

How To Fund Your New Health Technology Development Idea



The **Small Business Innovation Research (SBIR)** program provides two rounds of seed capital to help health entrepreneurs turn their innovative medical or healthcare technology concepts into commercially viable, problem-solving solutions.

Medical Technologies

Digital Health Technologies

Healthcare Information Technologies (IT)

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Welcome

Today's Agenda

Review Funding Programs:

- Small Business Innovation Research (SBIR)
- Pennsylvania Innovation Partnership (IPart)
- Preparing Winning SBIR Funding Proposals

How To Use Business Documents To Prepare A SBIR Phase I proposal:

- Business Model
- Business Plan



National Science Foundation (NSF) SBIR Program Basics

New Health Technology Development Industry

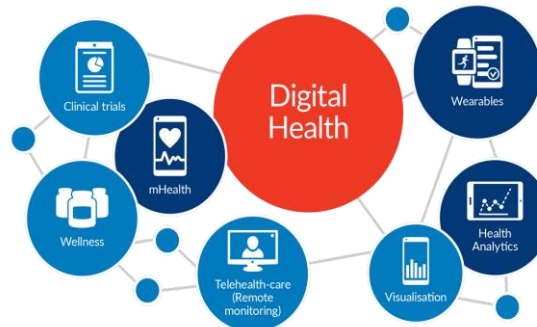
U.S. Healthcare System Challenges:

- Elderly population with multiple chronic conditions: Heart diseases, diabetes, high blood pressure
- Insurers want to spend less money on health and medical services with better patient outcomes
- Witnessing increased patient engagement with digital/mobile technologies
- Decreasing number of healthcare professionals need to serve patient demand
- Millennials want to spend less money and time on healthcare services
- Hospitals and health systems have to protect and secure patient data/medical records
- Healthcare organizations want maximize operational efficiencies and staff output
- Government forcing the U.S. healthcare system to better integrate, cost-effectively, information and digital technologies in the service delivery process

U.S Healthcare Industry: \$3Trillion



\$42 Billion Invested Since 2010



U.S Population Shift



Traditional New Health Technology Development Funding Options

Business Angels: Wealthy investors who are interested in financing a startup and its novel, problem-solving marketable technology concept.



Venture Capital: Institutional investors providing funding for business growth, rapid technology development, product launch and marketing.



Corporate Venture Capital: Providing funds to facilitate rapid technology development and product launch of a smaller company's innovative technology.

Examples: Johnson & Johnson and Novartis



Small Business Innovation Research (SBIR) Program

The Small Business Innovation Research (SBIR) program offers entrepreneurs an opportunity to acquire seed grants, a Phase I award and a Phase II award, for the development of innovative, marketable, problem-solving healthcare or medical solutions. Phase I funding is used for six months to demonstrate the feasibility of a proposed technology concept. Phase II funding is used for two years to produce a product prototype.



Through a competitive proposal development and submission process entrepreneurs are awarded the money. By using a company's business plan, market research & analysis findings and scientific reports/studies, applicants apply the necessary information to prepare a winning SBIR Phase I proposal. A Phase II proposal includes the same information sources plus the results from the successfully completed Phase I feasibility study.



After completing both funding phases, the company is expected to commercialize its new healthcare technology or medical device. The company, in particular, uses its business plan to enter the new technology into a designated market and offer it to identified potential buyers, such as hospitals, individuals, health systems, health insurers, pharmaceutical companies or large employers. On the other hand, the company can seek additional money from private sector investors, e.g., venture capitalists, business angels or corporate venture capitalists, to help manufacture, promote and sell the new technology solution.



National Institutes of Health (NIH) and National Science Foundation (NSF) SBIR Programs

The National Institutes of Health (NIH) Small Business Innovation Research (SBIR) program awards nearly **\$1billion** dollars in new technology development seed grants to health technology startups and emerging small firms. The money is designed to help small and emerging firms produce original products that solve unmet healthcare or medical problems and grow their businesses.

- Interested in funding marketable technology solutions focused on protecting, improving health and preventing diseases.



The National Science Foundation Small Business Innovation Research (SBIR) program awards new technology development seed grants to health technology startups and emerging small firms. The money is designed to help small and emerging firms produce original products that solve unmet healthcare or medical problems and grow their businesses.

-Interested in funding novel products, processes, or services that will enable the delivery of high quality, economically efficient healthcare and small business growth.



NIH SBIR Phase I and Phase II Funding Rounds

<u>Funding Rounds</u>	<u>Funding Amount</u>	<u>Use of Funds</u>
Phase I	\$225,000	Money is used, for six months, to conduct research to determine whether or not the technology concept is actually feasible.
Phase II	\$1 Million	Money is used, for two years, to produce a technology prototype.



NIH SBIR Program Eligibility

- ◎ Small companies 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.
- ◎ Small companies 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.
- ◎ Small companies that have no more than 500 employees.

NSF SBIR Phase I and Phase II Funding Rounds

<u>Funding Rounds</u>	<u>Funding Amount</u>	<u>Use of Funds</u>
Phase I	\$225,000	Money is used, for six months, to conduct research to determine whether or not the proposed technology concept is actually feasible.
Phase II	\$750,000	Money is used, for two years, to produce a technology prototype.



NSF SBIR Program Eligibility

- ◎ Small companies 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.
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- ◎ Small companies that have no more than 500 employees.

NSF & NIH SBIR Phase I Proposal Submission Deadlines

NSF SBIR Phase I Proposal Submission Deadlines

- NSF SBIR program has two submission dates: Mid-June and Mid-December. NSF SBIR usually releases solicitation, i.e. request for proposals (RFPs), two months before submission dates.
- Next solution release is scheduled for March 2019

NIH SBIR Phase I Proposal Submission Deadlines

- NIH SBIR program has three submission dates: April 5th, September 5th and January 5th. The NIH SBIR usually release solicitation, i.e. request for proposals (RFPs), around mid-January.
- Next solution release is scheduled for mid-January 2019

Funded Health Technology Development Areas

A list of selected health and medical technology development areas funded by the NIH and NSF SBIR programs

Telemedicine/Telehealth	Biosensors	Social Media	Point of Care Technologies
Data Analytics	Digital Wireless	Diagnostics	Internet of Things
Nanotechnology	Medical Imaging	Virtual Reality	Health Record Systems
Artificial Intelligence	Sensors	Surgical Tools	Medical Devices
Mobile Health (mHealth)	Robotics	Cybersecurity	Cloud Computing
Biomedical Engineering	Ultrasound	Gamification	Web-based tools

NSF & NIH SBIR Program Benefits

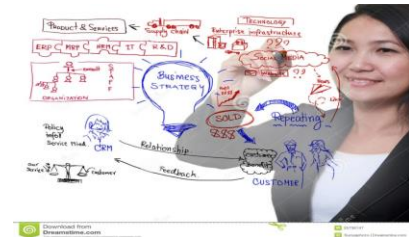
▶ Thirty percent (**30%**) of Phase I and Phase II grant budgets can be used to hire experienced personnel or experts needed to augment the project team.



▶ Small companies can earn a **7%** profit off the proposed project budgets.



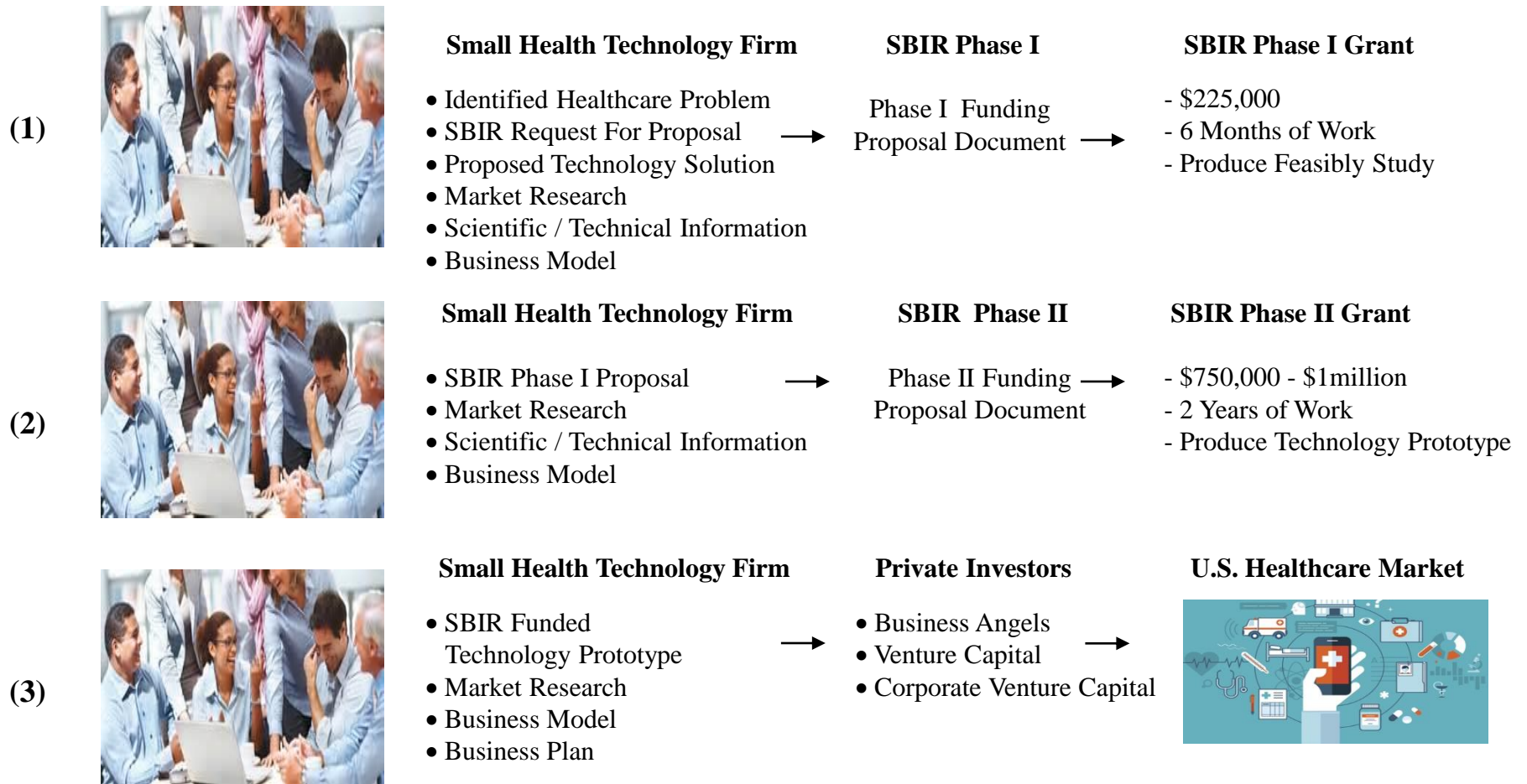
▶ Small companies retain the Intellectual Property (IP) rights from their inventions.



▶ Awarded companies are attractive candidates for private capital investors, e.g., Venture Capital, Business Angels, and Corporate Venture Capital.



NSF & NIH SBIR New Health Technology Developing Funding Process



An Illustration : How NSF SBIR Program Funding Process Works



Health Tech Startup



NSF SBIR Grants



New EHR Software



Patient Application

- (1) Based on its own market research findings, the health technology startup identifies an opportunity to develop data-mining software for Electronic Health Records (EHRs). The proposed technology solution is intended to help physician practices better use their EHRs as a clinical decision tool and improve outcomes for elderly diabetic patients.
- (2) The startup researched NSF SBIR's awards database and reviewed past request for proposals (RFPs) about the agency's interest in funding EHR solutions. The research revealed that NSF SBIR's Digital Health (DH) technology topic area offered funding to develop EHR solutions.
- (3) The startup prepared a two page executive summary that included the identified problem, the proposed solution and its potential commercial viability, the targeted technology users, the industry's competitors, and the firm's proposed research & development approach. Next the small firm sent the executive summary to the NSF SBIR Digital Health program director for review.
- (4) Following discussions with the Digital Health program director, the startup used market research, technical & scientific studies and its business strategy to prepare a winning NSF SBIR Phase I funding proposal. The successful completion of the Phase I project enabled the company to win Phase II money for the development of a technology prototype.
- (5) After winning two rounds of NSF SBIR program grants to develop the data-mining software, the startup sold the technology solution worldwide to physician practices providing health services to elderly diabetic patients. The startup, moreover, owned a new market-driven novel healthcare IT solution that helped grow its business.

Pennsylvania Innovation Partnership (IPart) Program

The Pennsylvania Innovation Partnership (IPart) offers financial assistance to Pennsylvania-based small businesses and entrepreneurs pursuing SBIR grants. Specifically, IPart provides a MicroVoucher which is used to hire a SBIR proposal preparation consultant. The consultant must come from IPart's Preferred Provider list. IPart MicroVouchers pay half of the proposal preparation costs, up to a maximum of **\$3,000**. The health technology entrepreneurs pay the remaining half of the proposal development cost.

Eighteen Ventures is a IPart Preferred Provider. The company utilizes the following National Science Foundation (NSF) SBIR Phase I proposal development service delivery approach:

- (1) Entrepreneur hires Eighteen Ventures from IPart's Preferred Provider list.
- (2) Eighteen Ventures conducts market and information research to support the entrepreneur's proposed health technology concept.
- (3) Entrepreneur and Eighteen Ventures draft the NSF SBIR Phase I proposal.
- (4) Entrepreneur and Eighteen Ventures, using the NSF SBIR Phase I proposal draft, prepare IPart MicroVoucher application.
- (5) Entrepreneur submits NSF SBIR Phase I proposal draft and MicroVoucher application to IPart.
- (6) IPart program reviews NSF SBIR Phase I proposal draft for approval.
- (7) Eighteen Ventures is paid directly from IPart program once the draft NSF SBIR Phase I proposal is approved.
- (8) Eighteen Ventures helps entrepreneur finalize and prepare NSF SBIR Phase I proposal for submission.

More information about the IPart program be found at **www.Innovationpartnership.net**

Preparing Winning SBIR Phase I Funding Proposals

Winning SBIR funding Phase I and Phase II proposals incorporate **five** things: Identified problem, defined technology concept, reliable market and scientific research information, realistic business case and qualified team.

Identified Problem The ideal identified problem affects a significant number of individuals, including patients, with few existing options to solve it. Moreover, the problem is either linked to lives being lost/injured, high costs of providing healthcare services, burden on the economy, or negative treatment outcomes.

Defined Technology Concept A defined technology concept includes a purpose, unique features, dimensions and potential benefits. It also focuses on solving an unmet medical, healthcare or public health problem. More importantly, the technology concept, as an alternative to existing solutions, discusses how it intends to save lives, reduce healthcare costs, or improve patient outcomes.

Reliable Market & Scientific Research Information Market research data and scientific studies are used to substantiate the development of the proposed technology concept. For example, the market research findings are needed to show the potential commercial viability of the proposed solution. The scientific studies support the company's research & development (R&D) testing approach.

Realistic Business Case Information from the company's business plan is used to illustrate how the new health technology will be introduced, marketed and sold in a designed marketplace.

Qualified Team The team includes individuals with outstanding qualifications, professional experiences and appropriate skills necessary to implement the research & development process and produce a prototype.

How To Use Business Documents To Prepare A SBIR Phase I proposal

Business Model

A design for the successful operation of a business, identifying revenue sources, customer base, products, and details of financing.

Lays out a step-by-step plan of action for profitably operating the business in a specific marketplace.

Elements: Proposed concept, identified customers, value proposition, revenue model, market opportunity, channel, competitive advantage, key activities, and key resources.

Business Plan

A document setting out a business's future objectives and strategies for achieving them.

Spells out purpose, vision and means of operation, i.e., marketing, management and finance. Also serves as the company's resume, explaining objectives to investors, partners, employees and vendors.

How To Use Business Documents To Prepare A SBIR Phase I proposal

Business Model

Elements:

- Identified Healthcare or Medical Problem
- Proposed Health Technology Concept
- Identified Customers
- Value Proposition
- Revenue Model
- Cost Model
- Market Opportunity
- Channels
- Competitive Advantage
- Key Activities (Research & Development)
- Key Resources
- Team



NIH & NSF SBIR Phase I Proposal Document

Elements:

- Identified Healthcare or Medical Problem
- Proposed Health Technology Concept
- Identify Customers
- Value Proposition
- Revenue Model
- Market Opportunity
- Commercialization Strategy
- Competitive Advantage
- Research & Development (R&D) Approach
- Resources & Materials
- Research Teams

Business Model Example

Use business model information/data to prepare NSF & NIH Phase I Proposals

<u>NSF SBIR Phase I Proposal</u>	<u>NIH SBIR Phase I Proposal</u>	<u>Business Model Information</u>
- Identify Healthcare/Medical Problem	- Identify Healthcare/Medical Problem	- Describes Healthcare/Medical Problem
- Patient Population/Targeted Audience Impacted	- Patient Population/Targeted Audience Impacted	- Identifies Patients/Audience Impacted
- Innovative Proposed Technology Solution	- Innovative Proposed Technology Solution	- Proposed Technology: Problem Solver
- Market Opportunity	- Market Opportunity	- Market Opportunity: Size & Competition.
- Research & Development Process	- Research & Development Process	- Research & Development: Technology Product Development
- Research Team	- Research Team	- Team: Management, Staff & Research Personnel

How To Use Business Documents To Prepare A SBIR Phase I proposal

Business Plan

Elements:

- Identified Healthcare or Medical Problem
- Proposed Health Technology Concept
- Identified Customers
- Market Opportunity
- Competitive Advantage
- Research & Development Strategy
- Marketing & Promotional Strategy
- Revenue & Cost Models
- Leadership & Personnel
- Key Resources
- Financials



NIH & NSF SBIR Phase I Proposal Document

Elements:

- Identified Healthcare or Medical Problem
- Proposed Health Technology Concept
- Identify Customers
- Value Proposition
- Revenue Model
- Market Opportunity
- Commercialization Strategy
- Competitive Advantage
- Research & Development (R&D) Approach
- Resources & Materials
- Research Teams

Business Plan Example

Use business plan information/data to prepare NSF & NIH Phase I Proposals

NSF SBIR Phase I Proposal

- Identify Healthcare/Medical Problem
- Patient Population/Targeted Audience Impacted
- Innovative Proposed Technology Solution
- Market Opportunity
- Research & Development Process
- Research Team

NIH SBIR Phase I Proposal

- Identify Healthcare/Medical Problem
- Patient Population/Targeted Audience Impacted
- Innovative Proposed Technology Solution
- Market Opportunity
- Research & Development Process
- Research Team

Business Plan Information

- Describes Healthcare/Medical Problem
- Identifies Patients/Audience Impacted
- Proposed Technology: Problem Solver
- Market Opportunity: Size & Competition.
- Research & Development: Technology Product Development
- Team: Management, Staff & Research Personnel

About Eighteen Ventures

Based in the Miami-Fort Lauderdale, FL metro area, Eighteen Ventures (EV) is a small business development consulting firm offering services nationwide. In particular, we help health technology entrepreneurs, such as engineers, physicians, nurses, researchers, inventors, technologists, scientists and non-medical, experienced healthcare industry professionals, start and build successful small businesses. We also help health technology entrepreneurs and startups organize and prepare National Science Foundation (NSF) and National Institutes of Health (NIH) Small Business Innovative Research (SBIR) grant proposals for the production of innovative, marketable, problem solving healthcare or medical solutions.

Eighteen Ventures is a Preferred Provider with the Pennsylvania Innovation Partnership (IPart) program. Pennsylvania based health technology entrepreneurs and startups can use IPart's **\$3,000** MicroVoucher to help pay for half of Eighteen Ventures' SBIR proposal development service.

Mr. Darrell Williams, Eighteen Ventures' founder President and CEO, is an experienced small business development consultant, who has been involved in the Small Business Innovation Research (SBIR) program since 1999. Mr. Williams can be reached at Darrell@eighteenventures.com or (305) 322-2443.



Health Technology Entrepreneur

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Innovative Health Technology

We help health technology entrepreneurs acquire and use SBIR grants to develop innovative healthcare technologies