2020 HHS Small Business Funding Opportunity Announcements

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HHS Small Business Program Lead, SEED (Small business Education & Entrepreneurial Development)
Office of the Director | Office of Extramural Research | National Institutes of Health
Coronavirus 2019:

Information for NIH Applicants and Recipients
Small Business Relief Options and Resources (SBA)

Clinical Trials & SBIR/STTR Funding
Learn how Clinical trials are changing the NIH SBIR/STTR application requirements, and find out which funding opportunity announcement (FOA) is right for you.

MORE DETAILS

https://sbir.nih.gov
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 $1.0 billion, STTR $146 million
- Centers for Disease Control and Prevention: SBIR $11 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.
“As a native Spanish-speaking curriculum designer with a background in literary and performing arts, I work as a principal investigator on a number of NIH-funded projects. The SBIR and STTR programs allow me to translate evidence-based practices into web-based multimedia programs that offer skill-building tools for improving health and educational outcomes among Latino audiences.”
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

$1.19 Billion Dedicated Funding via Set-aside from NIH’s R&D Budget

- SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM
  - 3.2%
  - $1.04 billion

- SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM
  - 0.45%
  - $146 million
NIH SBIR/STTR Budget Allocations FY2020

3.2% SBIR $1.04 billion
0.45% STTR $146 million
Total FY20 $1.19 billion
One of the largest sources of early-stage capital for life sciences in the United States

- Not a loan and non-dilutive **capital**
- **IP/data rights** protection through Bayh-Dole Act and SBIR Policy Directive
- Awardees can **leverage funding** to attract investors and partners
Lift Labs (Acquired by Google Sept 2014)

“My PhD research centered on vibration and motion cancellation, which is basic science that could have new application areas,” said Pathak, “After graduating, I talked to neurosurgeons, did research, and found out that Parkinson’s and essential tremor effects over ten million people.”
NIH Application & Review Process

1. Applicant initiates research idea
2. Small Business Concern confirms eligibility
3. Submits SBIR/STTR grant application to NIH electronically
4. NIH Center for Scientific Review assigns to IC and IRG
5. IC staff prepare funding plan for IC Director
6. Advisory Council or Board recommend approval
7. Scientific Review Group evaluates scientific merit
8. IC allocates funds
9. Grantee conducts research

1-2 Months
3 Months
2-4 Months
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>

  – 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
What is a **Women-Owned Small Business (WOSB)**?

- A firm must be at least 51% owned and controlled by one or more women, and primarily managed by one or more women
- The firm must be “small” in its primary industry in accordance with SBA’s [size standards](#) for that industry
- SBCs self certify on the SF 424 (R&R) Form

What is a **Socially and Economically Disadvantaged Business (SDB)**?

- The firm must be 51% or more owned and control by one or more disadvantaged persons
- The disadvantaged person or persons must be socially disadvantaged and economically disadvantaged
- The firm must be small, according to SBA’s [size standards](#)
- You must self-certify by registering your business in the [System for Award Management](#)
NIH Application & Review Process

Applicant initiates research idea

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3 Months

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Grantee conducts research

2-4 Months
Majority of the funding goes to investigator initiated applications

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

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

- General Omnibus Solicitations
  - Clinical Trial Not Allowed: SBIR (PA-20-260) and STTR (PA-20-265)
  - Clinical Trials Required: SBIR (PA-20-262) and STTR (PA-20-261)

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
- FY2021 Contract Solicitation is now available
- Receipt date is October 26th

https://sbir.nih.gov/funding
### SBIR and STTR Critical Differences

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<th>SBIR</th>
<th>STTR</th>
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<tr>
<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**
Feasibility

Phase I

Discovery

Development

Phase I Phase II

Full R/D

Fast-Track

Direct to Phase II (SBIR only)

Competing Renewal Award

Phase IIB

Commercialization Readiness Pilot (CRP)

Only Some ICs 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.
**Phase IIB**
- After Phase II award
- Phase II out-sourcing guidelines
- Encourages matching funding
- Through Omnibus (IC must accept competing renewals) or specific funding opportunities

**CRP**
- Concurrent with or after Phase II award
- Significant out-sourcing is allowed
- Three Funding Opportunities:
  - PAR-20-128: Technical Assistance
  - PAR-20-129: Technical Assistance/Late Stage Development
  - PAR-20-130: Technical Assistance/Late Stage Development (Clinical Trials)

**Only Some ICs Participate**
**Contact NIH Program Staff to discuss!**
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(s)) 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.

https://grants.nih.gov/policy/clinical-trials.htm
SBIR/STTR 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

**Helpful NIH Grants Registration Infographic**

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

Annotated Form Set for NIH Grant Applications

FORMS-F Series
Most Important Piece of Advice

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

List of HHS 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: sbir@od.nih.gov
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Review Criteria

Overall Impact Score

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

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

Center for Scientific Review
https://public.csr.nih.gov/
NIH 2019 SBIR/STTR Grants
Success Rate by Phase

https://sbir.nih.gov/statistics/award-data
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
More Than Funding: Introducing 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.

SBIR·STTR
America’s Seed Fund

smallbusinessinnovation

Small Business Innovation

Academic Innovation

Innovator Support

seed.nih.gov
Phase I:
Technical and Business Assistance:
Coming Soon: Needs Assessment Program

Entrepreneurial Assistance/Training:
NIH I-Corps™

Phase II/IIB:
Technical Assistance/Training:
Commercialization Accelerator Program (CAP)*

*Ending in FY2020

Phase I and Phase II/IIB:
Entrepreneurial Assistance/Training:
NIH C3i

Entrepreneurial Training:
Diversity Supplement (PA-18-837)

Technical Assistance Budget Allowance
Phase I- $6,500/year
Phase II- $50K
Request in Application
If requested, cannot participate in NIH centralized TABA programs (e.g. Needs Assessment Program)

Available Technical Assistance/Training:
https://sbir.nih.gov/tap
Strategy, Finance & Commercialization Experts:

Sr. Regulatory Specialist
Innovator Support Team Lead
Chris Sasiela, PhD

Ethel Rubin, PhD
John Sullivan, MBA
Steve Wolpe, PhD

Partnering Opportunities and Pitch Coaching:
21st Annual HHS Small Business Program Conference
April 27-29, 2021 | Las Vegas, Nevada
https://www.unlv.edu/econdev/hhsconf2021
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NIH Guide for Grants and Contracts (weekly notification)

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