicant's experience with SBIR, secure an MTIP or other third party review of the draft proposal. Even the most experienced applicants have a tendency to get "off point" when working through the details of so many sections. Invariably, good outside reviews help ensure the proposal is responsive to the instructions and identify meaningful ways in which to enhance both the content and the presentation of the proposal. Provide the proposal to a reviewer not less than one week before submission so that suggested changes can be implemented.
- **Submit early.** Applicants should plan to submit their proposals at least two days prior to the final due date. Early submission avoids the possibility of server overload, and gives applicants ample time to resolve any problems that arise during the electronic submission process.

## READY FOR THE NEXT STEP?

This agency-specific SBIR guide has been prepared by the Montana Technology Innovation Partnership (MTIP) and does not imply endorsement from the National Institutes of Health. A program of the Montana Department of Commerce, MTIP provides free coaching to Montana technology-based companies seeking help in applying to federal and state R&D and commercialization funding programs. For more information, contact the MTIP Program Manager at (406) 841-2734 or visit MTIP's website at [www.mtip.mt.gov](http://www.mtip.mt.gov).

Funded in part through a Cooperative Agreement  
with the U.S. Small Business Administration

