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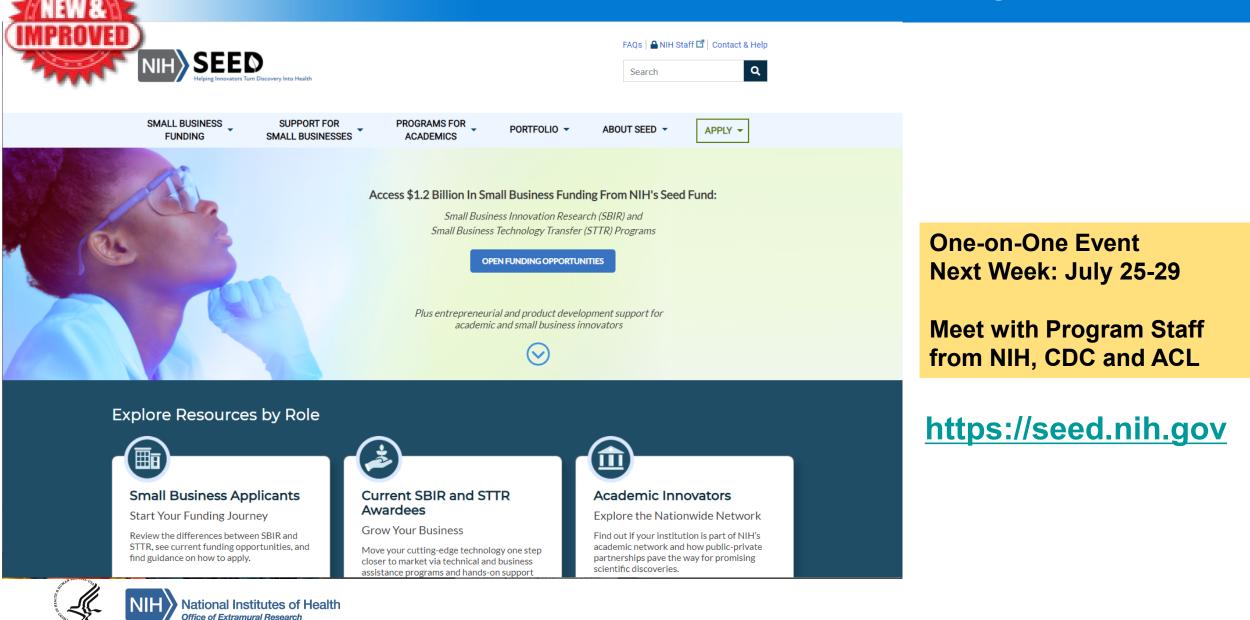
America's SEED Fund: Powered by NIH Dig into NIH's SEED Fund

Stephanie Fertig, MBA HHS Small Business Program Lead

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



Small Business Program Website





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.



National Institutes of Health SBIR and STTR \$1.2B



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



\$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



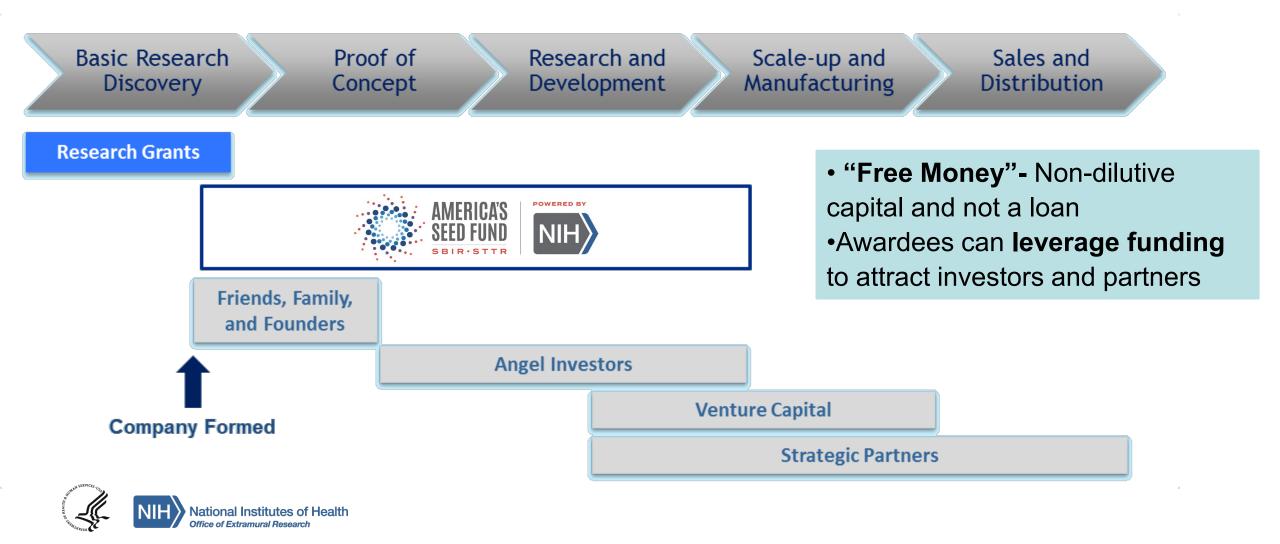
\$1.1 billion

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



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!



Companies that have developed their product with nondilutive small business program money are very attractive to investors and strategic partners.



Home / Portfolio / Success Stories

SUCCESS STORIES

Explore companies that received NIH SBIR or STTR funding for early-stage R&D.

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



Small Business Success Stories

Kansas Biomedical Company Advances Brain Disorder Research





Rural Maine Company Goes Deep in the Brain to Treat Movement Disorders





Digital Learning Company Supports Parents, Teachers, and Underserved Communities

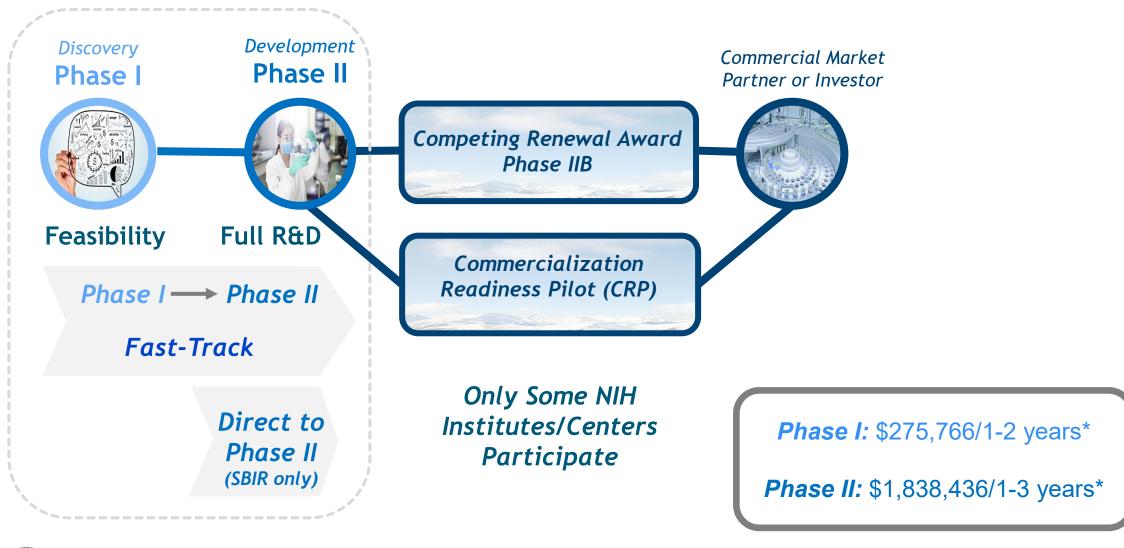




https://seed.nih.gov/portfolio/stories



Phased Programs



*NIH and CDC have a waiver from the Small Business Administration to exceed these budgets for selected <u>topics</u>



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 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



- 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



Funding Opportunities



Majority of the funding goes to investigatorinitiated grant applications

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

*New Omnibus Solicitations have been Issued!



Open Funding Opportunities

General Grant Omnibus Solicitations

Clinical Trial Not Allowed: SBIR (PA-22-176) and STTR (PA-22-178)

Clinical Trials Required: SBIR (PA-22-177) and STTR (PA-22-179)

Read the "Program Descriptions and Research Topics" Section in the Solicitation

Targeted Solicitations

Specific Grant Solicitations: https://seed.nih.gov/small-business-funding/

SBIR Contract Solicitation: <u>Pre-Solicitation</u> was just released! **READ CAREFULLY!**

Not all Institutes/Centers participate

Not all targeted solicitations have specific set-asides or review



I should apply to a specific program announcement because targeted funding opportunities have their own dedicated funding.



Most NIH awards (~80%) are made to applications submitted to the omnibus (general) solicitations.



SBIR and STTR Critical Differences

			Award is always made to the 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.



NIH Definition of a Clinical Trial

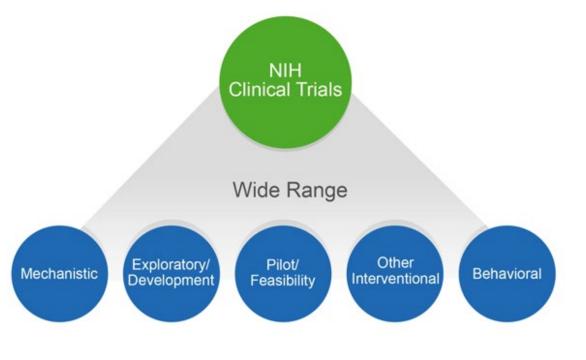
A research study in which one or more human subjects are <u>prospectively assigned</u> to one or more <u>interventions</u> (which may include placebo or other control) to evaluate the effects of those interventions on <u>health-related biomedical or behavioral outcomes.</u>

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





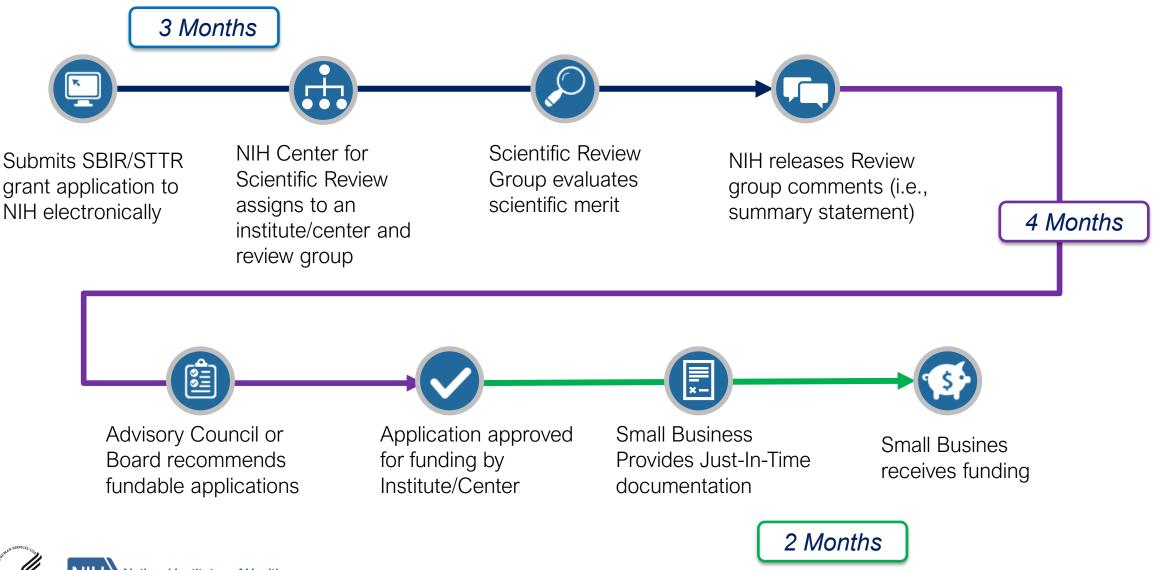
My project is low risk and only has a few human subjects, so it is not a clinical trial.



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!



NIH Application & Review Process: Submission



National Institutes of Health fice of Extramural Researc

Grant applications and SBIR contract proposals must be submitted electronically.

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

REQUIRED REGISTRATIONS

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



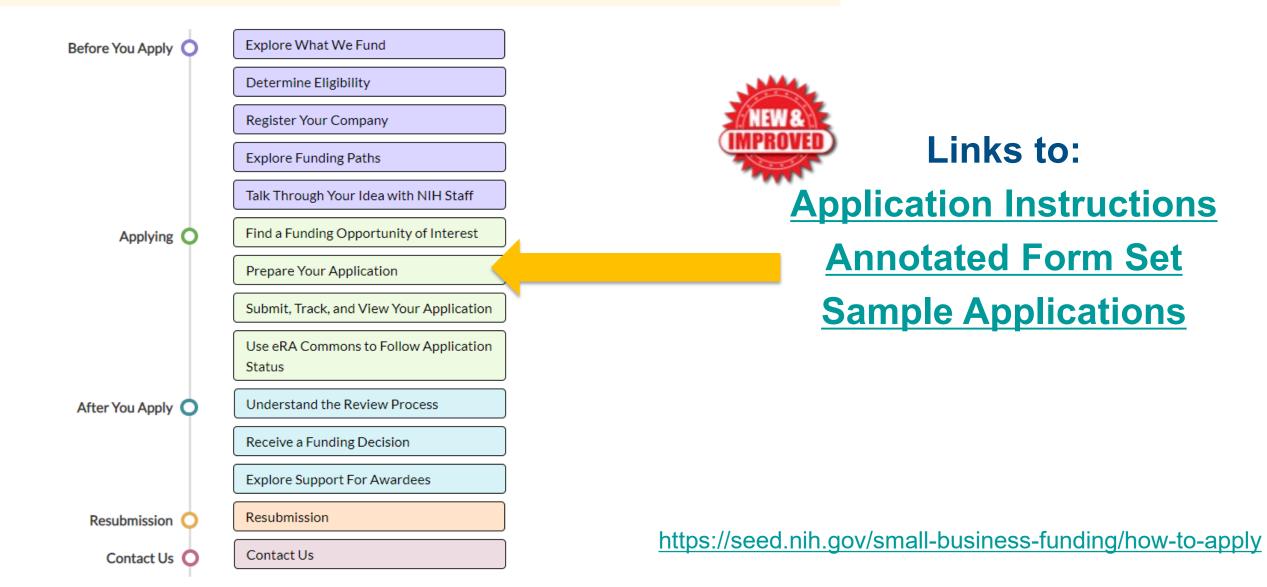


Helpful <u>NIH Grants Registration Infographic</u>

SMALL BUSINESS FUNDING

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

Resources



Novice applicants to the program are almost never successful at getting awards.

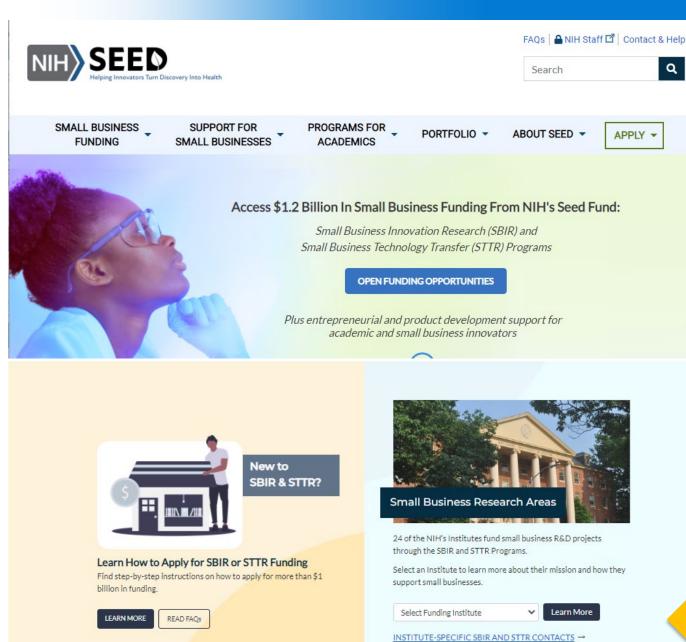


~1/4 of all SBIR and STTR awards go to new investigators. NIH strongly encourage new applicants - particularly from underrepresented innovators or parts of the country.

> NIH Applicant Assistance Program https://seed.nih.gov/small-business-funding/aap



Most Important Piece of Advice



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

List of SBIR Program Managers: https://seed.nih.gov

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

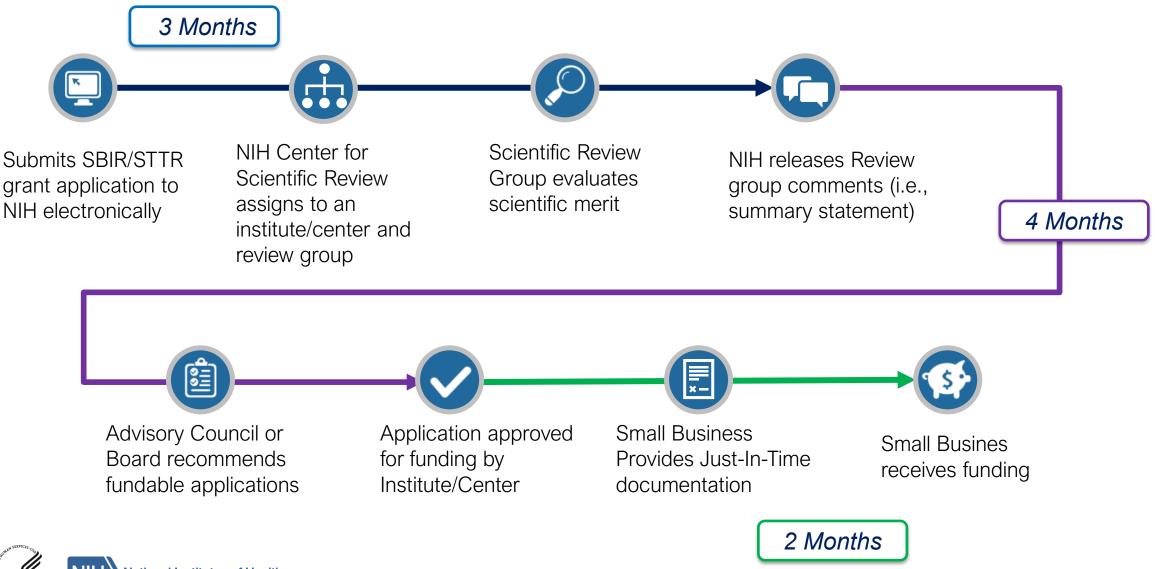
Not sure who to contact? https://public.era.nih.gov/commons/public /servicedesk/initseed.era or Email: <u>SEEDinfo@nih.gov</u> Applications are submitted to a specific Institute, so I need to choose the Institute and Study Section for my application.

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: Peer Review



NIH National Institutes of Health

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 <u>https://public.csr.nih.gov/</u>



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

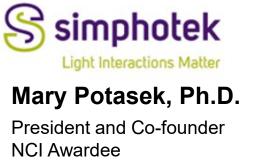


Many companies are funded after incorporating feedback into their resubmission. Tips: Read the summary statement carefully. Contact your program officer to discuss. Offer to be a reviewer.



Be Prepared to Resubmit!





NCI Awardee https://www.simphotek.com/





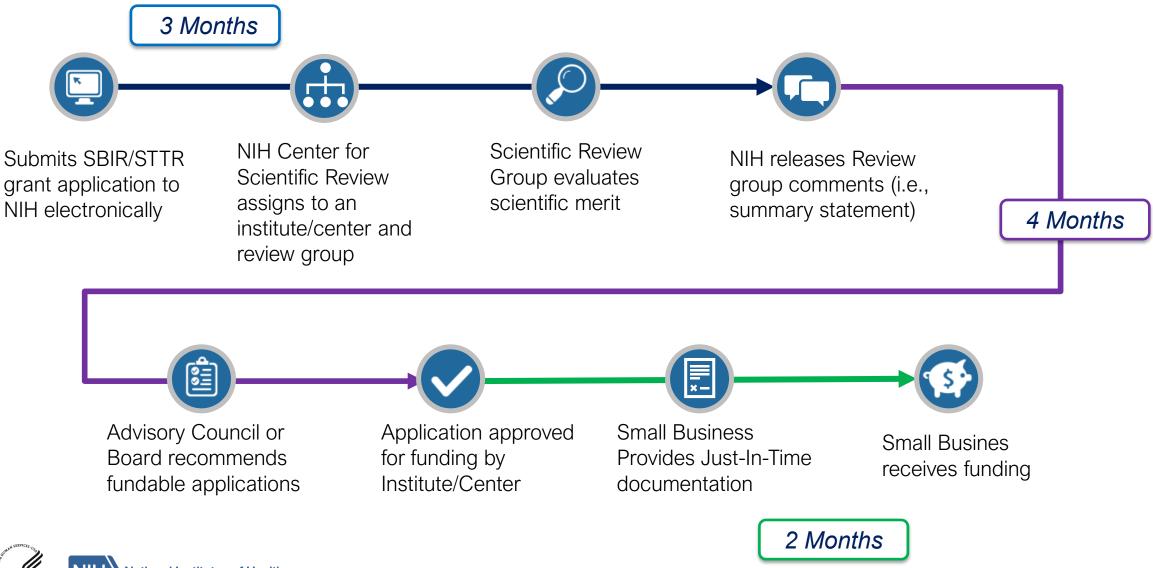
Laverne Morrow Carter, Ph.D.

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."



NIH Application & Review Process: Advisory Council and Due Diligence



NIH National Institutes of Health

Scientific review group (i.e. study section) determines if you are going to get Funded.



NIH staff use score and summary statement when developing the funding plan Advisory Council/Board has access <u>BUT</u> final funding decision is made by the Institute/Center Director

The Small Business Programs only provide money.



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



Innovator Support

Regulatory & Business Development Consultants



Entrepreneurs-in-Residence



Regulatory/Reimbursement

Partnering and Investment Opportunities

BIO International Convention



🔥 AdvaMed



ANGEL CAPITAL ASSOCIATION





Entrepreneurial Support Programs



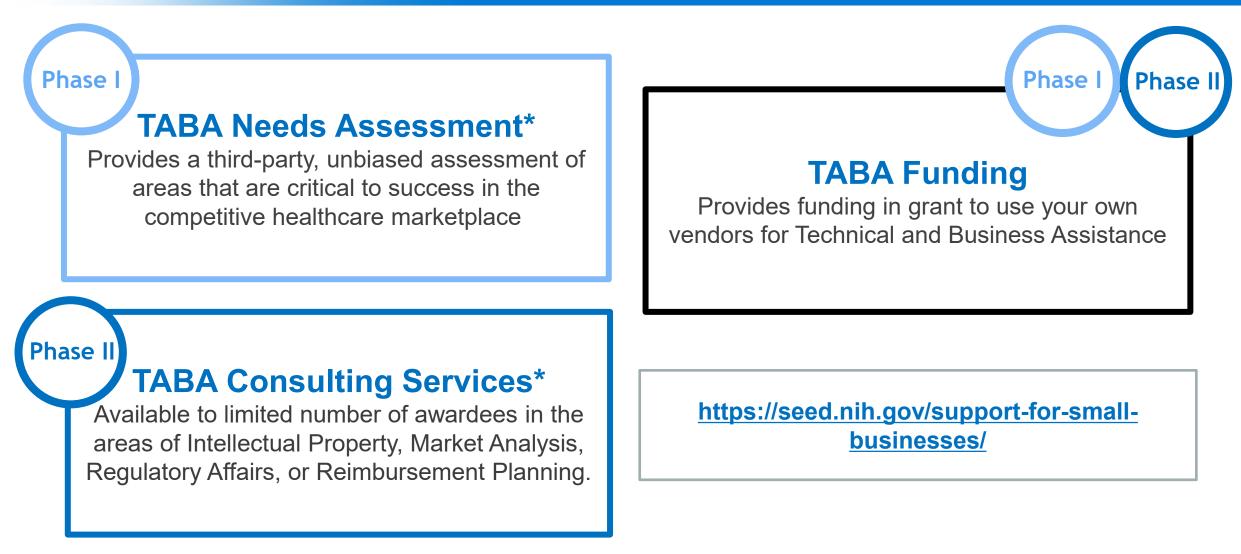


Concept to Clinic: Commercializing Innovation (C3i)

Intellectual

Property

Technical and Business Assistance (TABA)





*NIH ONLY

NIH SBIR/STTR Diversity Supplement

PA-21-345

Administrative Supplement to Promote Diversity in Research and Development Small Businesses

Purpose: Enhance the diversity of the research and entrepreneurial workforce

- Small Businesses with active small business awards (SBIR/STTR)
- Recruit and support individuals from diverse backgrounds

Career Level:

- Undergraduate
- Graduate
- Degree Holders

Rolling Deadline

- Postdoctoral
- Developing Independent Career

Amount: \$5,000- 100,000* *Depending on candidate career level



79 Awards to Date



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



The SEED Office and NIH program officers, scientific review officers, and grants managers are here to help!



Get Connected





America's SEED Fund: Powered by NIH Secrets of a Successful Submission

Tatiana Cohen, PhD **Center for Scientific Review (CSR) Scientific Review Officer**

Toyin Ajisafe, PhD Child Health (NICHD) **Program Director**

Miguel Contreras, PhD Research Infrastructure (ORIP) Program Director

Emily Caporello, PhD Neurology (NINDS) Program Director





