2021 HHS Small Business Funding Opportunity Announcements

Stephanie Fertig, MBA
HHS Small Business Program Lead

Robert Vinson
Small Business Program Manager

SEED (Small business Education & Entrepreneurial Development)
Office of the Director | Office of Extramural Research | National Institutes of Health
Small Business Program Website

UPDATED WEBSITE COMING FALL 2021

https://sbir.nih.gov

What are SBIR and STTR Programs?

The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, also

https://sbir.nih.gov
# 2021 HHS Small Business Program Conference

**Diverse Perspectives SEEDing Impactful Innovations**

**VIRTUAL CONFERENCE**

**APRIL 26 - 30**

## Conference Sessions

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<th>Speakers</th>
<th>Video</th>
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<tr>
<td>NIH Welcomes Diverse Perspectives</td>
<td>Matt McMahon, Director, SEED, Office of Extramural Research, NIH</td>
<td>YouTube (14:00)</td>
<td>N/A</td>
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<tr>
<td>Diversity and Bias Perceptions and Rea</td>
<td>Ericka Boone, Director of Division of Loan Repayment and Acting Director of Division of Biomedical Research Workforce, NIH</td>
<td>YouTube (5:008)</td>
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<td>Stephannie Fortip, HHS Small Business Program Lead, NIH</td>
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<td>Charlene E. Le Faivre, Senior Advisor to the Chief Officer for Scientific Workforce Diversity, NIH</td>
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<td>Eric W. Pardue, Senior Policy Advisor, NIH (Moderator)</td>
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<td>America's Seed Fund is Open for Busi</td>
<td>Rob Vlinson, Small Business Program Manager, NIH (Moderator)</td>
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<td>Stephanie Fortip, HHS Small Business Program Lead, NIH</td>
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<td>Secrets to a Successful Submission</td>
<td>Eva Garland, CEO, Eva Garland Consulting</td>
<td>YouTube</td>
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<td>Paul W. Martin, Associate Director of NIH, SBIR Development Center</td>
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To enhance the health and well-being of all Americans, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.

National Institutes of Health
SBIR and STTR $1.2 billion

Centers for Disease Control and Prevention
SBIR $12 million

Food and Drug Administration
SBIR $2 million

Administration for Community Living
SBIR $3 million
To seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

The Small Business Program helps NIH accelerate discoveries from bench to bedside.
**Congressionally Mandated Programs**

$1.2$ Billion Dedicated Funding via Set-aside from NIH’s R&D Budget

- **SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM**
  - Set-aside program for small business concerns to engage in federal R&D -- with potential for commercialization

- **SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM**
  - Set-aside program to facilitate cooperative R&D between small business concerns and US research institutions -- with potential for commercialization
The largest sources of early-stage capital for life sciences in the US

• “Free Money” - Non-dilutive capital and not a loan
• Data and intellectual property rights are protected
• Awardees can leverage funding to attract investors and partners
It is easier (and better) for a company to just get investors and avoid all the work and time to apply for an NIH grant!

Myth Busted

Companies that have developed their product with non-dilutive small business program money are very attractive to investors and strategic partners.
Small Business Success Stories

Diagnostics for the Real World
CA-19

Displaying results 1 to 10 of total 66
Results per page 10

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<th>Company</th>
<th>Story</th>
<th>State - District</th>
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<td>Cell Podium, LLC</td>
<td>Video Messages Sent Directly to Cell Phones Improve Public Health During Crises</td>
<td>NJ - 6</td>
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<tr>
<td>Advanced Circulatory Systems</td>
<td>A Life-Threatening Experience Inspires Enhanced CPR</td>
<td>MN - 4</td>
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<td>Cognition Therapeutics</td>
<td>Alzheimer’s Drug Shows Progress in Restoring Cognitive Function</td>
<td>PA - 18</td>
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Digital Learning Company Supports Parents, Teachers, and Underserved Communities

Latina-Owned Business Creates Effective Public Health Campaigns

sbir.nih.gov/stories
Phased Programs

Discovery Phase I
Feasibility

Development Phase II
Full R&D

Fast-Track (NIH only)

Competing Renewal Award Phase IIB

Commercialization Readiness Pilot (CRP)

Commercial Market Partner or Investor

Only Some NIH Institutes/Centers Participate

Phase I → Phase II

Direct to Phase II (NIH SBIR only)
It is much harder to get a NIH Fast-Track or Direct to Phase II, so don’t even bother applying for those.

Myth Busted

Although most new projects (74%) are Phase I, we support many Fast-Tracks and Direct to Phase II.

Speak with a program officer to determine the best path for your project.
Phased Programs - Budget

Phase I: $259,613/1-2 years*
Phase II: $1,730,751/1-3 years*

*NIH has a waiver from the Small Business Administration to exceed these budgets for many topics
Myth 3

The SBIR and STTR budget cap is too small to be useful. It is not worth the time or money!

Myth Busted

NIH can exceed the SBIR and STTR budget guidelines for many topic areas. A list of approved topics is published every year at https://sbir.nih.gov/funding. Institutes and Centers have different budget guidance.
Applicant initiates research idea
Small Business confirms eligibility
Submits SBIR/STTR grant application to NIH electronically
NIH Center for Scientific Review assigns to an institute and review group

1-2 Months

Institute staff prepare funding plan for Institute Director
Advisory Council or Board recommend Approval
Scientific Review Group evaluates scientific merit

3 Months

2-4 Months

Institute allocates funds
Grantee conducts research
Eligibility Criteria

• Organized as for-profit US business
• Small: 500 or fewer employees, including affiliates
• Work must be done in the US (with few exceptions)
• Individual Ownership:
  – Greater than 50% US-owned by individuals and independently operated <OR>
  
  – Greater than 50% owned and controlled by other business concerns that are greater than 50% owned and controlled by one or more individuals, an Indian tribe, ANC or NHO (or a wholly owned business entity of such tribe, ANC or NHO) <OR>

  – **SBIR ONLY**: Be a concern which is more than 50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these

Determined at the Time of Award
Applicant initiates research idea

Small Business confirms eligibility

Submits SBIR/STTR grant application to NIH electronically

NIH Center for Scientific Review assigns to an institute and review group

Institute staff prepare funding plan for Institute Director

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3 Months
Small Business Program Website – Application Receipt Dates

Majority of the funding goes to investigator-initiated applications

Standard receipt dates: September 5*, January 5, April 5

*September 7 Due to Holiday

https://seed.nih.gov/
SBIR/STTR Grant Solicitation Funding Opportunities

• General Omnibus Solicitations
  • Clinical Trial Not Allowed: SBIR (PA-21-259) and STTR (PA-21-262)
  • Clinical Trials Required: SBIR (PA-21-260) and STTR (PA-21-261)

*Read the “Program Descriptions and Research Topics” Section in the Solicitation*

• Targeted Solicitations (https://sbir.nih.gov/funding/individual-announcements)
  *Not all of these have a separate set-aside or peer review- Read Carefully!

SBIR Contract Solicitation

• Only some Institutes/Centers participate
• FY2022 Contract Solicitation is now available
• Receipt date is October 28th

Join us for the Contract Solicitation Webinar August 12th at 1PM ET

https://sbir.nih.gov/funding
I should apply to a specific program announcement because targeted funding opportunities have their own dedicated funding.

Myth Busted

Most NIH awards (79%) are made to applications submitted to the omnibus (general) solicitations. Not all targeted program announcements have special set-asides.
## SBIR and STTR Critical Differences

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<th>SBIR</th>
<th>STTR</th>
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<td><strong>Partnering Requirement</strong></td>
<td>Permits partnering</td>
<td>Requires a non-profit research institution partner (e.g., university)</td>
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<td><strong>Work Requirement</strong></td>
<td>Guidelines: May outsource 33% (Phase I) 50% (Phase II)</td>
<td>Minimum Work Requirements: 40% small business 30% research institution partner</td>
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<td><strong>Principal Investigator</strong></td>
<td>Primary employment (&gt;50%) must be with the small business</td>
<td>PI may be employed by either the research institution partner or small business</td>
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Award always made to small business.
Since SBIR is a bigger program, I have a better chance of getting an SBIR awarded.

Myth Busted

The size of the program does not correlate with the chance of getting an award.

For example, smaller programs (i.e., STTR) or NIH Institutes may have far fewer applications.
Clinical Trial Requirements for Grants and Contracts

NIH is launching a series of initiatives that are rolling out in 2017-2018 to enhance the accountability and transparency of clinical research. These initiatives target key points along the whole clinical trial lifecycle from concept to results reporting. Learn more about these changes and how they will affect your research.

**NIH Definition of a Clinical Trial**

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. Learn more

**DECISION TOOL**

Your human subjects study may meet the NIH definition of a clinical trial.

FIND OUT HERE
Myth 6

My project is low risk and only has a few human subjects, so it is not a clinical trial.

Myth Busted

The NIH definition of a clinical trial is not the same as the FDA’s and is not based on risk or number of subjects. Not all NIH Institutes accept applications with clinical trials, so it is important to talk with a program officer!
Grant applications and SBIR contract proposals must be submitted **electronically**.

**REQUIRED REGISTRATIONS**

- DUNS Number (Company)
- System for Award Management (SAM)
- Grants.gov (Company)
- eRA Commons (Company and all PD/PIs)
- SBA Company Registry at SBIR.gov

**Two-Factor Authentication:**

- login.gov will soon be required to access eRA Commons
- Use the same login.gov account for eRA, Grants.gov, and SAM

- Grants submit via ASSIST or Grants.gov Workspace
- For contracts, submit proposals with electronic Contract Proposal Submission (eCPS) website

Helpful [NIH Grants Registration Infographic](#)
Resources

Links to:

Annotated Form Set for NIH Grant Applications
FORMS-F Series

Application Instructions for FORMS-F

Sample Applications:

- NIAID: SBIR and STTR Phase I and Fast-Track
- NCI: SBIR and STTR Phase I
- NIA: SBIR Phase I (with resubmission) and Phase II

https://sbir.nih.gov
Most Important Piece of Advice

Talk to a Program Officer at least a month before the application deadline!

List of SBIR Program Managers: https://sbir.nih.gov/engage/ic-contacts

Research Portfolio Online Reporting Tools (RePORT): https://report.nih.gov/

Not sure who to contact? https://public.era.nih.gov/commons/public/servicedesk/initseed.era or Email: SEEDinfo@nih.gov
Applications are submitted to NIH and then assigned to a specific Institute and Study Section. You can request a specific Institute or Study Section, but you don’t have to!
NIH Application & Review Process: Review

1. Applicant initiates research idea
2. Small Business confirms eligibility
3. Submits SBIR/STTR grant application to NIH electronically
4. NIH Center for Scientific Review assigns to an institute and review group (1-2 Months)
5. Institute staff prepare funding plan for Institute Director (2-4 Months)
6. Advisory Council or Board recommend Approval (3 Months)
7. Scientific Review Group evaluates scientific merit
8. Institute allocates funds
9. Grantee conducts research
### Overall Impact Score

**Scored Review Criteria (score 1-9)**
- Significance (Real Problem/Commercial Potential)
- Investigators (Investigator and Team)
- Innovation (New or Improved?)
- Approach (Research Design, Feasible)
- Environment (Facilities/Resources)

**Additional Review Criteria (not scored individually)**
- Application Phase Specific Considerations
- Protection of Human Subjects
- Inclusion of Women, Minorities & Children
- Vertebrate Animals
- Biohazards

**Additional Review Considerations (not factored into the overall score)**
- Foreign Components
- Select Agent Research
- Resource Sharing Plans
- Authentication of Key Resources
- **Budget and Period of Support**

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Center for Scientific Review
[https://public.csr.nih.gov/](https://public.csr.nih.gov/)
Myth 8

My application didn’t get discussed or funded the first time. It’s a waste of time to try again.

Myth Busted

Very Competitive: Only 14% of new projects are funded
…BUT resubmissions have a higher success rate (18%)

Persistence is Key: Read the summary statement carefully and contact your program officer to discuss.

Offer to be a reviewer.
“SBIR is a tough route, and people should be aware of that. The reviewers are not concerned about feelings. But take the criticism seriously, correct the things that need correcting and be prepared to resubmit. Don’t give up because of a depressing review.”

“[SBIR] has been a long, trying, but worthwhile journey...from multiple submissions that were not discussed...to applications that scored below the funding levels...to concurrent applications (one Phase II and a Phase I) emerging from the rigorous peer review process with impact scores in the “Excellent" range.”
Novice applicants to the program are almost never successful at getting awards.

Myth Busted

25% of all SBIR and STTR awards last year went to new investigators. NIH strongly encourage new applicants - particularly from under-represented innovators or parts of the country.

NIH Applicant Assistance Program: https://sbir.cancer.gov/programseducation/aap
Funding and Support for NIH Innovators: Introducing NIH SEED

Small business Education and Entrepreneurial Development (SEED)

• Supports the NIH innovator community (funding and resources) to validate and advance discoveries to products that improve patient care and health.

• Develop relationships with strategic partners and build opportunities for NIH innovators to further their product development efforts.

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Ashim Subedee
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Chris Sasiela
chris.sasiela@nih.gov

SBIR·STTR
America’s Seed Fund

SEEDinfo@nih.gov
The Small Business Programs only provide money.

Myth Busted

The Small business Education and Entrepreneurial Development (SEED) Office provides technical and business assistance, education, partnering/investment opportunities, and commercialization support.
New Support for Awardees

Technical and Business Assistance (TABA)

TABA Needs Assessment  →  TABA Funding (requested in grant application)

Education
- I-Corps at NIH
- Concept to Clinic: Commercializing Innovation (C3i) Program

Funding and Support
- Commercialization Readiness Program (CRP)
- Regulatory & Business Development Consultants

Partnering and Investment Opportunities
- Company Showcase

https://sbir.nih.gov/support-for-awardees
TABA Needs Assessment

Help small businesses identify and address their most pressing product development needs.

- Validates request for TABA funding
- Helps Company write a strong Phase II Commercialization Plan

190 companies participating since launch in November of 2020.

“Information received was critically helpful in our business plan.”

“It is like having a professional roadmap.”

https://sbir.nih.gov/support-for-awardees/taba-needs-assessment
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NIH SEED

NIH Guide for Grants and Contracts

Read our NIH SBIR/STTR Success Stories

SEEDinfo@nih.gov

seed.nih.gov

sbir.nih.gov
Thanks for tuning in!

Any Questions?