

SBIR NIH Phase I Proposal Development Presentation

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**National Institutes of Health (NIH) Small Business
Innovation Research (SBIR) Program**

Table of Contents

<u>Sections</u>	<u>Pages</u>
Brief NIH SBIR Program Overview	2
Initial NIH SBIR Proposal Development Process	3
NIH SBIR Phase I Proposal Application Sections	4
Eighteen Ventures' Proposal Development Service	12

SBIR NIH Phase I Proposal Development Presentation

Brief NIH SBIR Program Overview

The NIH SBIR program funding enables health entrepreneurs and small health technology firms to convert their creative ideas, experiences, knowledge and skills into an innovative technology solution that meet an unmet medical or healthcare need. Moreover, the small firms can use both the funding and the new technology to grow their companies.

Eligibility Requirements

- A small company organized for profit, with a place of business located in the United States, which operates primarily within the United States or which makes a significant contribution to the United States economy through payment of taxes or use of American products, materials or labor.
- A small company formed as an individual proprietorship, partnership, limited liability company, corporation, joint venture, association, trust or cooperative, except that where the form is a joint venture, there must be less than 50 percent participation by foreign business entities in the joint venture.
- A small company has no more than 500 employees.

Comment [D1]: NIH SBIR Program Eligibility Requirements.

Funding Levels

<u>Phase I</u>	<u>Phase II</u>
\$225,000	\$1 million - \$1.5 million
Money is used, for six months, to conduct research to determine whether or not the product concept is actually feasible.	Money is used, for two years, to produce a product prototype.

Comment [D2]: The levels of funding under each round.

How It Works

Twenty-three (23) participating NIH Institutes/Centers (ICs), like the National Institute on Aging (NIA), issue request for proposals (RFPs), seeking technology solutions. More importantly, the ICs award funding to successful proposals that combine an original idea, market research & analysis findings, technical & scientific standard accepted research principles with a business strategy that leads to producing a market-driven technology that solves an unmet healthcare or medical problem.

Comment [D3]: The Institutes and Centers (ICs) issue broad request for proposals (RFPs) that are turned into specific proposed technology concepts by small firms. The proposed technology concepts must (1) focus on an identified medical/healthcare need or solve a medical/healthcare problem and (2) have the potential of being commercially viable in a designated marketplace.

SBIR NIH Phase I Proposal Development Presentation

Initial NIH SBIR Proposal Development Process

Business Registration

All small business registrations must be completed before the agency reviews any submitted proposal. This process should be started immediately once a company decides to participate in the program. The required registration process includes:

Dun and Bradstreet Universal Numbering System (DUNS) – All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin SAM, SBA Company, and eRA Commons registrations.

Employer Identification Number (EIN) – HHS requires both the EIN and a DUNS number prior to the issuance of a funding award. The EIN base for the organization is the IRS Tax ID number, for individuals it is their social security number, both of which are nine-digit numbers.

System for Award Management (SAM) – SAM can take a significant amount of time (days/weeks) to complete the registration or annual renewal process.

Grants.gov – Grants.gov is a federal-wide portal to find and apply for federal grant funding. It is used by all 26 federal grant-making agencies and requires registration by the applicant organization. The applicant organization will need to designate an E-Business Point of Contact (E-Biz POC). The E-Biz POC will approve Authorized Organization Representatives (AORs) to submit applications.

eRA Commons – eRA Commons is NIH's Electronic Research Administration system that allows applicants, grantees, and NIH staff to access, share and transmit application/grant information.

- eRA Commons requires registration by both the applicant organization and the Program Directors/Principal Investigators (PD/PIs). The organization's Authorized Organization Representative (also known at NIH as the Signing Official) must register or affiliate the PD/PI(s).

SBA Company Registry – All applicants are required to register at the SBA Company Registry prior to application submission and attach proof of registration in the Other Project Information, Other Attachments section of the application.

Comment [D4]: All applicants are required to register their company with the listed databases. This process should be the initial step taken when preparing a NIH SBIR Phase I proposal.

SBIR NIH Phase I Proposal Development Presentation

NIH SBIR Phase I Proposal Development Process

Identify Problem & Define Solution

Before preparing the NIH SBIR Phase I proposal, applicants must identify a health or medical problem that needs to be solved. Then, applicants need to define the proposed technology that will be used to solve the health or medical problem. Applicants, moreover, have to answer key questions, like the ones below, as they go through the process of identifying the problem and defining the proposed solution.

- What is the specific health or medical problem?
- What is the cause of the health or medical problem?
- What groups are most affected by the health or medical problem?
- How are large is the affected group?
- What is the social economic cost related to the health or medical problem?
- What is the proposed technology that will be used to solve the health or medical problem?
- How will the proposed technology solution solve the health or medical problem?
- How is the proposed technology solution different from existing solutions or treatments?
- What are the unique features of the proposed technology solution?

Comment [D5]: All NIH SBIR proposals start with identifying a medical or health problem that needs to be solved and defining the proposed solution that will be used to solve the problem.

Conduct Market Research

Once the health or medical problem is identified and the proposed solution is defined, they must be supported by market research & analysis. The market research information and data are used to answer the key questions about the problem and the proposed solution. In fact, the market research findings provide the reasons why the project is being undertaken in the first place.

Comment [D6]: Market research & analysis provides supporting information about the identified health or medical problem and the proposed technology solution. More importantly, the marketing research findings help establish why the project is being undertaken in the first place.

Select Appropriate Participating NIH Institute/Center (IC)

As mentioned above, the ICs are the funding source for the NIH SBIR program. Each IC has a prescribed operating mission and awards research dollars according its core mission. The National Institutes on Aging (NIA), for example, offers funding for technology development that aid the U.S. senior/elderly population. Thus, small companies with a specific interest serving this particular consumer group would submit funding proposals to NIA.

Comment [D7]: Applicants need to select the appropriate IC most likely to fund their projects. The selection is usually based on the identified medical or health problem. Also, the selection can be based on the proposed solution as well.

NOTE: The identification of the health or medical problem, as well as the proposed solution, helps applicants select the appropriate IC. At the same time, IC program officers are available to offer advice on whether or not a particular project is appropriate for their ICs.

SBIR NIH Phase I Proposal Development Presentation

NIH SBIR Request For Proposal (RFP)

Applicants have the option of proposing their own original research topic to a selected IC or respond to an issued IC request for proposal (RFP). Most applicants, however, focus on responding to IC issued RFPs, like the one below from the National Institutes on Aging (NIA).

NIA SBIR Phase I RFP Research Topic: The development of practical applications using innovative technologies (e.g. hand-held, internet, telemedicine GPS, robotics, social networking and communications technologies) to support and improve quality of life, well-being, and the ability of people with MCI, AD or other dementias of aging to live independently and safely at home for an extended period of time. Examples include systems and devices to: evaluate, monitor and improve or adapt to changes in cognition; improve health service delivery; support independent living and the conduct of everyday tasks at home; provide information to health care providers and family members with which to evaluate the need for intervention; and promote communication and interaction between individuals living in the community or in institutional settings and their health care providers, friends and family members.

Comment [D8]: Broad request for proposals (RFPs) are issued by the twenty-three participating NIH Institutes/Centers (ICs).

This is an example of a broad RFP issued by the National Institutes on Aging (NIA).

It is important to select an RFP research topic that fits your company's technology development interests and capabilities.

Things To Remember Going Forward

An identified, well researched health issue and an innovative proposed technology solution comprise the foundation of the NIH SBIR Phase I proposal. Furthermore, applicants must demonstrate that the health issue/problem is important and the proposed technology solution will help solve the identified health/issue problem. Applicants, in addition, must convince reviewers that the proposed solution is far better than existing treatments and the proposed solution helps reduce healthcare costs. Finally, applicants must show the proposed solution has the potential of gaining significant market acceptability from patients, health providers and payors.

In their NIH SBIR Phase I proposal applicants need to provide answers to questions like:

- What is the unmet medical need that the proposed product/technology will be addressing? Which market segments of the population will benefit from the proposed technology concept?
- What are the economic costs associated with the health or medical problem?
- How does the health or medical problem impact society?
- What is the market opportunity for the proposed technology concept?
- Who will buy and/or use the proposed technology concept?
- Who will be involved in conducting the research project and developing the proposed technology concept?
- How does the proposed technology concept compare to existing solutions?

SBIR NIH Phase I Proposal Development Presentation

NIH SBIR Phase I Proposal Application Sections

Comment [D9]: An outline of the NIH SBIR Phase I proposal application.

The NIH SBIR Phase I proposal application comprises the following:

Project Summary/Abstract (*Brief, detailed project description*)

Specific Aims (*Describe what will be done, why, how and where?*)

Research Strategy

- a. Significance (*Describes identified healthcare problem or unmet medical need*)
- b. Innovation (*Details the novel technology solution that solves the healthcare problem*)
- c. Approach (*Methodologies used to prove proposed concept feasibility*)

Facilities, Environment (*Resources and capabilities used to perform the work*)

Biographical Sketch (*Investigator and project team*)

- a. Personal statement, qualifications of the leading team members.
- b. Published publications, if applicable.

Budget (*How much money will be needed to complete project*)

Bibliography (*Cited references of studies or reports used*)

Letters of Support (*Demonstrated external support from opinion leaders or potential clients*)

It is worth noting that the completed NIH SBIR Phase I application should read less like a scholarly scientific paper, but more like a successful small business growth strategy. Since the NIH SBIR program is primarily a small business development initiative, proposal reviewers want to see how applicants intend to utilize the grant funding for the production of an innovative, market-driven healthcare or medical solution that contributes to the expansion of a small business. Thus, the information and data needed to complete each proposal section should reflect how applicants will develop a commercially viable technology that solves a problem and grow their companies simultaneously.

SBIR NIH Phase I Proposal Development Presentation

Project **Summary/Abstract**

Thirty (30) lines allowed. It needs to include:

- Public health problem
- Issues with current solution
- How proposed concept addresses unmet need/solves the problem
- Summary of approach
- Collaborators and unique resources and capabilities
- Phase I Specific Aims

Comment [D10]: The Project Summary/Abstract is prepared after the proposal is completed.

While reviewers usually do not read the entire proposal, they will take the time to read the Project Summary/Abstract. Thus, this section must stand out and initiate the process of convincing reviewers to award the grant money to your company.

NOTE: Do not include proprietary information because the abstract will made public if your company receive funding.

Specific **Aims** *(Describe what will be done, why, how and where?)*

A one page summary of what the company is going to accomplish, why it is worth doing, why and how its proposed solution is unique, and how the work will help the company accomplish its goals.

It needs to include:

- Healthcare Medical/health problem and its significance
- Current solutions, gaps and roadblocks
- Proposed innovative solution and how it will solve the problem
- Research approach and aims
- What will become possible after the research is conducted
- Why the company and its team are the best (most appropriate) to address the challenge

Comment [D11]: This section sets the direction for the entire proposal. The agency wants applicants to concisely state the goals of the proposed research and summarize the expected outcome(s).

Each Specific needs to identify the Who, What, Where, When, How and Why

- Who will be doing the work?
- What is the result?
- Where is the work being done?
- When will the work be finished?
- How the work be done?
- Why is the experiment planned?

SBIR NIH Phase I Proposal Development Presentation

Research Strategy

- a. Significance (*Describes identified healthcare problem or unmet medical need*)
- b. Innovation (*Details the novel technology solution that solves the healthcare problem*)
- c. Approach (*Methodologies used to prove proposed concept feasibility*)

Significance (*Describes identified healthcare problem or unmet medical need*)

Explain the importance of the healthcare problem or medical/health issue. In particular, provide background on the current solutions, their limitations, and the discoveries needed.

Demonstrate knowledge of the field using appropriate published/unpublished works.

Explain the importance of the problem or critical barrier to progress in the field

How will the proposed project improve scientific knowledge, technical capability and/or clinical practice.

Describe how the concepts, methods, and technologies, treatments, services or preventative interventions will be changed if the aims are achieved.

Describe the commercial potential of the project to lead to a marketable product, process or service.

- What is the healthcare or medical/health problem?
- How large is the problem?
- What are current solutions and their drawbacks?
- What progress is being made?

Innovation (*Details the novel technology solution that solves the healthcare problem*)

Describe any novel theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed

How will the results direct/inform future research/product development?

Will success improve the “State-of-the-art,” establish new research directions, change clinical practice?

Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation or interventions.

- What is the proposed technology solution?
- Why is it better than existing treatments or solutions?
- What are the milestones necessary to bring it to the point of sell?
- What is the exit strategy along the development pathway?
- Why is the product innovative (better, faster, at lower cost, etc.)

Comment [D12]: The most important section in the proposal. It is divided into three sections:

Significance, which identifies the health or medical problem that needs solving;

Innovation, which identifies the proposed solution for the problem;

Approach, which explains in-depth how the applicant will demonstrate whether or not the proposed solution is feasible.

SBIR NIH Phase I Proposal Development Presentation

Approach (*Methodologies used to prove proposed concept feasibility*)

This section must specifically indicate what research design the small company will use to demonstrate the feasibility of the proposed technology solution. In fact, it needs to spell-out in detail what the small company is going to do, how it is going to do it, and what criteria will be used to determine success. Moreover, it must rely on standard, accepted scientific & technical theories.

Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project.

Describe the experimental design and methods proposed and how they will achieve robust and unbiased results.

Discuss potential problems, alternatives strategies, and benchmarks for success anticipated to achieve the aims.

If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.

Point out any procedures, or materials that may be hazardous to personnel and precautions to be exercised.

Define the criteria for evaluating the success or failure of each set of experiments.

Describe the kinds of results the company expects and how they will support continuation of the project. Present other possible outcomes and contingency plans.

Discuss the PD/PI's preliminary studies, data, and/or prior experience/knowledge pertinent to the project.

This section should include the following:

- Who will be involved and what actions they will perform
- How the data will be used and collected
- Indicate potential problems and alternative strategies
- Preliminary data, which could include publications and unpublished data
- Timelines
- Where the work will be done and what equipment/materials will be used
- Expected results

SBIR NIH Phase I Proposal Development Presentation

Biographical Sketches

Proposal reviewers are looking to see if the small company has assembled an experienced, knowledgeable and skilled team who will be responsible for implementing a cost-effective research project. Thus, the small company's efforts need to focus on the following:

- Principal Investigator (PI) with experience/expertise in all aspects of the proposed work
- Team members with a previous record of success
- Include individuals who possess technical expertise in all areas of the proposal
- Consultants or organizations who can work as contractors on the project
- Biographical sketches for all Senior/Key personnel- defined as all individuals who contributed in a substantive, meaningful way to the project, whether or not salaries are requested.

Comment [D13]: The section describes the members of the research team. Their qualifications must demonstrate experience, knowledge and skills related to the proposed project.

Consultants Letters of Support

- 1) Show commitment
- 2) Express enthusiasm about the concept's potential to solve an unmet need.
- 3) Indicate total number of hours that the consultant will provide/commit to the project, as well as hourly rates
- 4) Describe the Specific role that the consultant will give in the project
- 5) List the consultant's expertise, knowledge expertise in a specific area.

Comment [D14]: Applicants must indicate which consultants have agreed to work on the project.

Budget Development

- Research Plan drives the budget decisions.
- Identify all the costs that are necessary and reasonable to complete the work described in the proposal.
- The total costs requested in your budget will include allowable direct costs (related to the performance of the grant).
- Direct costs: Those costs that are attributed to the project. It includes salaries, supplies, consultants and sub-contracts.
- Fringe Benefits: The fringe benefits rate is based on your company's policy; the NIH does not have a pre-set limit on fringe benefits.
- Phase I: 33% of the budget can be used to pay subcontractor.

Comment [D15]: Once the Approach section and research team have been established, then the small company can start developing the budget.

SBIR NIH Phase I Proposal Development Presentation

Environment

Explain how each of the resources will contribute to success of the project.

Other things to remember:

- Company is required to possess a physical facility for the project.
- Some of the work can be performed an academic institution or at a CRO.
- List all facilities and equipment needed to complete each aim of the project.
- Determine which facilities and equipment are already available for the company's use and which the company will needed.
- Describe your facilities and any unique company capabilities for the project.
- Include enough information to assure reviewers that you are not a virtual company.
- Describe collaborators' resources that will be used for the project. If you propose subcontracts, describe what resources and capabilities the subcontractors bring to the project.

Comment [D16]: Applicants must detail where the research will take place and how the facility will help their companies succeed in implementing the research approach.

Letters of Support

Letters of support are important to reviewers as they demonstrate external enthusiasm for the project.

- All consultants should provide a letter of support
- If possible, obtain letters from opinion leaders and potential clients
- Consider healthcare providers
- All consultants should provide a letter
- If possible, obtain letters from opinion leaders and potential clients

Letters from Customers, Clinicians, etc. should address some or all of the following points.

- Enthusiasm for the technology and how it will address an unmet need
- Business case for the product/technology
- Ability of your team to successfully commercialize the product
- Need all letters one month before submission

Comment [D17]: It is very important to show reviewers those who will be involved and who will potentially support, e.g. purchase, the completed technology.

SBIR NIH Phase I Proposal Development Presentation

Eighteen Ventures' SBIR Proposal Development Service

Helping your company meet the NIH SBIR **September 5th 2017** submission deadline, we provide the following proposal development service.

- Working with the client to define and turn the creative idea into an innovative proposed technology concept. Also, help the client identify and select the appropriate NIH SBIR Institute or Center (IC) sponsoring funding for the client's proposed technology concept.
- Conducting market research and analysis to identify the following: (1) potential users, such as patient population and/or health providers and potential buyers, (2) competitors and competing technologies, (3) market size and opportunity and (4) industry conditions/growth associated with the client's proposed technology solution. The assembled information/data will be used to prepare the NIH SBIR Program Phase I proposal.
- Working with the client to identify, establish contact and communicate with the NIH SBIR IC Program Officer responsible for the proposed technology concept. This action includes developing a two-page executive summary about the proposed technology concept and the proposed Phase I project.
- Researching, collecting and reviewing scientific/technical studies and reports that will be included into a NIH SBIR Program Phase I proposal.
- Working with the client to draft and edit a NIH SBIR Phase I proposal that meets all agency requirements and supports the funding of \$225,000.

Service Performance Implementation Steps

- (1) Client provides information about its technology concept through a detailed questionnaire provided by Eighteen Ventures.
- (2) Eighteen Ventures conduct the necessary market and scientific/technical information research that will be used to support both the proposed technology concept and research & development process.
- (3) Eighteen Ventures prepares a two (2) page project Executive Summary to be used when contacting identified Institute/Center Program Officer representing the selected funding Institute/Center.
- (4) Apply questionnaire answers with market and scientific/technical information research to Eighteen Venture's NIH SBIR Proposal Development Template. The Template incorporates all of the necessary NIH SBIR Phase I document, i.e., Abstract, Specific Aims, Research Strategy, Bio Sketch, etc., sections.
- (5) Use NIH SBIR Proposal Development Template to produce Phase I proposal drafts.