

SEEDing Biomedical Innovation: Support for Small Businesses at NIH

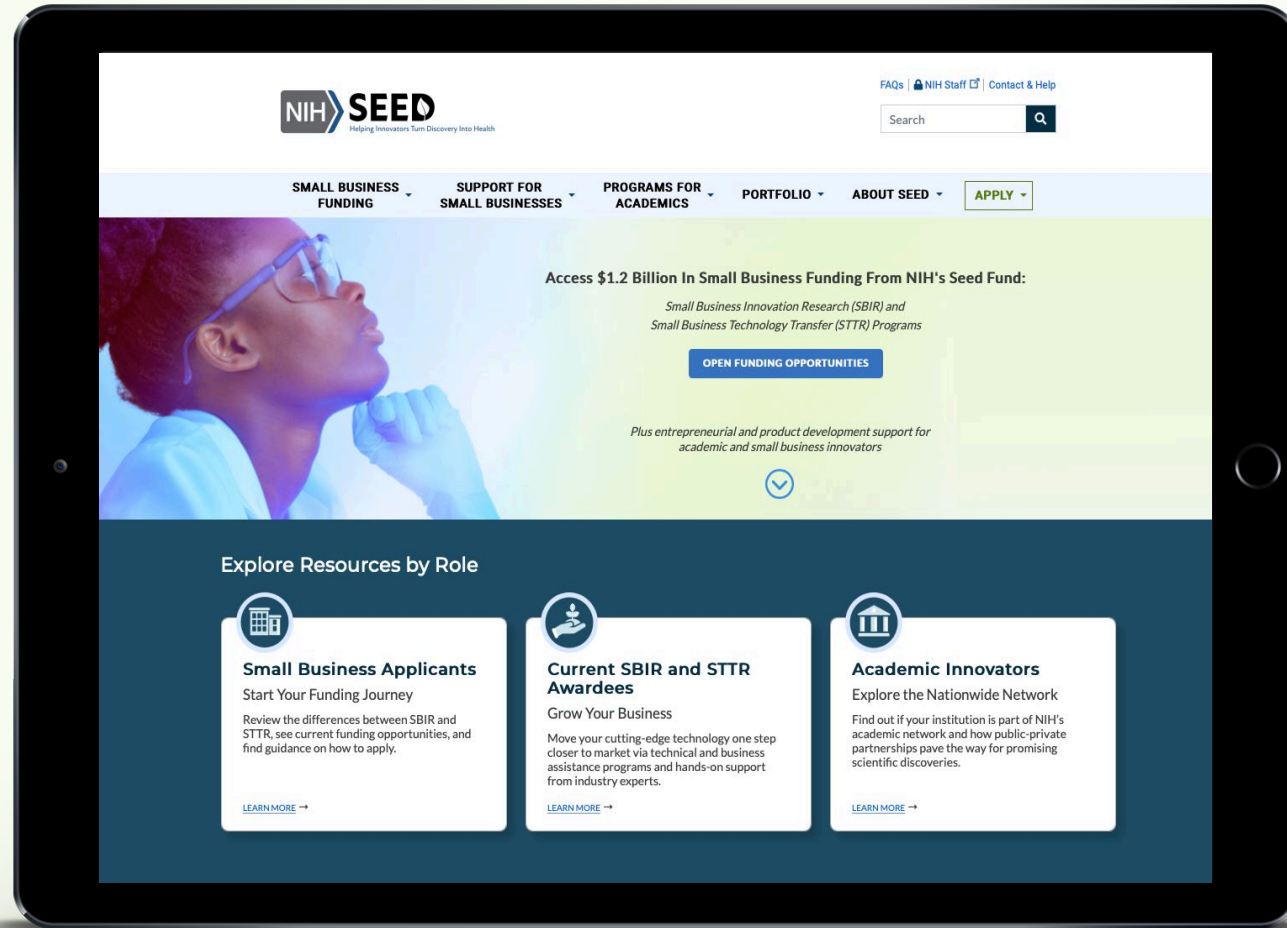
STEPHANIE FERTIG, MBA

HHS Small Business Program Lead

SEED (Small business Education & Entrepreneurial Development)

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

Small Business Program Website



<http://seed.nih.gov>

NIH Mission

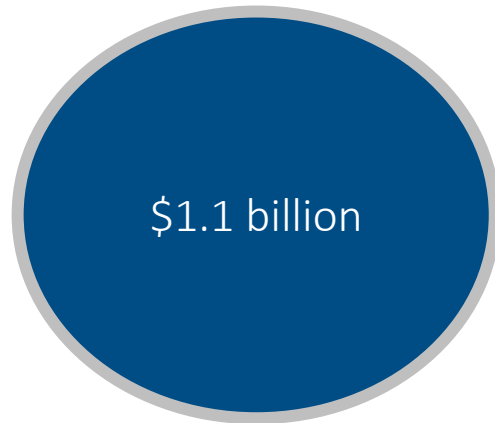


*To seek fundamental knowledge about the nature and behavior of living systems and the **application of that knowledge to enhance health, lengthen life, and reduce illness and disability.***

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

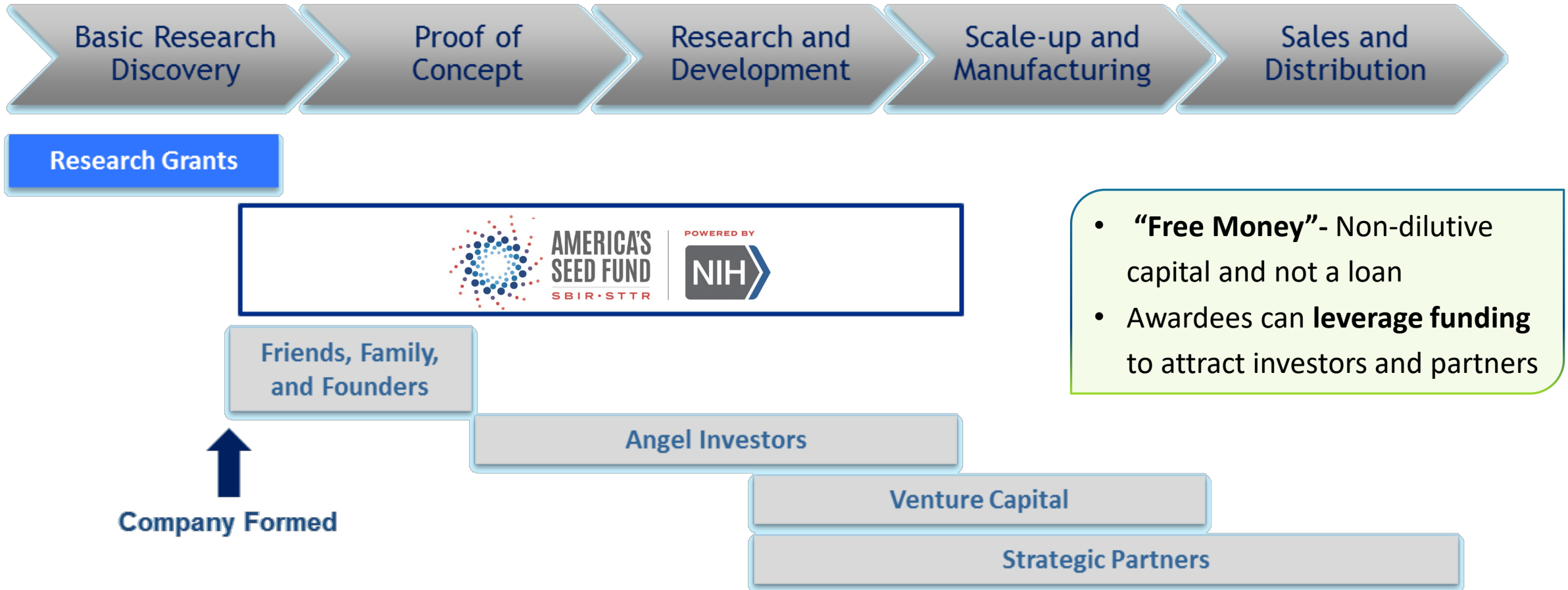


SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM

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

Benefits of NIH Funding

The largest sources of early-stage capital for life sciences in the US



Small Business Success Stories

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.

Technology

- Diagnostic
- Digital Health
- Drug
- Medical Device
- Research Tool

Development Stage

- Approved for Use
- Early Development
- Human Testing

Innovator Setting

- Academic Innovation
- Small Business
- Women/Minority



Displaying results 1 to 10 of total 76

Results per page 10

Company / Institution	Story	State - District
Nanovis, LLC	Nanotechnology Promotes Faster Bone Growth Around Spinal Implants	IN - 3
University of Minnesota Research Evaluation and Commercialization Hub	Caring for the Caretakers: Addressing First Responder Burnout with an Online Toolkit	MN - 5



Alzheimer's Drug Shows Progress in Restoring Cognitive Function



Immunotherapy Company Triggers Immune System to Fight Cancer

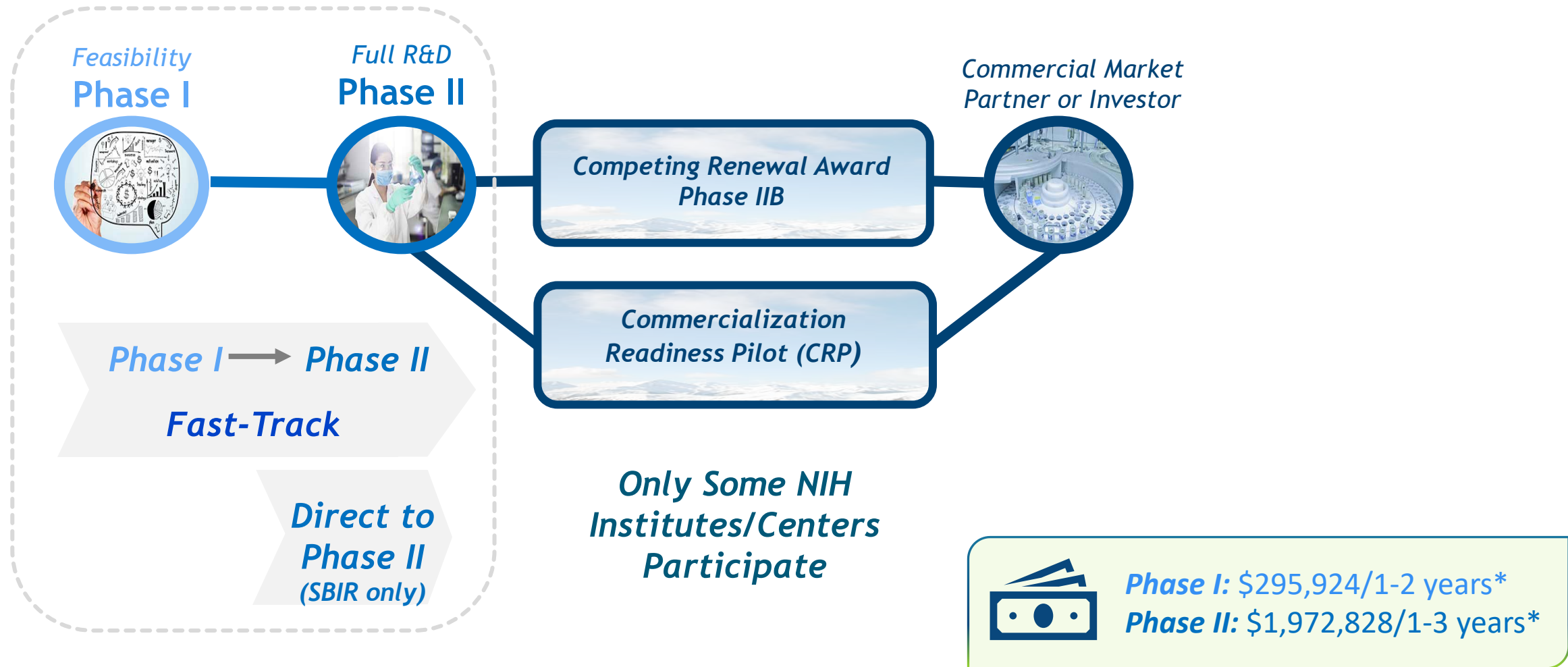


Innovative motion + Positive outcomes

Using Vibrations in Medical Devices

<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 topics

Myth 1

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

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*

Funding Opportunities

<https://seed.nih.gov>

NIH SEED
Helping Innovators Turn Discovery Into Health

FAQs | NIH Staff | Contact & Help

Search

SMALL BUSINESS FUNDING | SUPPORT FOR SMALL BUSINESSES | PROGRAMS FOR ACADEMICS | PORTFOLIO | ABOUT SEED | APPLY

Access \$1.2 Billion In Small Business Funding From NIH's Seed Fund:
Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs

OPEN FUNDING OPPORTUNITIES

Plus entrepreneurial and product development support for academic and small business innovators

Majority of the funding goes to investigator-initiated grant applications

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

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: **Deadline Nov 4**

<https://seed.nih.gov/small-business-funding/find-funding/sbir-contracts>

READ CAREFULLY!

Not all Institutes/Centers participate

Not all targeted solicitations have specific set-asides or review

Myth 2

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

Myth Busted

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

Myth 3

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.

Clinical Trials

NIH Definition of a Clinical Trial

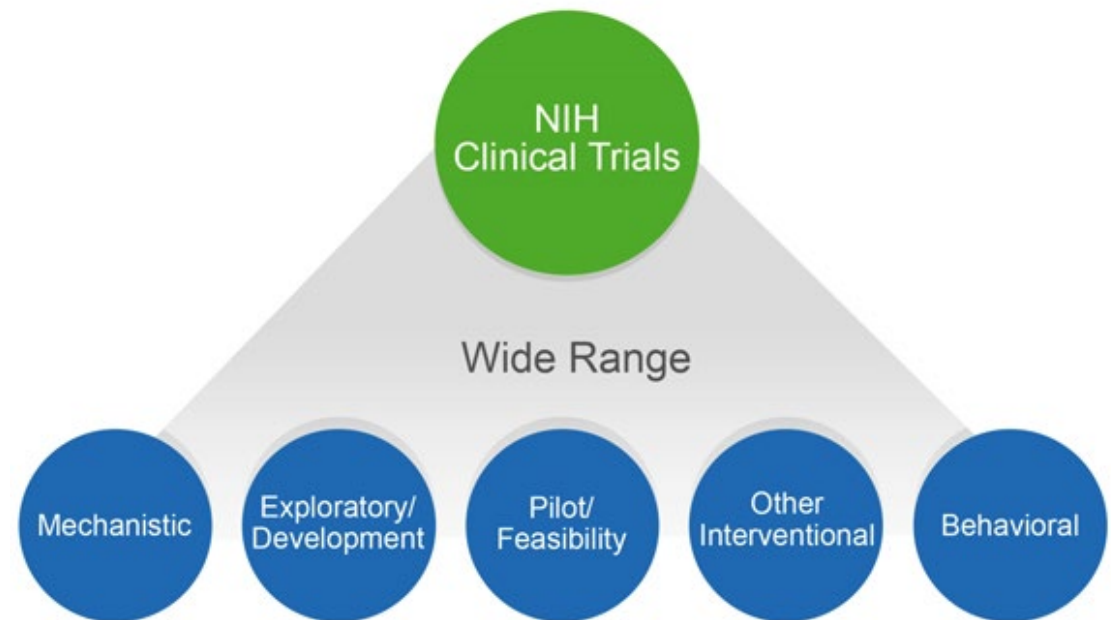
A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

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>



Myth 4

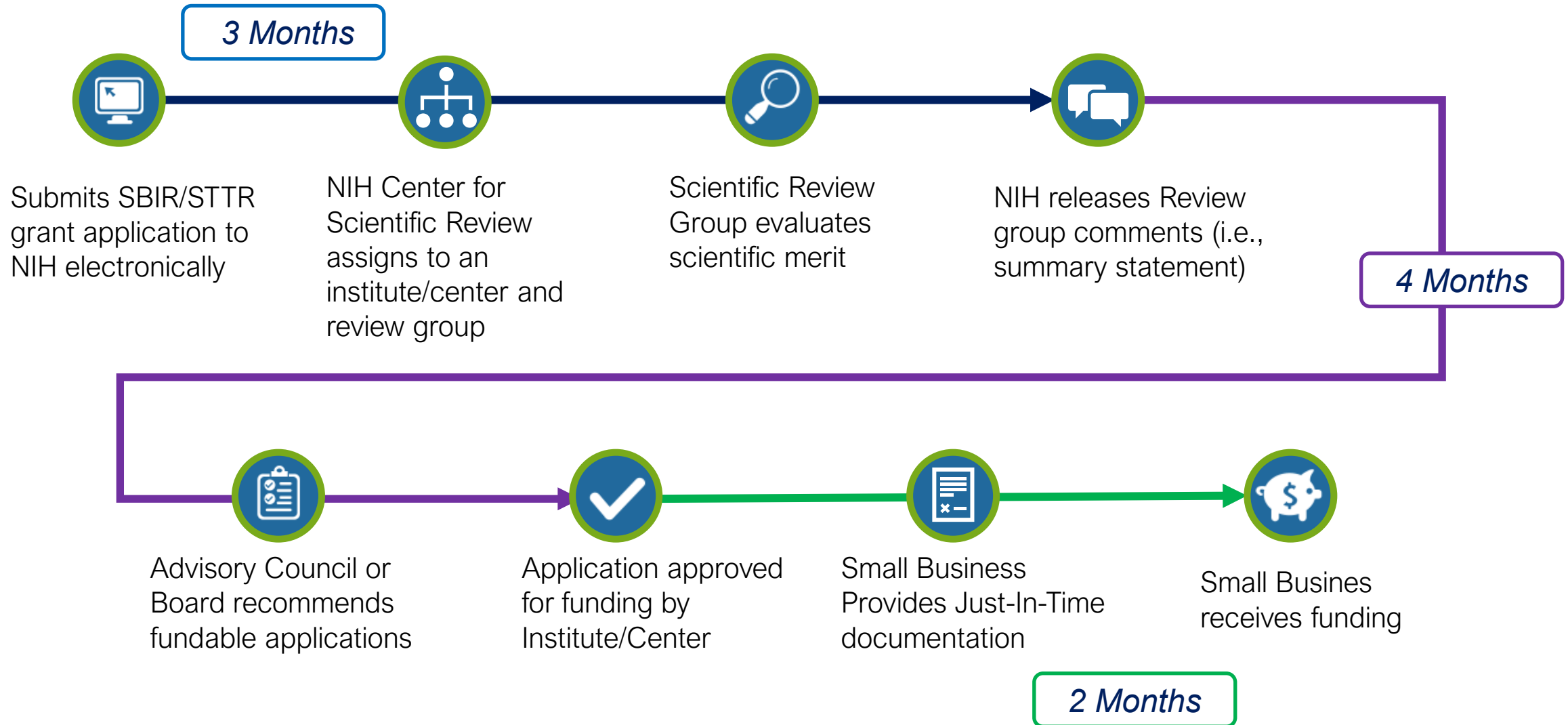
My project is low risk and only has a few human subjects, so it is not a clinical trial.

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!

NIH Application & Review Process: Submission



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



**Two-Factor Authentication
is Required**

[login.gov](#)

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

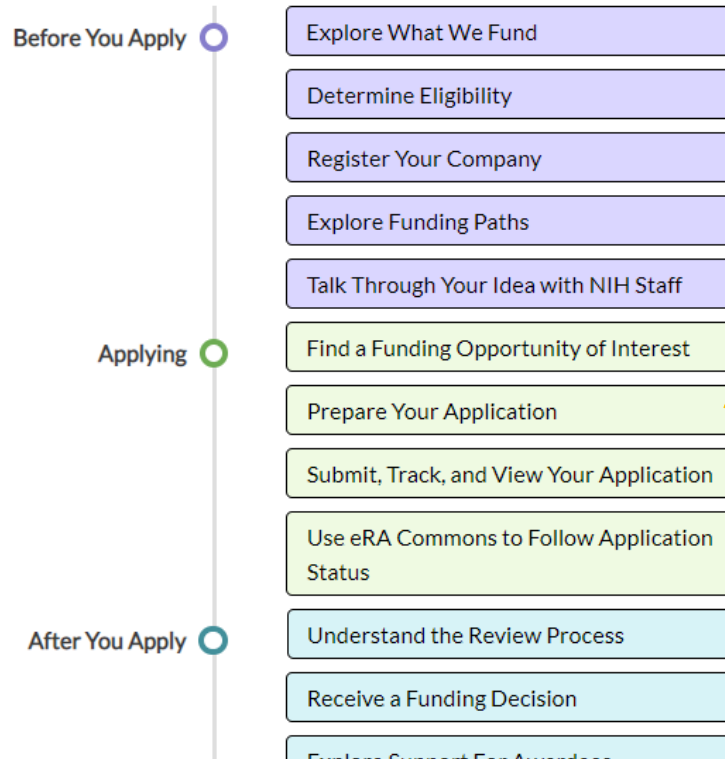
Resources

<https://seed.nih.gov/small-business-funding/how-to-apply>

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.



Links to:
[Application Instructions](#)
[Annotated Form Set](#)
[Sample Applications](#)

Programs for Applicants:

- NIH Applicant Assistance Program
- Health Disparities Pre-Application (HDPReAPP) Program

<https://seed.nih.gov/aboutseed/diversify-entrepreneurial-workforce>

Myth 5

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

Myth Busted

~1/4 of all SBIR and STTR awards go to new investigators.

NIH strongly encourage new applicants - particularly from under-represented innovators or parts of the country.

Most Important Piece of Advice

NIH SEED
Helping Innovators Turn Discovery Into Health

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OPEN FUNDING OPPORTUNITIES

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New to SBIR & STTR?

Learn How to Apply for SBIR or STTR Funding
Find step-by-step instructions on how to apply for more than \$1 billion in funding.

LEARN MORE | READ FAQ

Small Business Research Areas

24 of the NIH's Institutes fund small business R&D projects through the SBIR and STTR Programs.
Select an Institute to learn more about their mission and how they support small businesses.

Select Funding Institute | Learn More

INSTITUTE-SPECIFIC SBIR AND STTR CONTACTS

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

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

Not sure who to contact?

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

Email: SEEDinfo@nih.gov

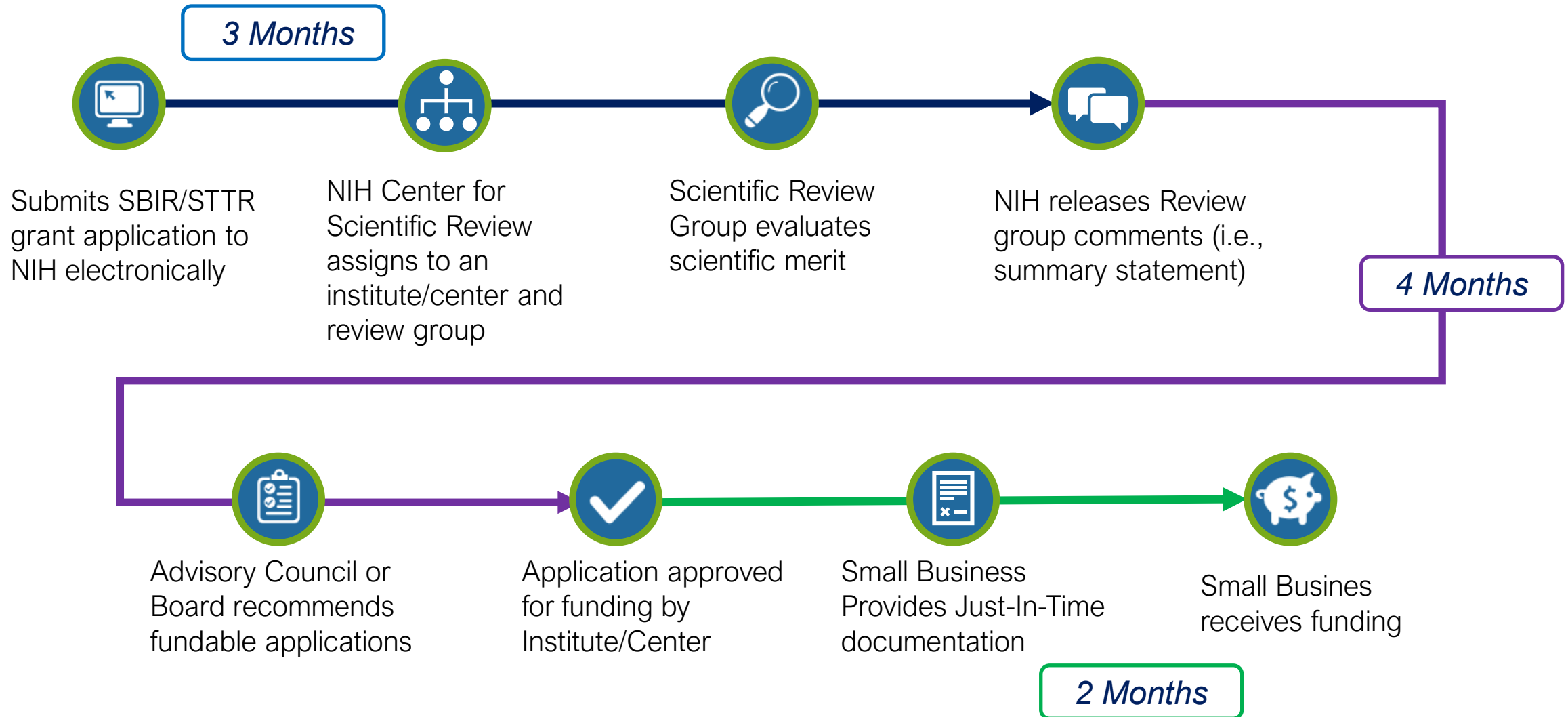
Myth 6

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



Myth 7

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.

Tips: Read the summary statement carefully.

Contact your program officer to discuss.

Offer to be a reviewer.

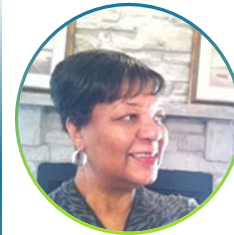
Be Prepared to Resubmit



MARY POTASEK, PH.D.

President and Co-founder
NCI Awardee

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



LAVERNE MORROW CARTER,
PH.D.

President and Co-founder
NCI Awardee

<https://www.simphotek.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.”

Myth 8

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

Myth Busted

NIH staff use score and summary statement when developing the funding plan

Advisory Council/Board has access

BUT final funding decision is made by the Institute/Center Director

Myth 9

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.

Technical and Business Assistance (TABA) Programs

Phase I

TABA Needs Assessment*

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

Phase II

TABA Consulting Services*

Available to limited number of awardees in the areas of Intellectual Property, Market Analysis, Regulatory Affairs, or Reimbursement Planning.

*NIH ONLY

Phase I

TABA Funding

Provides funding in grant to use your own vendors for Technical and Business Assistance

Phase II

<https://seed.nih.gov/support-for-small-businesses/>

Innovator Support

Regulatory & Business Development Consultants



Entrepreneurial Support Programs



Concept to Clinic: Commercializing Innovation (C3i)

Partnering and Investment Opportunities



Powered by AdvaMed



ANGEL CAPITAL ASSOCIATION



Myth 10

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!

Connect with SEED



Online

<http://seed.nih.gov/>



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SEEDinfo@nih.gov



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<https://twitter.com/nihseed>



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<https://seed.nih.gov/subscribe>

The NIH Guide for Grants and Contracts:

<http://grants.nih.gov/grants/guide/listserv.htm>



NIH SEED Events

<https://seed.nih.gov/aboutseed/events>