America's Seed Fund is Open for Business

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Office of the Director | Office of Extramural Research | National Institutes of Health
To enhance the health and well-being of all Americans, buy providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.

<table>
<thead>
<tr>
<th>Organization</th>
<th>SBIR and STTR Funding</th>
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</thead>
<tbody>
<tr>
<td>National Institutes of Health</td>
<td>SBIR and STTR $1.2 billion</td>
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<tr>
<td>Centers for Disease Control and Prevention</td>
<td>SBIR $12 million</td>
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<tr>
<td>Food and Drug Administration</td>
<td>SBIR $2 million</td>
</tr>
<tr>
<td>Administration for Community Living</td>
<td>SBIR $3 million</td>
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</table>
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
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.
Myth #2

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.
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
Small Business Success Stories

The NIH is actively turning discovery into health by helping small businesses develop innovative technologies that improve health and save lives.

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

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
- Direct to Phase II (SBIR only)

**Commercial Market**
- Competing Renewal Award Phase IIB
- Commercialization Readiness Pilot (CRP)

**Only Some NIH Institutes/Centers Participate**

- Phase I: $256,580/1-2 years*
- Phase II: $1,710,531/1-3 years*

*NIH has a waiver from the Small Business Administration to exceed these budgets for most topics*
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 the majority of 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.
Myth #4

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

Myth Busted

NIH can exceed the SBIR/STTR budget guidelines for many topic areas. A list of approved topics is published every year at https://sbir.nih.gov/funding.
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
Myth #6

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.
Myth #7

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!
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.

DECISION TOOL

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

FIND OUT HERE

NIH Clinical Trials

Wide Range

Mechanistic
Exploratory/Development
Pilot/Feasibility
Other Interventional
Behavioral
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!
Be Prepared to Resubmit!

“[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.”

Laverne Morrow Carter, Ph.D.
Founder & President, REESSI
NIMHD SBIR Awardee
http://www.reessi.com
Myth #9

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

Myth Busted

Many companies are funded after incorporating feedback into their resubmission.

Read the summary statement carefully and contact your program officer to discuss. Offer to be a reviewer.
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 *Phase I
- Concept to Clinic: Commercializing Innovation (C3i) Program

Funding and Support

- CRP Funding *Phase II/IIB
- Regulatory & Business Development Consultants

Partnering and Investment Opportunities

- Company Showcase

https://sbir.nih.gov/support-for-awardees
Innovator Support

Finance, Strategy, Intellectual Property, Regulatory Experts

Investor-in-Residence

Entrepreneurs-in-Residence

Intellectual Property

Regulatory/Reimbursement
Myth #11

NIH bureaucrats are unapproachable and I should minimize my discussions with them.

Myth Busted

The SEED Office and NIH program officers, scientific review officers, and grants managers are here to help!
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/institute.era
or
Email: SEEDinfo@nih.gov
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