

## SBIR/STTR Information Guide

An overview of the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs at the Federal agencies with research topics relevant to medical technology.



### :: Introduction

The [Small Business Innovation Research \(SBIR\) and Small Business Technology Transfer \(STTR\) programs](#) encourage U.S. small businesses to conduct research and development (R&D) and commercialize innovation. Through a competitive awards-based program, SBIR and STTR grants and contracts enable small businesses to demonstrate the scientific and technical merit and commercial potential of a project. These awards also provide a foundation for private follow-on funding. The SBIR and STTR programs address the nation's specific R&D needs by including qualified small businesses in high-tech innovation.

Federal agencies with external R&D budgets greater than \$100 million are required to set aside 3.2% of this extramural R&D budget for small businesses through the SBIR and STTR programs. Each agency administers its own individual program within Congressional guidelines. Agencies designate R&D topics in their solicitations and accept proposals from small businesses. Awards are made on a competitive basis after proposal evaluation.

The critical [difference between SBIR and STTR](#) is the STTR program requirement for the small business to formally collaborate with a research institution. The SBIR and STTR program is divided into [three phases of funding](#).

- **Phase I: Feasibility and proof-of-concept**  
*generally \$250,000 for six to 12 months*
- **Phase II: Continued R&D**  
*generally \$750,000 for two years*
- **Phase III: Commercialization**  
*no SBIR/STTR funding*

This guide provides an overview and links to specific information on the SBIR/STTR programs at the National Institutes of Health (NIH), National Science Foundation (NSF), the Department of Defense (DoD), and the National Aeronautics and Space Administration (NASA), each of which fund grants and contracts relevant to medtech companies conducting R&D and product development.



## National Institutes of Health

The NIH SBIR/STTR program invests over \$1 billion annually in small companies through 24 participating Institutes and Centers (ICs). [Eligible companies](#) interested in [funding opportunities](#) are encouraged to identify ICs with relevant research topics by referencing the [NIH Matchmaker](#) tool. Prior to submitting an application, companies are advised to speak with an [HHS SBIR/STTR program manager](#), and review the [Application Infographic](#) for in-depth information on each step of the application and review process.

[Engage and connect](#) with the NIH SBIR/STTR program to stay informed of upcoming webinars and other educational programs. The [NIH Small business Education & Entrepreneurial Development \(SEED\) office](#) also fosters collaboration and connections across the spectrum of the NIH innovation community.

### APPLICANT RESOURCES:

- [Contact the SEED Office](#)
- [Small Business Support](#)
- [Step-by-Step Application Instructions](#)
- [NIH Grants & Funding Application Guide](#)
- [Clinical Trial Requirements](#)
- [Develop Your Budget](#)
- [Entrepreneurial Finance Course](#)



## National Science Foundation

The [SBIR/STTR program](#) is housed within the Division of Industrial Innovation and Partnerships of the Directorate of Engineering at the NSF. [NSF funds startups with transformative science and engineering innovations](#) that have the potential for commercial success and societal impact. Following the three phase program startups can receive up to \$2M in non-dilutive funding to support translational R&D.

Get started by understanding these [basics of the program](#) and exploring the various technology topic areas, including the [Medical Devices topic](#). Then prepare your [Project Pitch](#) to determine if your innovation is a good fit for NSF funding, before being invited to submit a full proposal. Stay informed by participating in [NSF events](#) and referencing the following applicant resources.

### APPLICATION RESOURCES:

- [Project Pitch](#)
- [Full Proposal Guidance](#)
- [Proposal Review and Decision](#)
- [Review Process](#)
- [FastLane Guide](#)
- [Project Pitch Guide](#)
- [COVID-19 Proposal Instructions](#)



## Department of Defense

The [DoD SBIR/STTR program](#) is a requirements-driven process, following specific topics (or technology gaps) that are set by each of the 14 participating Components within the DoD (i.e. Department of the Army, Defense Health Agency, DARPA). Topics relevant to medical technology are found in many of the DOD SBIR/STTR agency announcements. The DoD issues only contracts (not grants). Proposals are allowed a single submission and are reviewed by Government subject matter experts.

The [Defense SBIR/STTR Innovation Portal \(DSIP\)](#) is the official proposal submission website with a searchable list of topics, the schedule of Broad Agency Announcements, and other applicant resources. When preparing a submission, companies should also note the registration requirement with the [System for Award Management \(SAM\)](#), relevant [Export Control restrictions](#), as well as the national network of [Procurement Technical Assistance Centers](#).

## RELEVANT PROGRAMS AND RESOURCES:

- [Defense Health Agency \(DHA\) Office of Small Business Programs](#)
  - [Military Health System: Research and Innovation](#)
- [Department of the Army SBIR/STTR Program](#)
- [Defense Advanced Research Projects Agency \(DARPA\) SBIR/STTR Programs](#)
- [Defense Threat Reduction Agency \(DTRA\) Contracts \(Business Opportunities\)](#)
- [Chemical and Biological Defense \(CBD\) SBIR Program](#)
- [U.S. Army Medical Research and Development Command \(USAMRDC\)](#)
  - [OTA: Medical Technology Enterprise Consortium \(MTEC\)](#)
- [Joint Program Executive Office \(JPEO\) for Chemical, Biological, Radiological, & Nuclear Defense \(CBRND\)](#)
  - [OTA: Medical CBRN Defense Consortium](#)
- [Congressionally Directed Medical Research Programs \(CDMRP\)](#)
- [Homeland Defense and Security Information Analysis Center \(HDIAC\) – Medical Technical Focus Area](#)



## National Aeronautics and Space Administration

The National Aeronautics and Space Administration (NASA) is an independent Federal agency responsible for the civilian space program. NASA conducts research, testing, and development of aeronautics and space technologies to enable future exploration and benefit life on Earth. The [NASA SBIR/STTR program](#) funds technologies that fulfill NASA needs as described in the [annual solicitations](#). While predominantly focused on space technologies, recent solicitations have included topics focused on "Human Research and Health Maintenance." Additionally, NASA has developed a [Human Research Roadmap](#) to investigate and mitigate the highest risks to astronaut health and performance for exploration missions. The NASA SBIR/STTR program awards Phase I and Phase II grants and contracts and has [several initiatives to fund and support small businesses beyond Phase II](#).

### APPLICANT RESOURCES:

- [Interactive Participation Guide](#)
- [Program Schedule and Award Announcements](#)
- [Award and Solicitation Search](#)
- [Awarded Projects' Abstracts Search](#)
- [Resource Library](#)



U.S. Small Business Administration

## U.S. Small Business Administration

The U.S. Small Business Administration (SBA) serves as the coordinating agency for the SBIR and STTR program. SBA provides numerous [resources for entrepreneurs](#), including in-depth [online tutorials](#) and extensive [frequently asked questions](#). SBA offers a separate [Lender Matching Program](#) that enables companies to apply for business loans.

Beyond SBA, small business resources include the [Federal Laboratory Consortium](#), which offers access to facilities and expert collaborators, and the US Patent and Trademark Office (USPTO), which maintains an [Investor and Entrepreneur Resources hub](#) for companies to protect their intellectual property.

### State and Local Programs

Several states have created dedicated Phase 0 award programs to help small businesses navigate the complex and resource-intensive application process. Some states also offer matching programs that provide grant funding to match federal SBIR/STTR Phase I and Phase II awards. SBA publishes a list of [Phase 0 and State Matching Grant Programs](#), and on page 5 of this guide, we have compiled a table of selected programs in states with concentrations of medtech companies. SBA also supports multiple [programs that offer local assistance](#) to small businesses throughout the application and award process.

## State Funding Programs

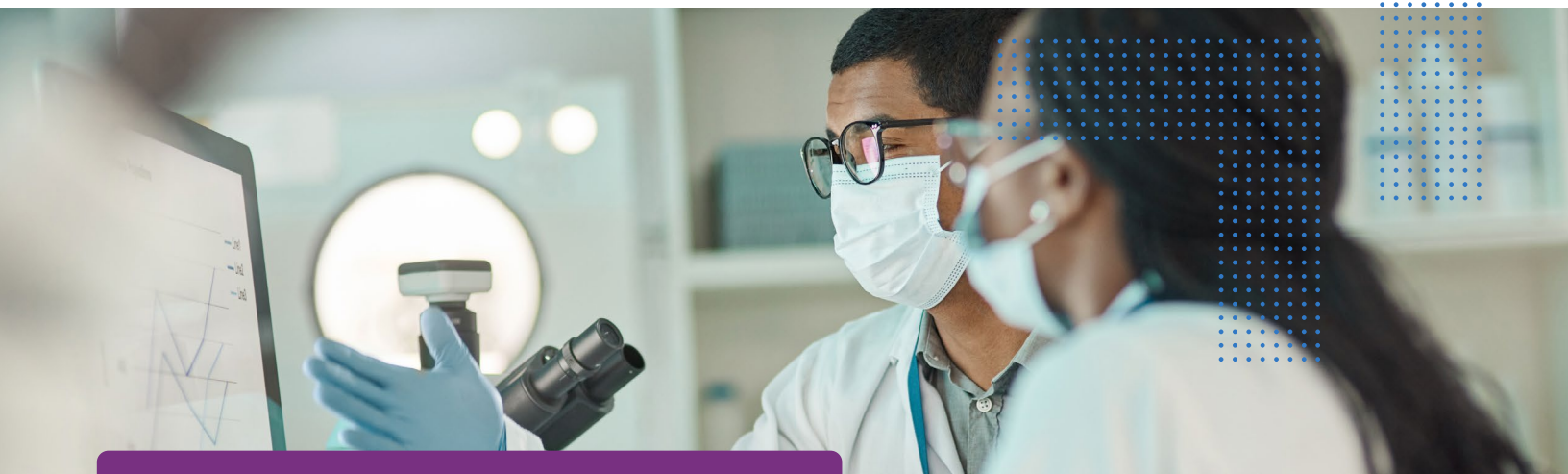
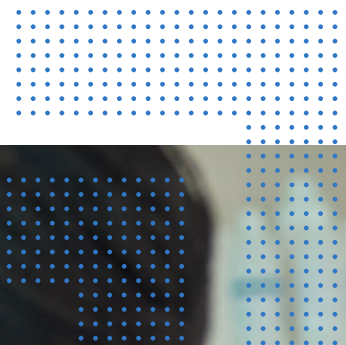
STATE	PHASE 0 PROGRAMS	PHASE I/II STATE MATCHING FUNDS
Arizona	<a href="#">Arizona FAST Partnership Program</a>	
Colorado	<a href="#">Colorado SBDC Techsource</a>	
Florida		<a href="#">Florida High Tech Corridor Council Matching Grants Research Program</a>
Indiana		<a href="#">Indiana SBIR/STTR Matching Awards</a>
Illinois	<a href="#">FAST Partnership Center at the University of Illinois Urbana-Champaign</a>	<a href="#">Illinois SBIR &amp; STTR Matching Program</a>
Massachusetts		<a href="#">MassVentures' START Award Program</a>
Michigan	<a href="#">Michigan Assistance Program</a>	<a href="#">Michigan Emerging Technologies Fund</a>
Minnesota		<a href="#">Launch Minnesota SBIR/STTR Matching Grant</a>
New Jersey		<a href="#">New Jersey CSIT SBIR/STTR Direct Financial Assistance Program</a>
New York	<a href="#">New York WIN SBIR/STTR Assistance Program</a> <a href="#">NY STAR SBIR/STTR Assistance Program</a>	
North Carolina	<a href="#">SBIR/STTR Phase I Incentive Funds Program</a>	<a href="#">SBIR/STTR Phase I Matching Funds Program</a>
Pennsylvania	<a href="#">Innovation Partnership FAST Program</a>	
Utah	<a href="#">Utah Innovation Center</a>	<a href="#">Utah Technology Innovation Funding (UTIF)</a>
Wisconsin	<a href="#">Wisconsin Center for Technology Commercialization - SBIR/STTR Assistance Microgrants</a>	<a href="#">Wisconsin Center for Technology Commercialization - SBIR Advance</a>

\*This table includes select states with medtech industry clusters. SBA publishes a [full list of state funding programs](#).

### FEDERAL GRANT WRITING AND GRANT MANAGEMENT CONSULTANTS

- [BBC Entrepreneurial Training & Consulting](#)
- [Eva Garland Consulting](#)
- [DeSalvo & Company](#)
- [Jameson & Company](#)
- [Intelispark](#)
- [Altaclair Consulting Services LLC](#)
- [BioScience Advising](#)
- [Amala Consulting](#)
- [Lighthouse Consulting](#)

This is a list of known consultants and advisory firms providing grant writing and grant management support for small businesses. Inclusion on this list does not constitute a recommendation in any form.



## National Institutes of Health



## Introduction

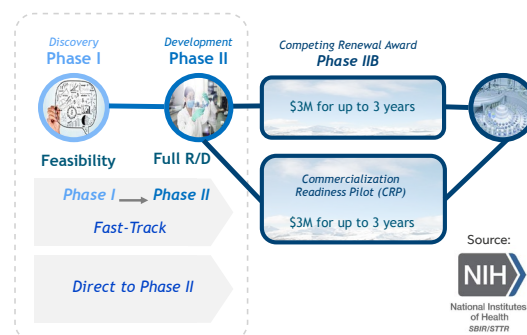
The NIH SBIR/STTR Programs invest over **\$1 billion** in life science companies annually.

The **National Institutes of Health (NIH)** is the largest government research agency in the world and spends more than \$32 billion annually to fund research that advances scientific discovery. A portion of the money spent goes towards non-dilutive funding programs, which enable early-stage medtech and other life science companies to advance and de-risk product development, while also providing scientific and technical validation that attracts investors and supports reimbursement.

The NIH offers non-dilutive funding through the highly-competitive **Small Business Innovation Research (SBIR)** and **Small Business Technology Transfer (STTR)** programs. In FY20, these programs invested over \$1.2 billion in life science companies (over \$1 billion in SBIR projects and nearly \$150 million in STTR projects). Approximately 30% of this funding was awarded to medical technology companies.

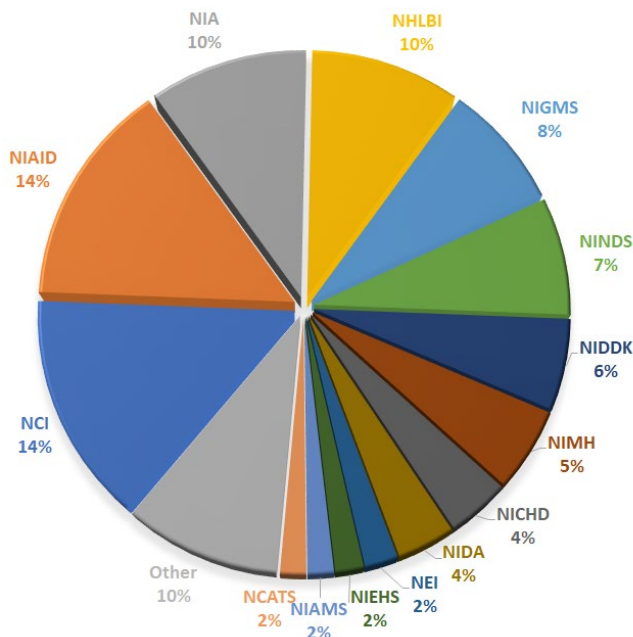
Source: NIH RePORTER

NIH SBIR/STTR is a **Three-Phase Program** that covers a product's life cycle from proof-of-concept and feasibility to advanced product development and clinical studies.





## Over \$300 million in SBIR/STTR funding for medtech in FY20



FY20 SBIR/STTR Funding by Institute/Center

Source: NIH RePORTER

Key institutes and centers that extensively fund and collaborate with medtech companies

[National Cancer Institute](#) (NCI)

[National Eye Institute](#) (NEI)

[National Heart, Lung, and Blood Institute](#) (NHLBI)

[National Institute of Allergy and Infectious Diseases](#) (NIAID)

[National Institute of Arthritis and Musculoskeletal and Skin Diseases](#)

[National Institute of Biomedical Imaging and Bioengineering](#) (NIBIB)

[National Institute of Diabetes and Digestive and Kidney Diseases](#) (NIDDK)

[National Institute of General Medical Sciences](#) (NIGMS)

[National Institute of Neurological Disorders and Stroke](#) (NINDS)



## NIH Small business Education and Entrepreneurial Development (SEED)

SEED coordinates early-stage product development activities across the NIH, and develops relationships with universities and research institutions, small businesses, trade associations, societies, angel investors, venture capitalists, and strategic partners to build opportunities for NIH-funded innovators to further their product development efforts. SEED oversees multiple programs to support small businesses including [Technical and Business Assistance](#), [Commercialization Enhancement Programs](#), and [Funding to Diversify Your Workforce](#).

Small businesses are encouraged to [contact the SEED team](#) for questions on eligibility, applications, and funding opportunities. SEED can help small businesses connect with the right NIH staff depending on where they are in the process. SEED also hosts and promotes numerous [educational events](#) with information on funding opportunities and the application and review process. [Subscribe to the mailing list](#) for the latest news from NIH SEED.

## Five Scored Review Criteria



### Significance

Addresses critical problem and advances scientific knowledge with commercially-viable technology



### Approach

Well-reasoned strategy, methodology, and milestones



### Innovation

Novel concept presents value over current standard of care



### Investigators

Clinical and technical expertise and experience in the field



### Environment

Appropriate facilities, equipment, and institutional resources

### Specific Aims

Executive summary of review criteria; can submit in advance to confirm project fit with funding priorities of individual ICs.

### Research Strategy

Addresses the most critical scored review criteria of Significance, Innovation, and Approach, including detail on the scientific and clinical impact, as well as project methodology and milestones.

### Biographical Sketches

Includes a personal statement along with CV, which allows a place for startups companies to capture industry experience and demonstrate strength of team.

### Letters of Support

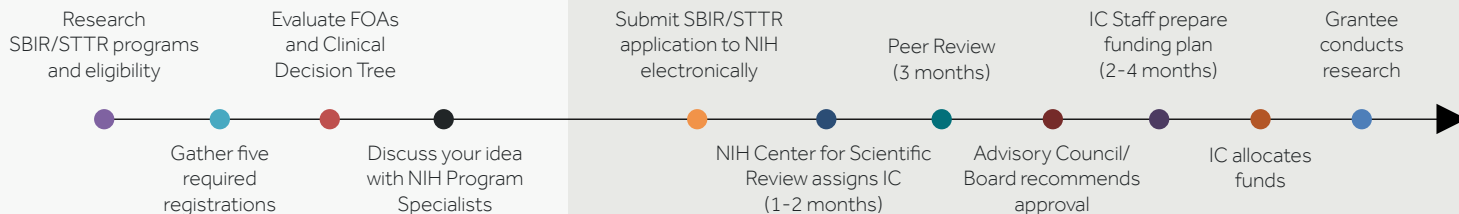
Optional but critical component to provide technical and commercial validation for proposed project (no limit on the number of letters; 2-5 recommended).

### Commercialization Plan

Offers a clear and concise description of the proposed work's market potential and path to commercialization (*Phase II and Fast Track only; not required for Phase I*).

## NIH SBIR/STTR Application and Review Timeline

Pre-application Steps





## Commercialization Plan



### Application Submission and Review

- 1 | Understand the [basics of the SBIR and STTR programs](#), the [different funding paths and phases](#), and [eligibility criteria](#) for small businesses.
- 2 | [Talk through your idea with NIH staff](#) at relevant Institutes and Centers (ICs) – share a 1-page concept paper or specific aims document in advance of a phone consultation. Each IC has different rules, contacts, and budgets. The NIH Center for Scientific Review will assign each application to an IC.
- 3 | [Prepare to apply](#) by understanding the various application systems and allowing sufficient time to obtain the required registrations (DUNS Number, System for Award Management, Grants.gov, eRA Commons, SBA Company Registry at SBIR.gov).
- 4 | [Identify the right funding opportunity](#) - SBIR and STTR omnibus grant solicitations have three standard application cycles per fiscal year (September 5, January 5, and April 5) and targeted solicitations on specific research areas are issued by individual ICs.
- 5 | [Understand the Review Process](#), including Peer Review (panels of outside experts) and the role of the NIH Center for Scientific Review, which reviews most applications and gives an overall impact score on five scored review criteria as well as additional criteria (not scored; vary by application type and aspects of research project).
- 6 | [Prepare your application](#), paying close attention to the content and format of key documents: Specific Aims, Research Strategy and Letters of Support. Use [ASSIST](#) (the NIH online application preparation and submission system) to submit and [eRA Commons](#) (NIH electronic Research Administration) to track your application.
- 7 | [Know the reporting and financial management requirements for an award](#). Develop and maintain a budget – know what type of budget will be required, understand various components, and track expenditures for project reporting. Note the [requirements for registering & reporting NIH-funded clinical trials in ClinicalTrials.gov](#).

## :: AdvaMed Member Recommendations

- **Focus on the Five Review Criteria:** Significance, Approach, Innovation, Investigators, Environment.
- **Follow the application guides:** prepare application side-by-side with the [NIH SBIR/STTR Instructions](#) and the [NIH Grants & Funding Application Guide](#).
- **Spend time developing your budget,** and be as specific and inclusive of the project costs as possible.
- **Plan accordingly for the significant time required to prepare application** (over 100 hours on average per application, according to company applicants).
- **Emphasize the real-world impact** and commercial potential of the project.
- **Seek strong academic partners,** who can provide research assistance and access to facilities, labs, equipment, personnel.
- **Clearly define roles** for collaborating Primary Investigators.
- **Bring in outside talent or experience** to support specific project objectives, when necessary.
- **Employ a finance grant specialist** to make funding requests, gather evidence, develop budget.
- **Allow sufficient lead time** to gather strong letters of support from key opinion leaders and investors.

### Pointers from NIH Program Managers

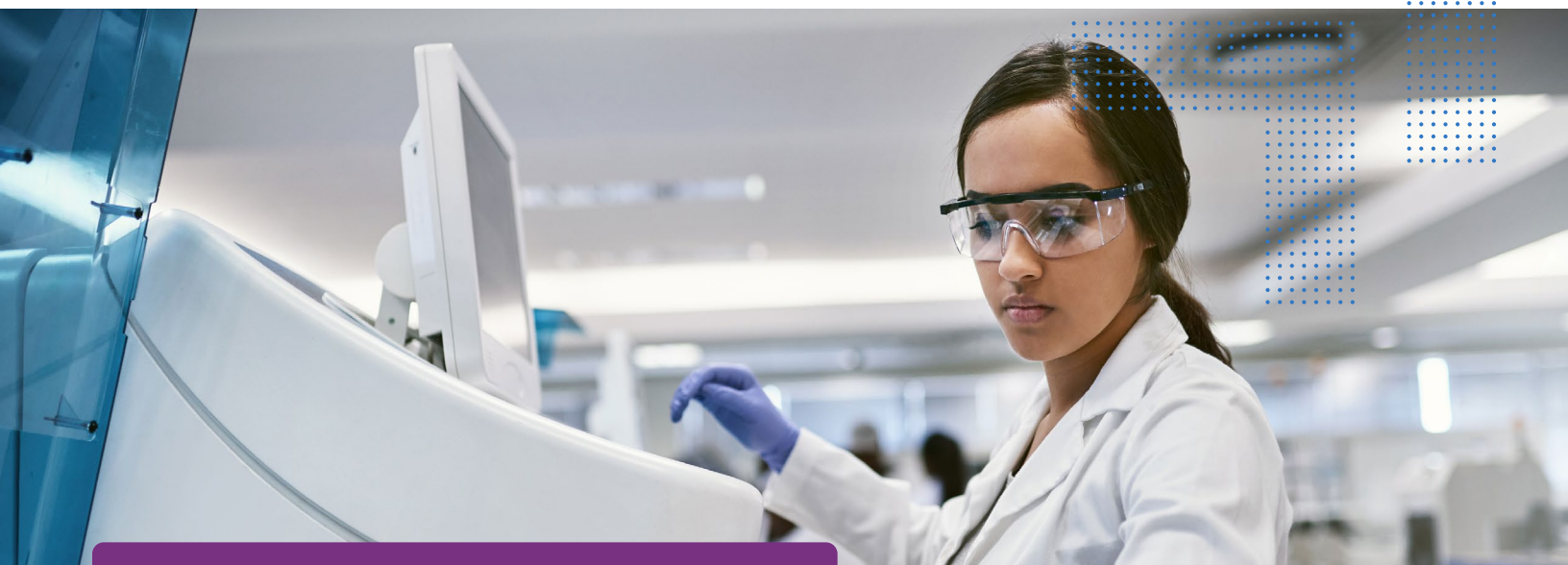
- **Contact NIH Program Specialists** to gauge relevance of a specific project to individual IC's priority areas of interests.
- **Start early** to gather required registrations and build relationships with key opinion leaders and NIH Program Specialists.
- **Be prepared to resubmit** – majority of first-time applicants do not get awards (12% success rates for Phase I applications in FY20); all applicants receive feedback from review panel.

### Potential Pitfalls:

- **No significance** – no compelling case for commercial potential and societal impact.
- **Lack of innovation** – does not present value over current technology or standard of care.
- **Diffuse research plans** – superficial or unfocused research plans.
- **Overly ambitious scope of work** – exceeds reasonable milestones and budget resources.
- **Weak or unsubstantiated Commercialization Plan** – lack of clarity on go-to-market strategy.

### Additional Resources

- :: [Small business Education and Entrepreneurial Development \(SEED\)](#)
- :: [HHS Small Business Program Managers](#)
- :: **How to Apply**
  - [Step-by-Step Instructions](#)
  - [Application Guide](#)
  - [Develop Your Budget](#)
- :: [Application Assistance Program](#)
- :: [Forms Library](#)
- :: [Clinical Trial Requirements](#)
- :: [Technical and Business Assistance Programs](#)
- :: [Commercialization Enhancement Programs](#)
- :: [Entrepreneurial Finance Course](#)



## National Science Foundation



**America's  
SEED FUND**  
SBIR.STTR

### :: Introduction

The U.S. National Science Foundation (NSF) is a federal agency dedicated to research and education across the fields of science and engineering. NSF employs a merit review process and a budget of \$8.5 billion to fund startups with science, engineering, and technology-based innovations that improve the quality of life for Americans and stimulate economic activity.

The NSF Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) program funds early-stage research and development (R&D) projects with the potential for societal benefit and commercial success.

America's Seed Fund powered by NSF enables startups and small businesses to de-risk technologies for commercialization and make them more attractive to private capital. Startups who apply for NSF funding also benefit from the feedback of technical and commercial experts on the review panel and validation of the merit review process.

**America's Seed Fund  
powered by NSF  
funds startups with ...**



**IMPACT**



**TECHNOLOGY  
INNOVATION**



**MARKET PULL**



**SCALE**



## ⚡ Phases of Funding

NSF SBIR/STTR awards can provide up to \$2 million in non-dilutive funding over three years.

### Phase I

up to \$256,000 for proof-of-concept R&D projects for six to 12 months

### Phase II

up to \$1 million for prototype development over the course of 24 months

### Phase IIB

up to \$500,000 in supplemental funding; NSF matches \$1 for every \$2 of private investment

## Accel Member Case Studies

### SONOVEX, INC.

[Sonavex was awarded Phase I and Phase II SBIR grants](#) to develop a novel approach to measuring vascular flow that enables early detection of localized post-operative clot formation, a cause of common and costly surgical failures. The Baltimore-based company and Johns Hopkins spin-out announced the Phase II award in 2017

as part of a \$3 million series A funding round and has since received FDA clearance for two products.



### PATH EX

[PATH EX was awarded Phase I SBIR grant](#) in 2017 to validate a novel blood cleansing therapeutic for diseases such as sepsis. A [Phase II SBIR grant](#) followed in 2018 for the ongoing development of a dialysis-like platform that in pre-clinical studies has demonstrated a more than 95% reduction in the concentration of bacteria in the bloodstream in a single pass. In 2019 the FDA granted Breakthrough Device designation for the PATH EX device, CycloPE. The startup company has raised seed

funding from angel and early-stage investors and has won multiple startup award competitions.



## Research Topics

NSF focuses on deep technologies based on discoveries in fundamental science and engineering, and funds almost all areas of technology (except for clinical trials and schedule I controlled substances). There are several relevant solicitation topics for medical technologies.

- ⚡ [Medical Devices](#)
- ⚡ [Biomedical Technologies](#)
- ⚡ [Digital Health](#)
- ⚡ [Nanotechnology](#)
- ⚡ [Biological Technologies](#)

[A full list of topics is available here.](#)

## Tips for Applicants

- ⚡ Reach out early to discuss your R&D project ideas with [NSF Program Directors](#) responsible for relevant solicitation topics.
- ⚡ Demonstrate that your R&D project has high technical risk and strong commercialization potential.
- ⚡ Read the solicitations carefully to ensure all requirements are met.
- ⚡ NSF funding does not support clinical trials.
- ⚡ Phase II supplements strengthen commercialization strategy and follow-on investment.
- ⚡ Unsuccessful applicants may request a debrief call with Program Director.

## Application and Review Process

## STEP 1

### PROJECT PITCH

Interested in NSF funding? The first step is to submit a Project Pitch to determine if your idea is a good fit. The NSF accepts Project Pitch submissions any time during the year and usually responds in about one month. Your Project Pitch should answer four key questions:

1. **What is the technical innovation** and how does it meet the NSF mandate to support unproven, high-impact R&D?
2. **How will the proposed R&D help prove** the technical feasibility and commercial viability of the product?
3. **What is the market opportunity** and the near-term commercial focus of the project?
4. **What is the status of your small business** and who is the team that will lead the proposed project?

[Submit your Project Pitch here.](#) If successful, your company will be invited to submit a full proposal for Phase I funding and assigned a Program Manager.

Annually the NSF SBIR/STTR programs award over \$200M in funding to roughly 400 startups, most of which have fewer than five employees.

## STEP 2

### FULL PROPOSAL

Upon invitation you may submit a full proposal for Phase I funding during quarterly submission windows and within one year of receiving the invitation.

#### STEP 1

##### Read the solicitations

Solicitations (or calls for proposals) are policy documents that outline the official requirements for a full proposal. Each year the NSF releases Phase I solicitation for SBIR and STTR (these are identical, except STTR proposals require the small business to partner with an eligible research institution).

#### STEP 2

##### Register your company

Complete these required, free registrations (before you enter your proposal in FastLane):

- [Dun and Bradstreet \(DUNS number\)](#)
- [System for Award Management \(SAM\)](#)
- [Research.gov \(required to login to FastLane\)](#)
- [SBIR Company Registry](#)

#### STEP 3

##### Submit in FastLane

Full proposals are submitted on [FastLane](#), which allows companies to create a proposal section by section. The NSF offers this [guide to submitting a Phase I proposal in FastLane](#).



## PROPOSAL REVIEW AND DECISION

Full proposals will be reviewed by three external experts in technology and commercialization on a merit basis to determine:

- (1) intellectual/technical merit
- (2) broader impact of innovation
- (3) commercial potential

[Detailed merit review guidelines can be found here.](#) The NSF Program Director may conduct due diligence and request additional information from the Principal Investigator.

Within five to seven months of submission, the NSF will notify applicants if the proposal is accepted or declined. Unsuccessful applicants may hold a debrief call with the relevant NSF Program Director after reading the proposal's reviews and panel summary.

Successful applicants can expect to receive Phase I funding for a period of six months to one year and should visit the [Phase I awardee section](#) on NSF's website for detailed next steps. Awardees are required to participate in a Phase I SBIR/STTR Workshop and a Beat-the-Odds Boot Camp. Awardees may take part in the Commercialization Assistance Program, designed to help small businesses develop a commercialization plan.

[NSF reporting requirements](#) instruct Phase I awardees to provide formal reports on two separate occasions: (1) at the end of the Phase I award period and (2) when submitting a proposal for Phase II.





## PHASE II FUNDING

Recent NSF SBIR/STTR Phase I awardees may apply for Phase II funding, which is designed to continue to the R&D started in Phase I. At the start of a Phase I award, it is recommended to review [important information on Phase II SBIR/STTR administrative and financial capabilities](#). Proposals may be submitted via FastLane six months to two years following the start date of Phase I funding.

Prior to submitting a Phase II proposal, applicants should read the [SBIR Phase II and STTR Phase II solicitations](#). If the Phase II proposal is submitted before the Phase I project ends, the interim report should be included. Alternatively, the final report for Phase I projects will fulfill the requirement of a technical narrative for a Phase II proposal.

**Phase II Supplements** are additions to Phase II awards formally requested through FastLane:

### Phase IIB Match Funding

NSF will match up to \$500,000 per award (requires third-party investment commitment of at least \$100,000).

### Technology Enhancement for Commercial Partnerships (TECP)

additional funding (up to 20% of Phase II award) for R&D beyond Phase II objectives to enhance strategic partnerships and investment.

### Technical and Business Assistance (TABA)

up to \$50,000 in funding per Phase II award for third party service providers in regulatory/reimbursement strategy, protection of intellectual property, fundraising advice, and commercialization strategy.



## Additional Resources

- ⌘ [Resources for Applicants](#)
- ⌘ [FAQs: SBIR/STTR Phase I](#)
- ⌘ [Project Pitch Guide](#)
- ⌘ [FastLane Guide](#)
- ⌘ [Review Process](#)
- ⌘ [Merit Review Guidelines](#)
- ⌘ [COVID-19 Proposal Instructions](#)

## Department of Defense



### :: Introduction

The Department of Defense (DoD) is America's oldest and largest government agency that provides military resources to help prevent war and ensure national security. The DoD has the largest research budget of all the Federal agencies that participate in the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. The DoD SBIR/STTR budget was \$1.8 billion in FY2019, and the agency awards roughly 2,800 SBIR/STTR contracts annually.

The DoD SBIR/STTR program issues only contracts, not grants, and is a requirement-driven process. There are 14 different departments or agencies within the DoD, known as Components, that have an SBIR/STTR program. Each Component has its own set of solicitations for contracts and specific proposal instructions and research topics.

Applicants who receive DoD SBIR/STTR awards retain full rights to their intellectual property and opportunities for follow-on sole source contracts.

### DoD Components



[Defense Health Agency](#)



[Department of the Army](#)



[Defense Threat Reduction Agency](#)



[Chemical and Biological Defense](#)



[Defense Advanced Research Projects Agency](#)

### Topics = Technology Needs

DoD SBIR/STTR programs establish individual requirements, from which topics, or technology gaps, are identified. Roughly 600 topics are issued each year across all DoD SBIR/STTR programs.

Medical-related topics may be found in the Broad Agency Announcements for many DoD Components, primarily:

- [Defense Health Agency](#)
- [Department of the Army](#)
- [Defense Advanced Research Projects Agency](#)
- [Defense Threat Reduction Agency](#)
- [Chemical and Biological Defense](#)

## ❖ Phases of Funding

DoD SBIR/STTR contracts can provide up to \$2 million in non-dilutive funding over three years.

### Phase I

\$167,500 for six to ten months for proof of concept and feasibility studies (\$250,000 for Defense Health Agency)

### Phase II

\$1.1 million for 24 months for continued R&D and prototype development

### Enhanced Phase II

Up to \$500,000 in matched funding, \$1 for \$1 of private investment

#### DoD Components



## Defense SBIR/STTR Innovation Portal (DSIP)

*The official proposal submission website for the DoD*

### ❖ [Topics and a Topic Q/A](#)

Search by number, title, or keyword, and filter by program, technology area, and topic status.

### ❖ [Schedule of Broad Agency Announcements \(BAA\)](#)

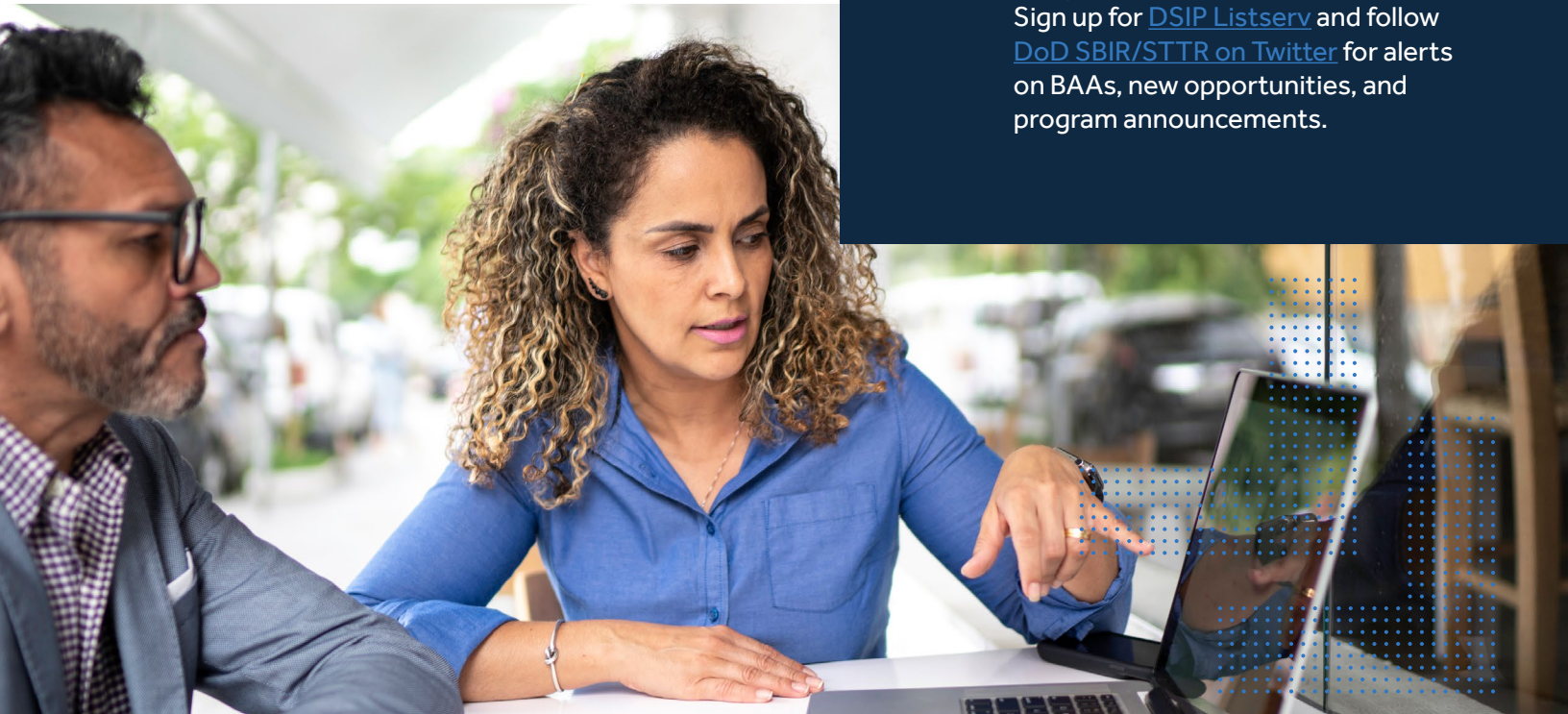
Not all Components participate in each BAA cycle; some may release BAAs outside of the normal schedule, which are listed as Component BAAs or Annual BAAs with specific topics.

### ❖ [Learning & Support](#)

Templates of company registrations and certifications, and guidelines on proposal development; training materials and Frequently Asked Questions for applicants.

### ❖ [Stay Informed](#)

Sign up for [DSIP Listserv](#) and follow [DoD SBIR/STTR on Twitter](#) for alerts on BAAs, new opportunities, and program announcements.





## Application Process Overview

1

### Explore the Defense SBIR/STTR Innovation Portal (DSIP):

- Use the Topic and Topic Q&A search function to identify topics relevant to your technology.
- Review the BAA Schedule and the Learning & Support section for additional program information.

2

### Required registrations

- Create an account on DSIP ([DUNS number](#), [NAICS](#) and [CAGE](#) codes required).
- Register on the System of Award Management ([SAM.gov](#)).

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### Prepare Proposal

- Read the instructions: carefully read both the over-arching DoD instructions in the BAA, and the Component solicitation for each topic or Request for Proposal.
- Note the pre-release, open and close dates for proposals.
- Proposal submission requirements vary among Components (i.e. proposal page numbers, funding amounts, period of performance, etc.).
- Direct contact with the topic Technical Point of Contact (TPOC) is permitted during the pre-release period.

#### DoD SBIR/STTR Distinctions

- **DoD SBIR/STTR is a requirement-driven process:** Each of the 14 Components establish requirements, from which specific topics (or Requests for Proposals) are issued.
- **DoD issues only contracts, not grants:** SBIR/STTR awards are R&D contracts tied to specific technology topics.
- Small businesses submit **proposals, not applications.**

#### DoD Components



- **No peer review:** proposals are reviewed by government subject-matter experts.
- **No resubmissions** or revisions of denied proposals.
- **Special DoD requirements** for research using Animal Subjects or Human Subjects.

## ❖ Application Process Overview *continued*

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### Submit Proposal

- SBIR/STTR Phase I, Direct to Phase II, or Phase II proposals must be submitted through the DSIP.
- Applicants may only submit proposals for topics released within the current Announcement.
- Proposals should include:
  1. the specific problem identified by the Component solicitation and addressed by your proposed R&D project.
  2. information regarding your company and the team conducting the project.
  3. details on your innovation's potential for private investment and commercial success.

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### Proposal Review

- Conducted by U.S. Government subject matter experts.
- Strong focus on proposal's alignment with a specific topic area.
- Three Evaluation Criteria:
  1. Innovation and technical merit
  2. Key personnel qualifications, and facilities.
  3. Commercial potential.
- If your proposal is denied, you cannot resubmit or make revisions.

### Additional Resources

❖ [Defense SBIR/STTR Innovation Portal](#)

A comprehensive resource for applicants

❖ [Health.mil](#)

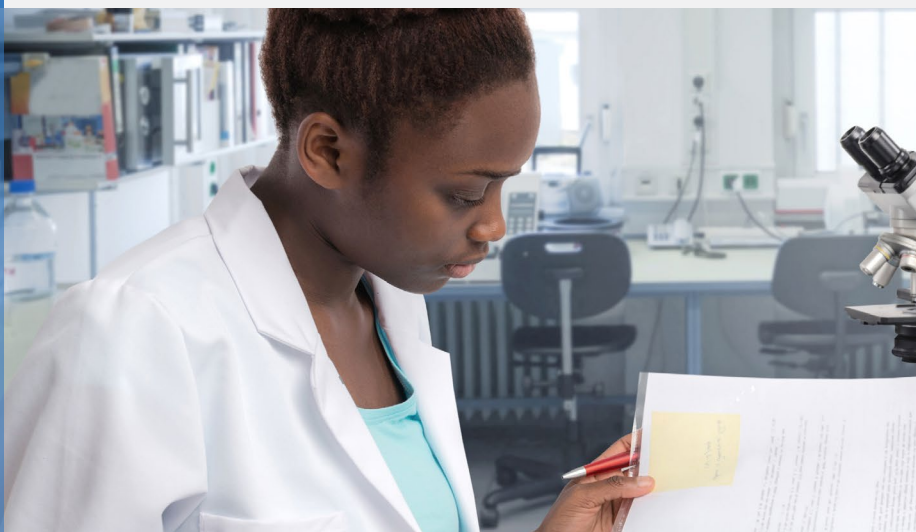
Defense Health Agency acquisition, procurement, and small business resources

❖ [Procurement Technical Assistance Centers](#)

Help with U.S. Government contracting

❖ [SBIR/STTR Awards Statistics](#)

Award data by Federal Agency, Phase of funding, Program and Year



## ❖❖ Non-SBIR/STTR R&D and Procurement Opportunities



### CDMRP

**The Congressionally Directed Medical Research Programs (CDMRP)** funds biomedical research in response to the expressed needs of Service Members, the American public, and Congress. Since 1992 CDMRP has managed \$7.7 billion in Congressional appropriations to fund peer-reviewed research to prevent, control, and cure disease.

- [Currently funded research programs](#)
- [Open funding opportunities](#)
- [How to apply](#)



**The U.S. Army Medical Research and Development Command (USAMRDC)** funds a wide range of extramural research programs (i.e., Gulf War Illness, breast cancer, prostate cancer) through contracts, grants, or cooperative agreements.



- [Partner with USAMRDC](#)
- [How to Submit a Research Proposal](#)
- [Additional Information, open BAA, and open special BAA](#)

USAMRDC includes multiple subordinate commands:

- U.S. Army Aeromedical Research Laboratory (USAARL)
- U.S. Army Institute of Surgical Research (USAISR)
- U.S. Army Medical Materiel Development Activity (USAMMDA)
- U.S. Army Medical Research Acquisition Activity (USAMRAA)
- U.S. Army Medical Research Institute of Chemical Defense (USAMRICD)
- U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)
- U.S. Army Research Institute of Environmental Medicine (USARIEM)
- Walter Reed Army Institute of Research (WRAIR)