

NIH Small Business 101: America's Seed Fund is Back- Powered by HHS

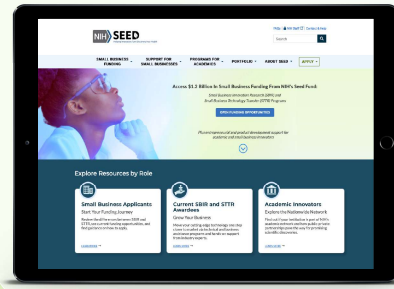
Stephanie Fertig, M.B.A.
Director, NIH Small Business Program
SEED (Small business Education & Entrepreneurial Development)

OFFICE OF EXTRAMURAL RESEARCH | OFFICE OF THE DIRECTOR | NATIONAL INSTITUTES OF HEALTH

This presentation may include presenter's notes.

NIH SEED

Small Business Program Website



seed.nih.gov



Designates Changes

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HHS Mission and Divisions

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.



Food and Drug Administration
SBIR \$6.5 million



National Institutes of Health
SBIR and STTR \$1.35B



Centers for Disease Control and Prevention
SBIR \$9 million



Advanced Research Projects Agency for Health
SBIR and STTR \$37 million



Administration for Community Living
SBIR \$3.5 million

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ARPA-H Open Solicitation and Proposers' Day

Challenge: Many of the most innovative health solutions originate in small, agile companies – but these businesses often lack access to early-stage capital, technical resources, and commercialization pathways. Traditional funding mechanisms can be slow, complex, and misaligned with the speed required to translate breakthrough ideas into real-world impact. As a result, promising technologies stall before reaching patients.

Goal: Enable small businesses to rapidly develop and scale transformative health technologies by providing flexible, milestone-driven funding (up to ~\$600K for Phase I and ~\$3.5M for Phase II), along with access to expert guidance, technical resources, and partner networks to accelerate commercialization.

Proposers' Day: June 11, 2026

Learn more and register by June 10



ARPA H



What if the most transformative health solutions could come from small businesses and reach patients faster?

Supported by: Federal Reserve Bank of New York

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NIH Mission



National Institutes of Health
Turning Discovery Into Health



*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

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Congressionally Mandated Programs

~\$1.4 Billion Dedicated Funding
Largest source of early-stage capital for life science in the US



SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

For small business concerns to engage in federal R&D -- with potential for commercialization

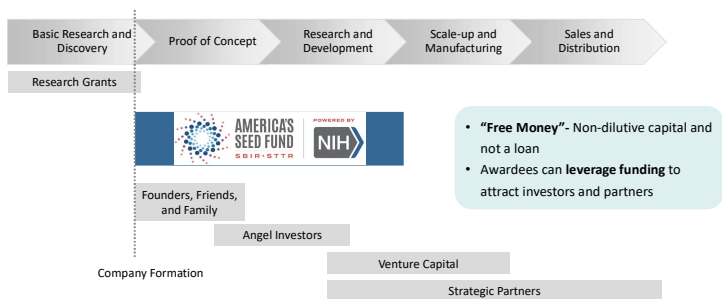
SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM

To facilitate cooperative R&D between small business concerns and US research institutions with potential for commercialization

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Benefits of NIH Funding



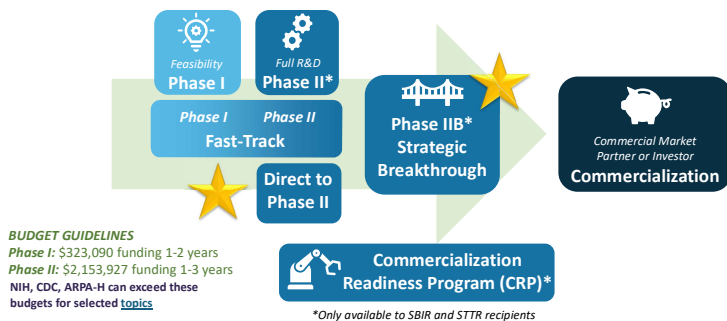
Eligibility Criteria

Determined at the time of award
SBA eligibility guide: [sbir.gov/apply](https://www.sbir.gov/apply)

- Organized as for-profit US business
- Small: 500 or fewer employees, including affiliates
- Individual Ownership:
 - Greater than 50% US-owned by individuals and independently operated <OR>
 - 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
- Work must be done in the US
- Foreign subawards/subcontracts: Only unfunded international collaborations or foreign components will be considered



Phased Programs



Funding Opportunities



Majority of the funding goes to investigator-initiated grant applications

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

Funding Opportunities

Parent Notices of Funding Opportunity (NOFOs)

- Parent SBIR: [PA-27-100](#)
- Parent STTR: [PA-27-102](#)
- Phase IIB Strategic Breakthrough (SBIR): [PA-27-101](#)
- Commercialization Readiness Pilot (CRP): [PAR-27-098](#)



Review the [Small Business Funding Considerations and Contacts Webpage!](#)

Notice of Funding Opportunity (NOFO) Includes:

Table of Contents

Part 1. Overview Information	Participating Institutes/Centers
Key Dates	Due Dates
Part 2. Full Text of Announcement	
Section I. Notice of Funding Opportunity Description	Purpose/Objectives
Section II. Award Information	Budget Guidance
Section III. Eligibility Information	
Section IV. Application and Submission Information	
Section V. Application Review Information	Review Criteria
Section VI. Award Administration Information	
Section VII. Agency Contacts	Scientific/Research Contacts
Section VIII. Other Information	

Clinical Trials

- All Parent Notices of Funding Opportunity (NOFOs) are Clinical Trial Optional
- Not all participating Institutes/Centers accept clinical trials!
- In NOFO: Section I. "Applications Not Responsive to this NOFO"
- Generally: [Small Business Funding Considerations and Contacts](#) Webpage

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](#)

<https://grants.nih.gov/policy/clinical-trials.htm>

Other Funding Opportunity Changes

- Regulatory Plan Attachment Required for:
 - SBIR and STTR Phase I and Phase II that propose a Clinical Trial
 - ALL Phase IIB Strategic Breakthrough and Commercialization Readiness Pilot (CRP)
- [Data Management and Sharing Plans](#) are no longer accepted for SBIR/STTR

Phase IIB Strategic Breakthrough vs. Commercialization Readiness Pilot (CRP) Program

	Commercialization Readiness CRP (PAR-27-098)	Phase IIB Strategic Breakthrough (PA-27-101)
Timing	Concurrent with or after Phase II award	After Phase II award only
Type of Support Provided	Later-stage R&D and Technical Assistance	Later-stage R&D
Work Requirement	Significant out-sourcing is allowed	Guidelines: May outsource 33% (Phase I) 50% (Phase II)
Matching Funding	Matching Funding is NOT required	Requires 1:1 Matching Funding

All Applicants MUST have been awarded a Phase II SBIR or STTR

Electronic Submission

- Grant applications **and** SBIR contract proposals must be submitted **electronically**.
- Grants submit via **ASSIST** (recommended) or Grants.gov Workspace
- For contracts, submit proposals with [electronic Contract Proposal Submission](#) (eCPS) website

REQUIRED REGISTRATIONS

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

Common Forms for Biographical Sketch is REQUIRED

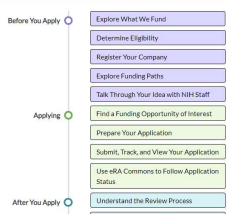
All Senior/Key Personnel must have an [ORCID ID](#) and link it to the eRA Commons Personal Profile

APPLY EARLY! No Late Submissions for SBIR or STTR (NOT-OD-26-064)

Application Resources

SMALL BUSINESS FUNDING HOW TO APPLY

Find step-by-step instructions to apply for SBIR and STTR grants along with contact touchpoints at each step.



Prepare Your Application links to:

- [Application Instructions](#)
- [Annotated Form Set](#)
- [Sample Applications](#)
- [State Resources through SBA FAST Program](#)

NOT-OD-25-132: Limits PIs to 6 applications per calendar year and limits use of AI in writing applications

NOT-OD-26-073: Small Businesses are now limited to 9 applications/proposals per fiscal year

seed.nih.gov/howtoapply

Request Commercialization Funding in Your Application

Technical and Business Assistance (TAB) Funding seed.nih.gov/TABA

Support for companies to identify and address product development needs with new or existing staff, vendors, consultants, or subawards (See [NOT-OD-26-075](#)).

Small businesses may request per project:

- Phase I: \$6,500
- Phase II: \$50,000

SBIR and STTR Fee

A reasonable fee (profit) of up to 7% of total costs for use by the small business for any purpose, including commercialization activities

Most Important Piece of Advice



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

[Small Business Funding Considerations and Contacts](#)

Small Business Funding Considerations and Contacts

The information found in the [Small Business](#) overview applies across all NIH institutes, centers, and offices (ICOs). This page provides ICO-specific interest areas, due dates, and contacts related to small business.

[Learn More](#)

Not sure who to contact?

NIH RePORTER: reporter.nih.gov

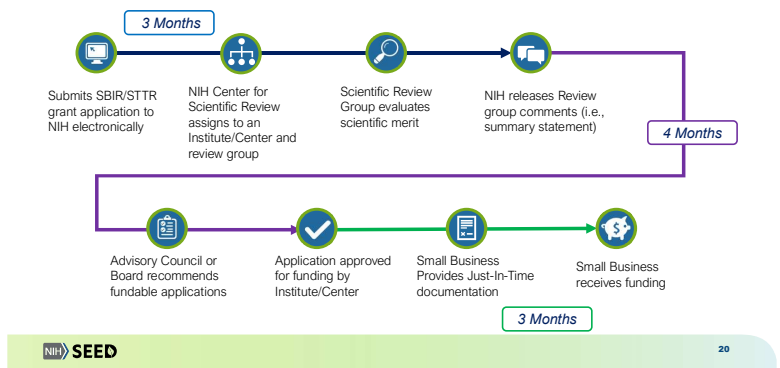
Email: SEEDinfo@nih.gov

Small Business Funding Considerations and Contacts

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Institute/Center	Due Date	Contact
National Center for Advancing Translational Sciences (NCATS)		
National Center for Complementary and Integrative Health (NCCIH)		
National Cancer Institute (NCI)		
National Eye Institute (NEI)		
National Human Genome Research Institute (NHGRI)		
National Heart, Lung, and Blood Institute (NHLBI)		

NIH Peer Review and Funding Decision Process



NIH Peer Review and Funding Decisions

- [Center for Scientific Review](#) conducts all peer review
- Five Review Criteria (Significance, Investigators, Innovation, Approach, Environment)
 - Focus on product development/commercialization
 - Notice of Funding Opportunity gives specific questions in Section V
- Overall Impact Score is given after discussion by the Scientific Review Group
- Not all applications are discussed but **all** applications receive reviewer comments!
- [No Payline](#): Scores and reviewer comments are considered along with other factors (e.g. strategic plans, budgets)
- [Small Business Funding Considerations and Contacts](#) have funding considerations and interest areas specific to SBIR and STTR

Be Prepared to Resubmit!

Foreign Disclosure and Risk Assessment

- HHS will assess all SBIR and STTR applications for foreign security risks prior to award
- Disclosure is required for all owners and covered individuals (e.g. senior key personnel) using the [Required Disclosures of Foreign Affiliations or Relationships to Foreign Countries Form](#)
- NIH cannot make an award if a foreign risk is identified in any of the denial categories (see [NOT-OD-26-074](#))
 - Small businesses are responsible for monitoring relationships with [foreign countries of concern](#)
 - Foreign risk identified? Small businesses can address a foreign risk and resubmit next receipt date

Process, denial categories, and case studies can all be found on the public [SEED Foreign Disclosure and Risk Management](#) webpage!

Connect with SEED

seed.nih.gov/

SEEDinfo@nih.gov

NIH Central Resource for Research Grants and Funding Information:
grants.nih.gov

National Institutes of Health
NIH Innovates

[@NIH](#)
[@NIH_Innovates](#)

SBIR and STTR Critical Differences

Partnering Requirement

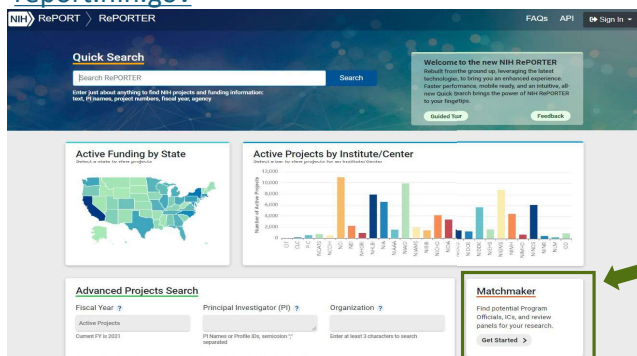
Work Requirement

Principal Investigator

SBIR	STTR
Permits partnering	Requires a non-profit research institution partner (e.g., university)
Guidelines: May outsource 33% (Phase I) 50% (Phase II)	Minimum Work Requirements: 40% small business 30% research institution partner
Guidelines: Primary employment (>50%) with the small business	Employed by <u>either</u> the research institution partner or small business

Award is always made to the small business

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



Other Product Development Support

Needs Assessment

SBIR/STTR Phase I Awards

Provides a third-party, unbiased assessment of areas that are critical to success in the competitive healthcare marketplace

Innovator CONSULTING

SBIR/STTR Awards

Provides consulting in the following areas: Regulatory, Reimbursement, Business Development, Pitch Review

Training Programs

I-CORPS™ AT NIH SBIR/STTR Awards



Concept to Clinic: Commercializing Innovation (C3i) Medical Device Awards



<https://seed.nih.gov/product-development-support>