



# ***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**

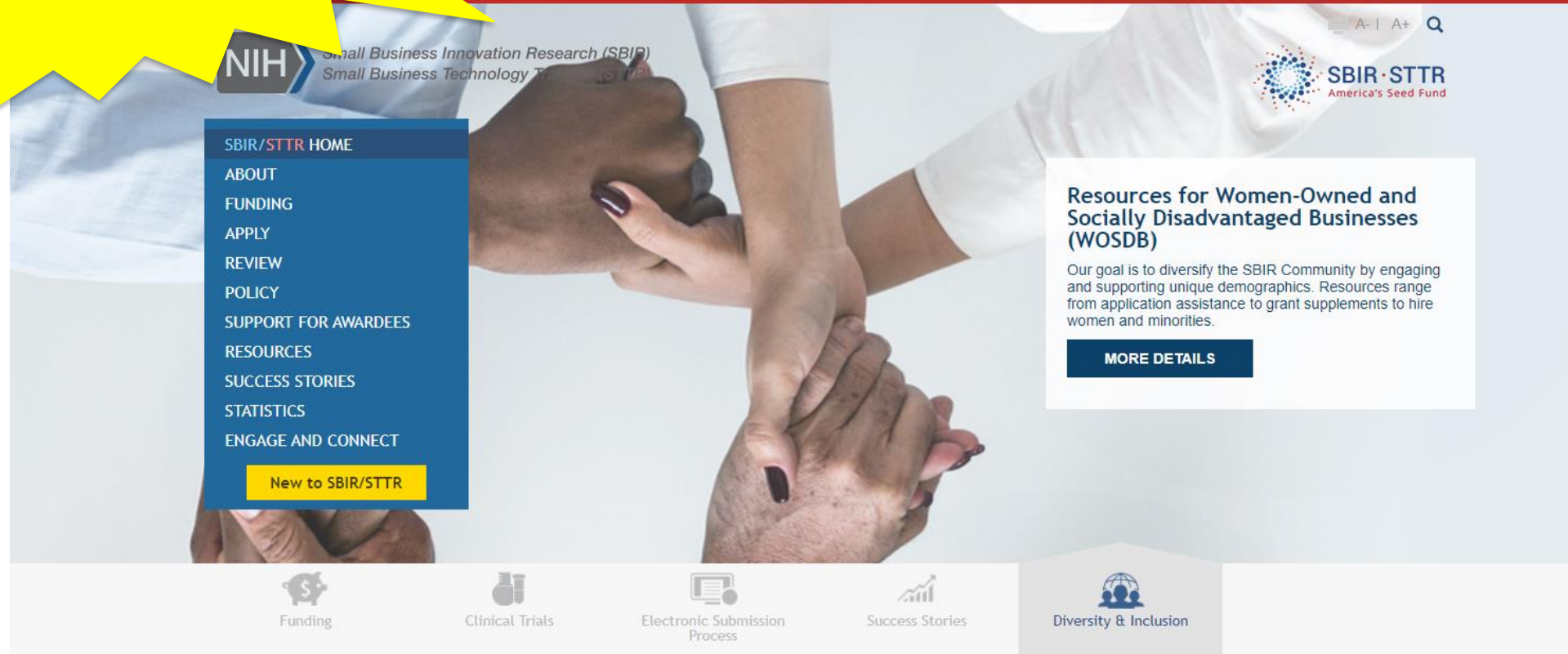


# Small Business Program Website

**UPDATED WEBSITE  
COMING FALL 2021**

Coronavirus 2019:

[Information for NIH Applicants and Recipients](#)  
[Small Business Relief Options and Resources \(SBA\)](#)



## What are SBIR and STTR Programs?

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

HHS SBIR/STTR COMPONENT PROGRAM LINKS

NIH INSTITUTES & CENTERS



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New to SBIR/STTR



## 2021 HHS Small Business Program Conference

Diverse Perspectives SEEDing Impactful Innovations



VIRTUAL CONFERENCE

APRIL 26 - 30

### Conference Sessions

Session Title	Speakers	Video	Slides	Transcript
NIH Welcomes Diverse Perspectives	<ul style="list-style-type: none"><li>Matt McMahon, Director, SEED, Office of Extramural Research, NIH</li></ul>	<a href="#">YouTube (14:00)</a>	N/A	<a href="#">Word (.docx)</a>
Diversity and Bias: Perceptions and Reality	<ul style="list-style-type: none"><li>Ericka Boone, Director of Division of Loan Repayment and Acting Director of Division of Biomedical Research Workforce, NIH</li><li>Stephanie Fertig, HHS Small Business Program Lead, NIH</li><li>Charlene E. Le Fauve, Senior Advisor to the Chief Officer for Scientific Workforce Diversity, NIH</li><li>Eric W. Padmore, Senior Policy Advisor, NIH (Moderator)</li></ul>	<a href="#">YouTube (50:08)</a>	<a href="#">Slides</a>	<a href="#">Word (.docx)</a>
America's Seed Fund is Open for Business	<ul style="list-style-type: none"><li>Rob Vinson, Small Business Program Manager, NIH (Moderator)</li><li>Stephanie Fertig, HHS Small Business Program Lead, NIH</li></ul>	<a href="#">YouTube (42:14)</a>	<a href="#">Slides</a>	<a href="#">Word (.docx)</a>
Secrets to a Successful Submission	<ul style="list-style-type: none"><li>Eva Garland, CEO, Eva Garland Consulting</li><li>Beth Weber, Program Director of MCH SBIR Development Center</li></ul>	<a href="#">YouTube</a>	<a href="#">Slides</a>	<a href="#">Word (.docx)</a>



*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**



\$1.1 billion

## **SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM**

Set-aside program for small business concerns to engage in federal R&D -- with potential for commercialization



\$150  
million

## **SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM**

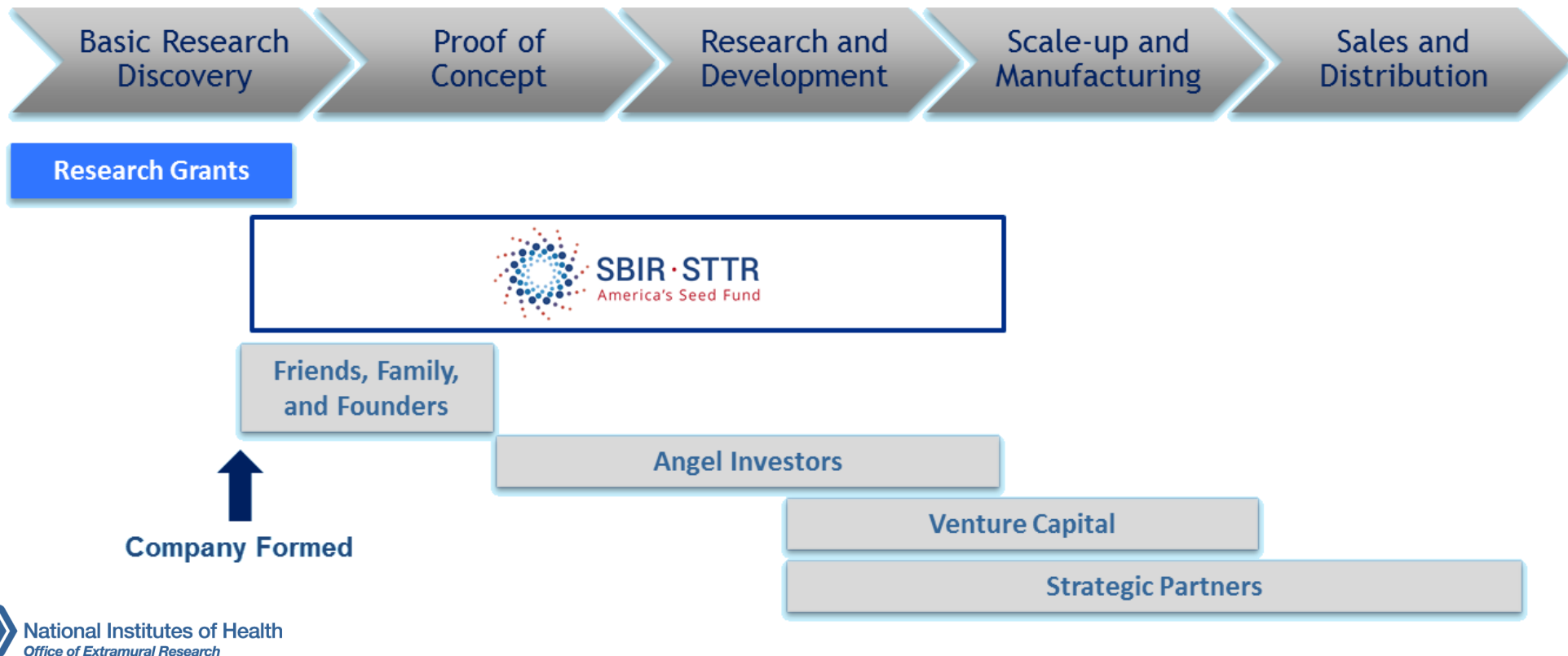
Set-aside program to facilitate cooperative R&D between small business concerns and US research institutions -- with potential for commercialization





## 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

## 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.

Technology

☐ Diagnostic

☐ Digital Health

☐ Drug

☐ Medical Device

☐ Research Tool

Development Stage

☐ Approved for Use

☐ Early Development

☐ Human Testing


Company Ownership

☐ Woman Owned

☐ Minority Owned

State

Select State



Displaying results 1 to 10 of total 66

Results per page 10

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

## Digital Learning Company Supports Parents, Teachers, and Underserved Communities



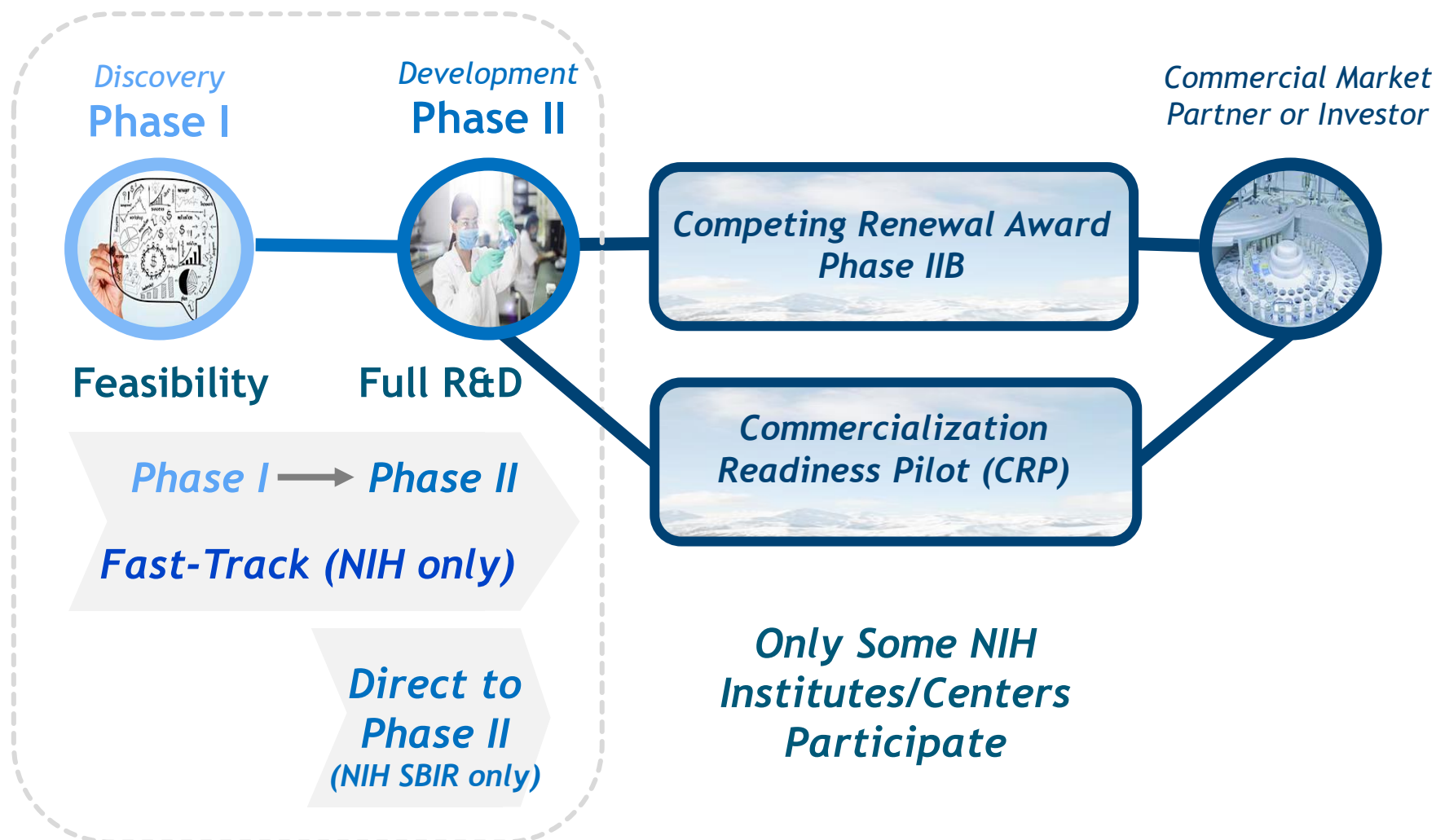
## Latina-Owned Business Creates Effective Public Health Campaigns



[sbir.nih.gov/stories](https://sbir.nih.gov/stories)



# Phased Programs



**It is much harder to get a NIH Fast-Track or Direct to Phase II, so don't even bother applying for those**

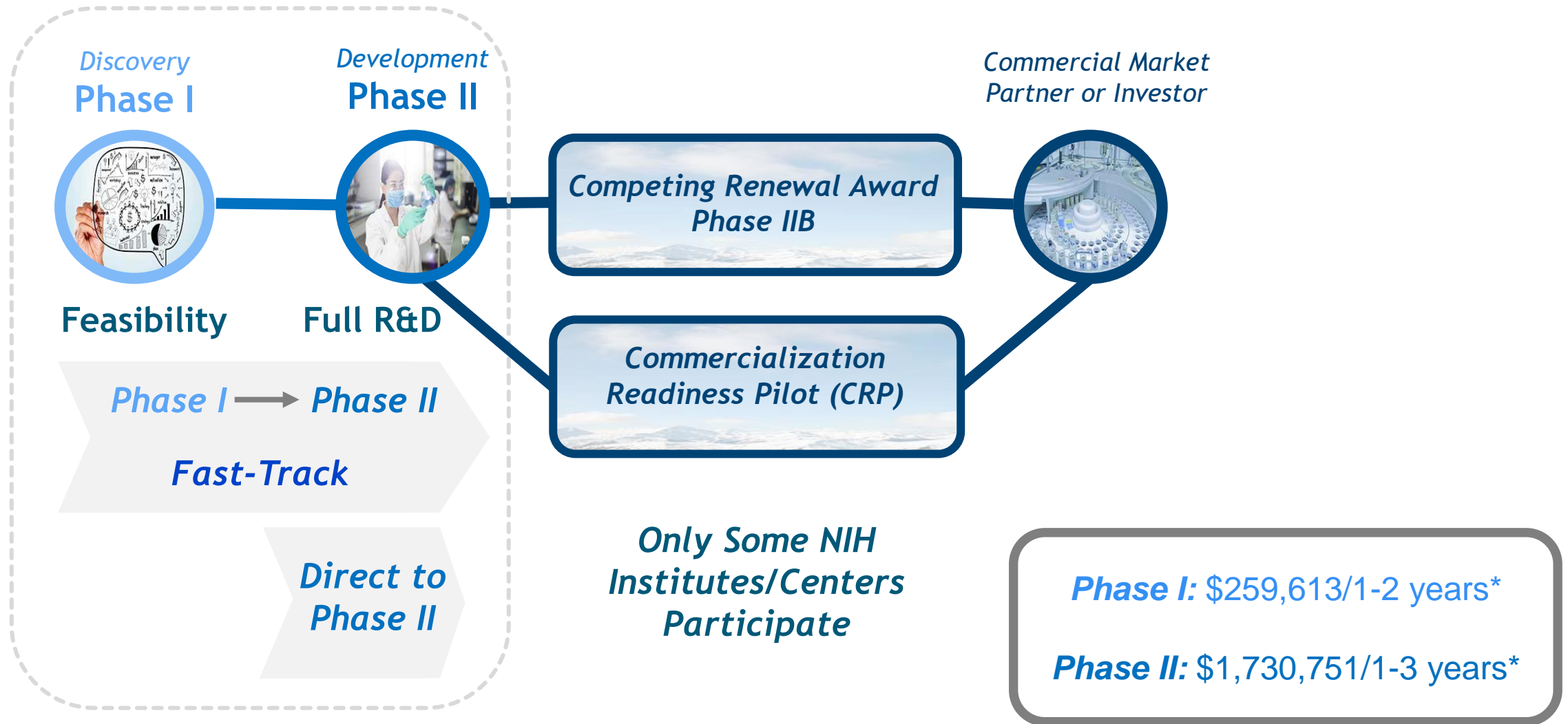
**Myth Busted**

**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



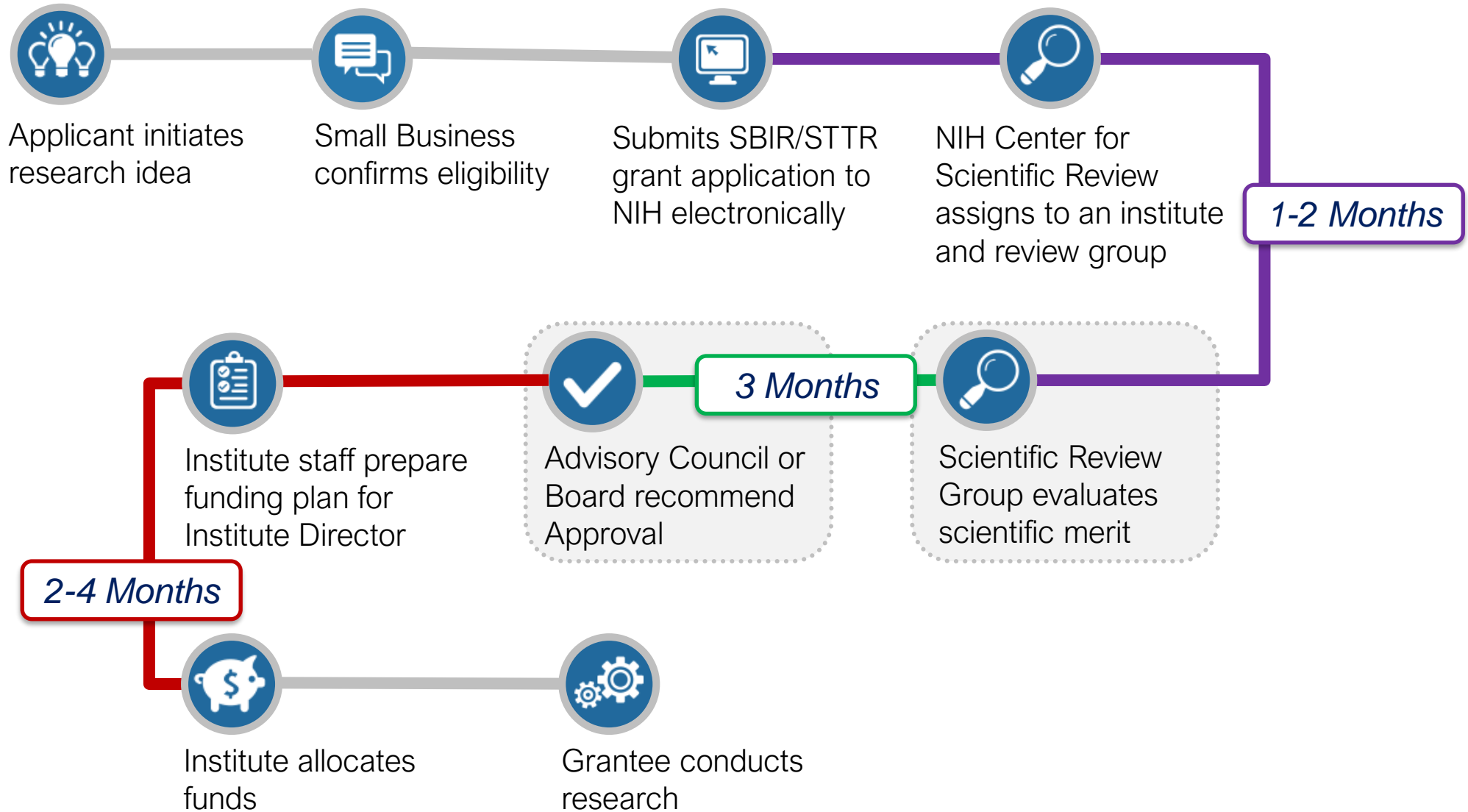
**The SBIR and STTR budget cap is too small to be useful.  
It is not worth the time or money!**

**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.**



# NIH Application & Review Process



# Eligibility Criteria

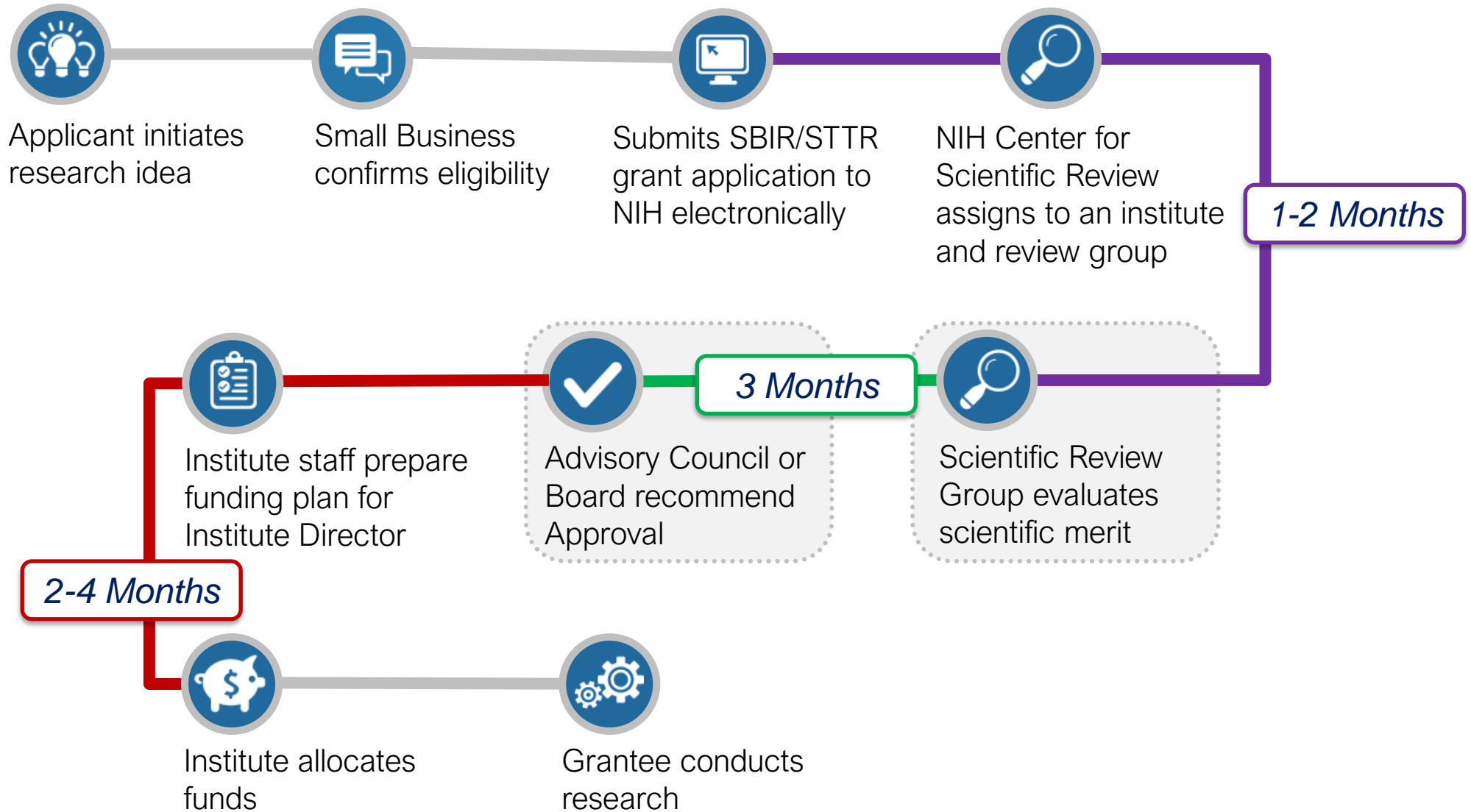
- Organized as for-profit US business
- Small: 500 or fewer employees, including affiliates
- Work must be done in the US (with few exceptions)
- Individual Ownership:
  - Greater than 50% US-owned by individuals and independently operated <OR>
  - Greater than 50% owned and controlled by other business 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**





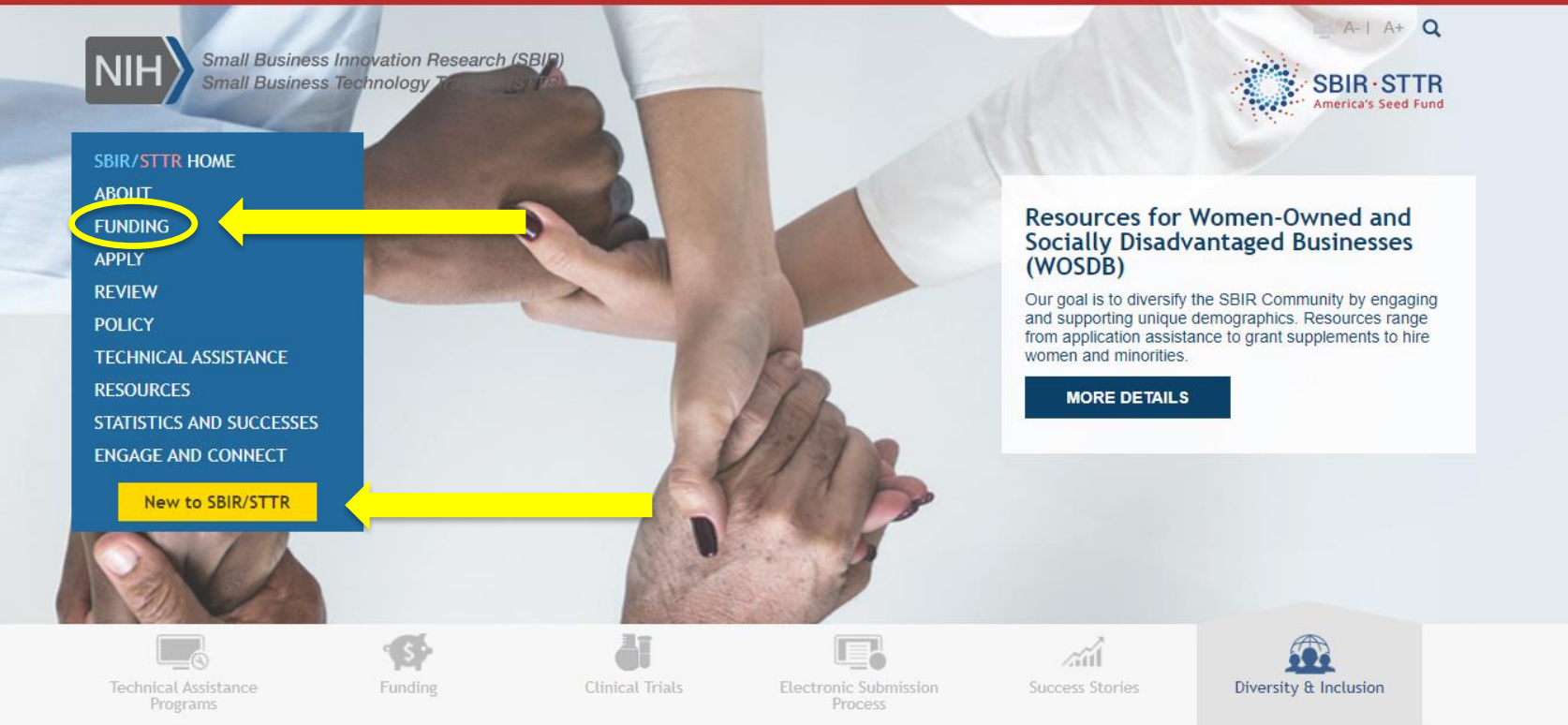
# NIH Application & Review Process: Submission



# Small Business Program Website – Application Receipt Dates

Coronavirus 2019:

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



**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/>

## What are SBIR and STTR Programs?

The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, also known as America's Seed Fund, are one of the largest sources of early-stage capital for technology

HHS SBIR/STTR COMPONENT PROGRAM LINKS



**NIH** National Institutes of Health  
Office of Extramural Research

## SBIR and 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 12<sup>th</sup> 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

**Award always  
made to  
small business**

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



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

## 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.

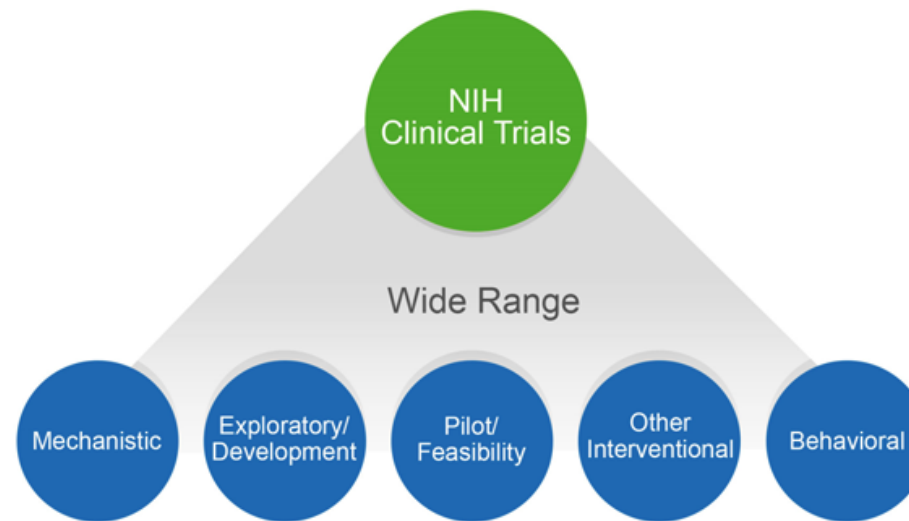
### NIH Definition of a Clinical Trial

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 intervention 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**





**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**.

## Two-Factor Authentication:

[login.gov](https://www.login.gov)

will soon be required to access  
eRA Commons

Use the same login.gov account  
for eRA, Grants.gov, and SAM

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



# 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

Coronavirus 2019:  
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Small Business Relief Options and Resources (SBA)

NIH Small Business Innovation Research (SBIR)  
Small Business Technology Transfer (STTR)

SBIR/STTR HOME  
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New to SBIR/STTR

Resources

- Application Instructions
- Annotated Form Set
- Sample SBIR Applications from NIAID
- NIH SBIR/STTR Just-in-Time (JIT) Procedures
- Agency and State Contacts
- Life Science Contacts by State
- NIH SBIR/STTR Fact Sheet
- SBIR/STTR Tutorials
- Events
- Webinars
- Financial Questionnaire
- FAQs

Electronic Submission Process

The electronic application submission process for HHS SBIR and STTR grants is multi-step, and can take six to eight weeks to complete the five registrations required prior to application submission.

More Details

Funding Clinical Trials Electronic Submission Process Success Stories Diversity & Inclusion

## What are SBIR and STTR Programs?

The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, also known as America's Seed Fund, are one of the largest sources of early-stage capital for technology commercialization in the United States. These programs allow US-owned and operated small businesses to receive

HHS SBIR/STTR COMPONENT PROGRAM LINKS		
NIH INSTITUTES & CENTERS		
NCATS	NICHD	NHLBI

<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](mailto:SEEDinfo@nih.gov)**

NIH Small Business Innovation Research (SBIR) Small Business Technology Transfer (STTR)

SBIR/STTR HOME ABOUT FUNDING APPLY REVIEW POLICY TECHNICAL ASSISTANCE RESOURCES STATISTICS AND SUCCESS ENGAGE AND CONNECT

SBIR/STTR Home > Engage & Connect > IC Program Contacts

**Contact**

- Contact SBIR/STTR
- IC Program Contacts
- eRA Service Desk (for electronic submission Qs)
- Connect

**Engage**

- Twitter
- Listserve
- News
- Webinar
- Events

Questions? Use the NIH PDF Version

**/Grants Mgmt Contact**

rez  
01-402-7739  
sie.perez@nih.gov

National Institute on Alcohol Abuse and Alcoholism <a href="http://www.niaaa.nih.gov">http://www.niaaa.nih.gov</a>	Megan Ryan Phone: 301-443-4225 Email: <a href="mailto:mryan1@mail.nih.gov">mryan1@mail.nih.gov</a>	Jeff Thurston Phone: 301-443-9801 Fax: 301-443-3891 Email: <a href="mailto:jeffrey.thurston@nih.gov">jeffrey.thurston@nih.gov</a>
National Institute of Allergy and Infectious Diseases <a href="http://www.niaid.nih.gov">http://www.niaid.nih.gov</a>	Natalia Kruchinin Phone: 240-669-2919 Fax: 240-627-3162 Email: <a href="mailto:kruchinn@niaid.nih.gov">kruchinn@niaid.nih.gov</a>	Vandhana Khurana Phone: 240-669-2966 Fax: 301-493-0597 Email: <a href="mailto:khuranav@niaid.nih.gov">khuranav@niaid.nih.gov</a>



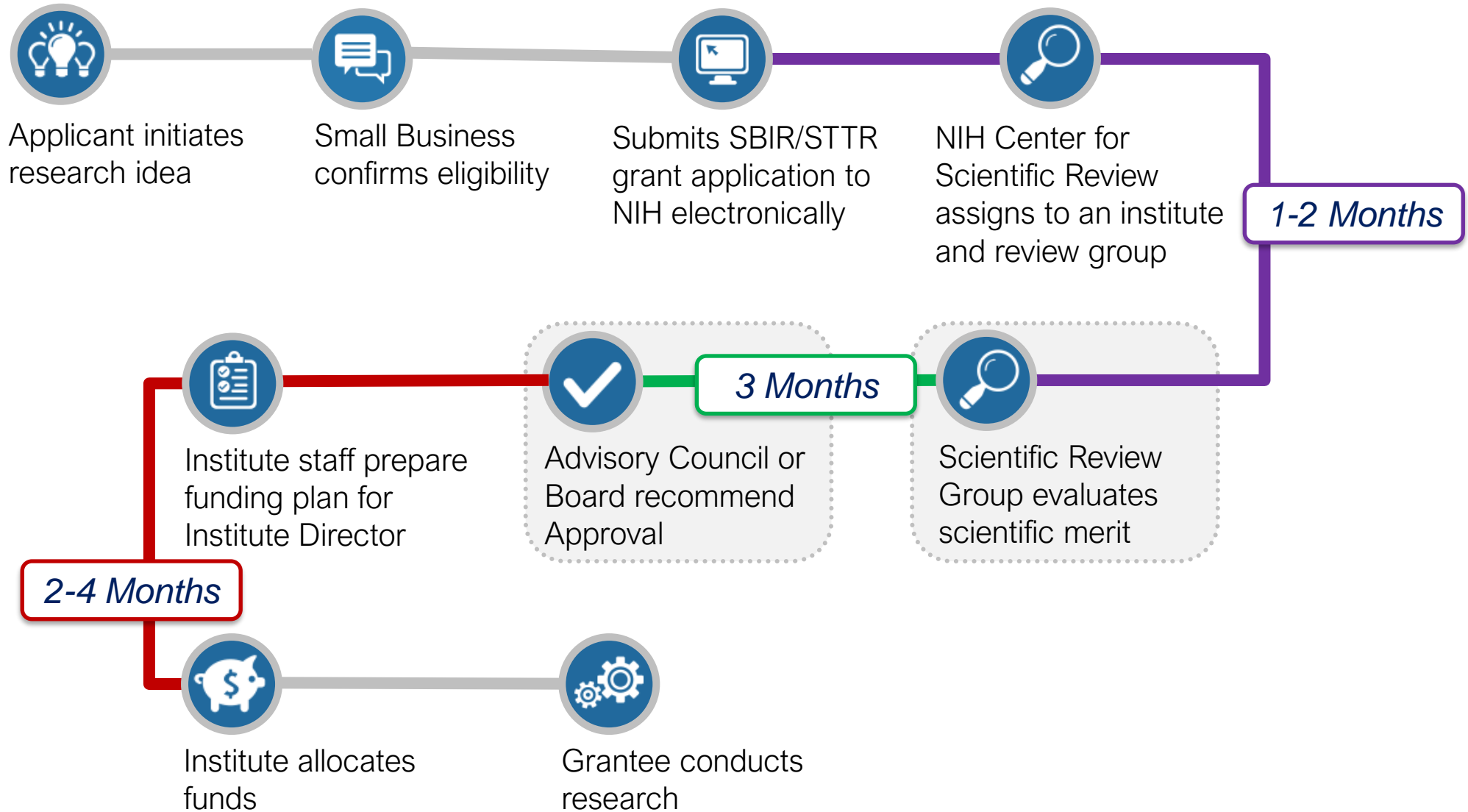
**Applications are submitted to a specific Institute, so I need to choose the Institute and Study Section for my application.**

**Myth Busted**

**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



## 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**

Center for Scientific Review  
<https://public.csr.nih.gov/>





**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.**



# Be Prepared to Resubmit!



**Mary Potasek, Ph.D.**

President and Co-founder  
NCI Awardee

<https://www.simphotek.com/>



**Laverne Morrow Carter, Ph.D.**

Founder & President, REESSI  
NIMHD SBIR Awardee

<http://www.reessi.com>

*“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.



Matt McMahon  
[mm@nih.gov](mailto:mm@nih.gov)



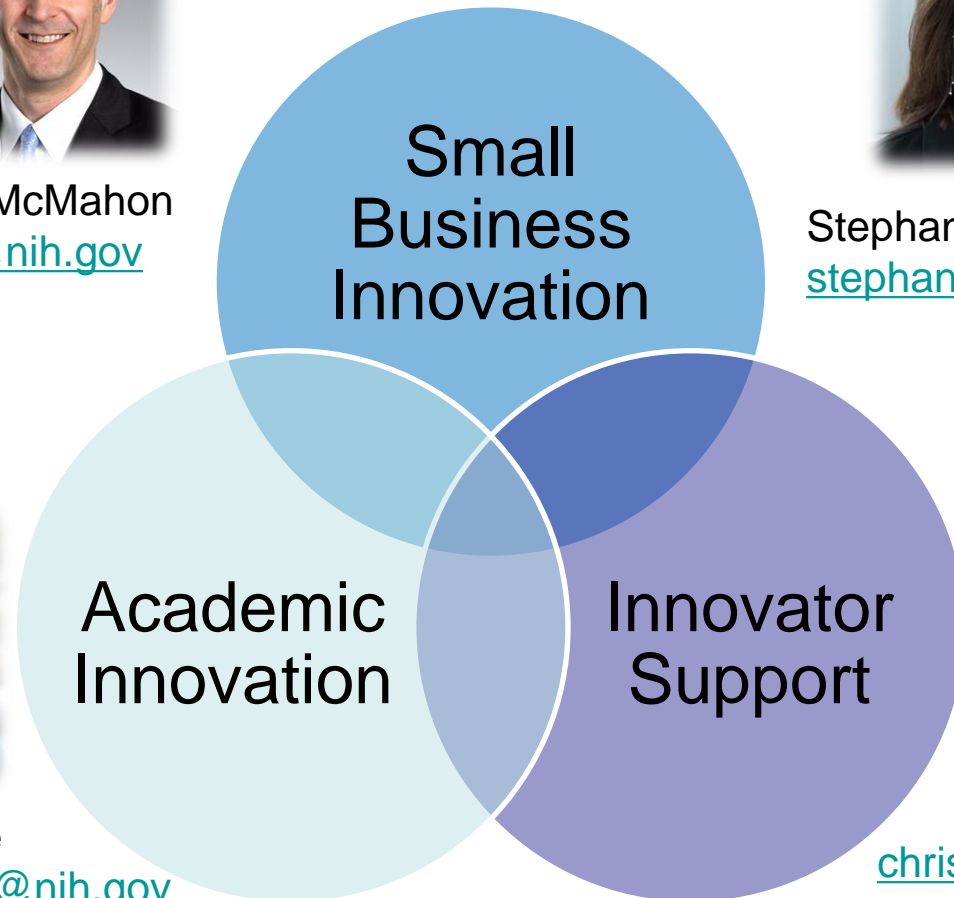
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Ashim Subedee  
[ashim.subedee@nih.gov](mailto:ashim.subedee@nih.gov)



Chris Sasiela  
[chris.sasiela@nih.gov](mailto:chris.sasiela@nih.gov)



**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



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

## TABA Needs Assessment



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

Summary Analysis/Company Summary.....  
Target Market Attractiveness.....  
Technology and Market Needs.....  
Regulatory/Clinical.....  
Business Model Profitability.....  
Reimbursement.....  
Competitive Advantage and Intellectual Property....  
Market Access/Sales and Marketing Strategy.....  
Management Team.....  
Strategic Partners.....  
Funding Status.....  
Recommended Actions/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>



# Innovator Support

## Regulatory & Business Development Consultants



Investor-in-Residence



Regulatory/Reimbursement



Intellectual Property



Entrepreneurs-in-Residence

## Partnering and Investment Opportunities

### Company Showcase



ANGEL CAPITAL ASSOCIATION



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NIH Guide for  
Grants and  
Contracts



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SBIR/STTR Success  
Stories



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Thanks for tuning in!

# Any Questions?



National Institutes of Health  
Office of Extramural Research