

Navigating America's Seed Fund at NIH

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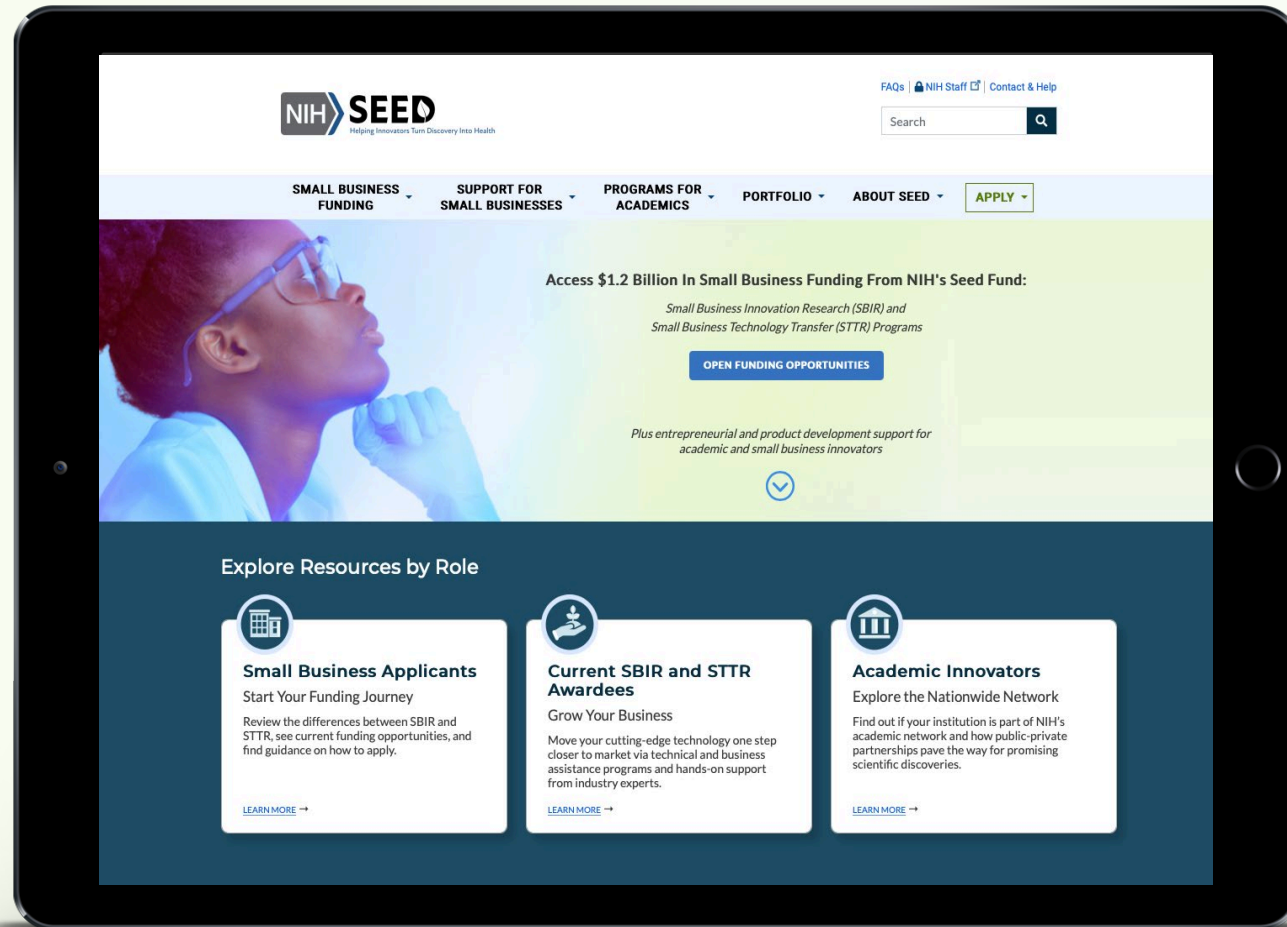
Director, NIH Small Business Program

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.

Small Business Program Website



<http://seed.nih.gov>

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.



National Institutes of Health
SBIR and STTR \$1.3B



Centers for Disease Control and Prevention
SBIR \$11 million



Food and Drug Administration
SBIR \$2 million



Administration on Aging
Community Living
SBIR \$3 million

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



**\$1.3 Billion Dedicated Funding via Set-aside
from NIH's R&D Budget**

SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

\$1.2 billion set-aside for small business concerns to engage in federal R&D -- with potential for commercialization

SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM

\$166 million Set-aside 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



Research Grants



Friends, Family, and Founders

Angel Investors

Venture Capital

Strategic Partners

Company Formed

- “Free Money”- Non-dilutive capital and not a loan
- Awardees can **leverage funding** to attract investors and partners

Myth 1

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



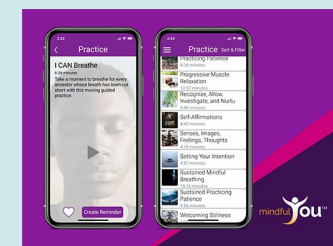
Kansas Biomedical Company Advances Brain Disorder Research



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

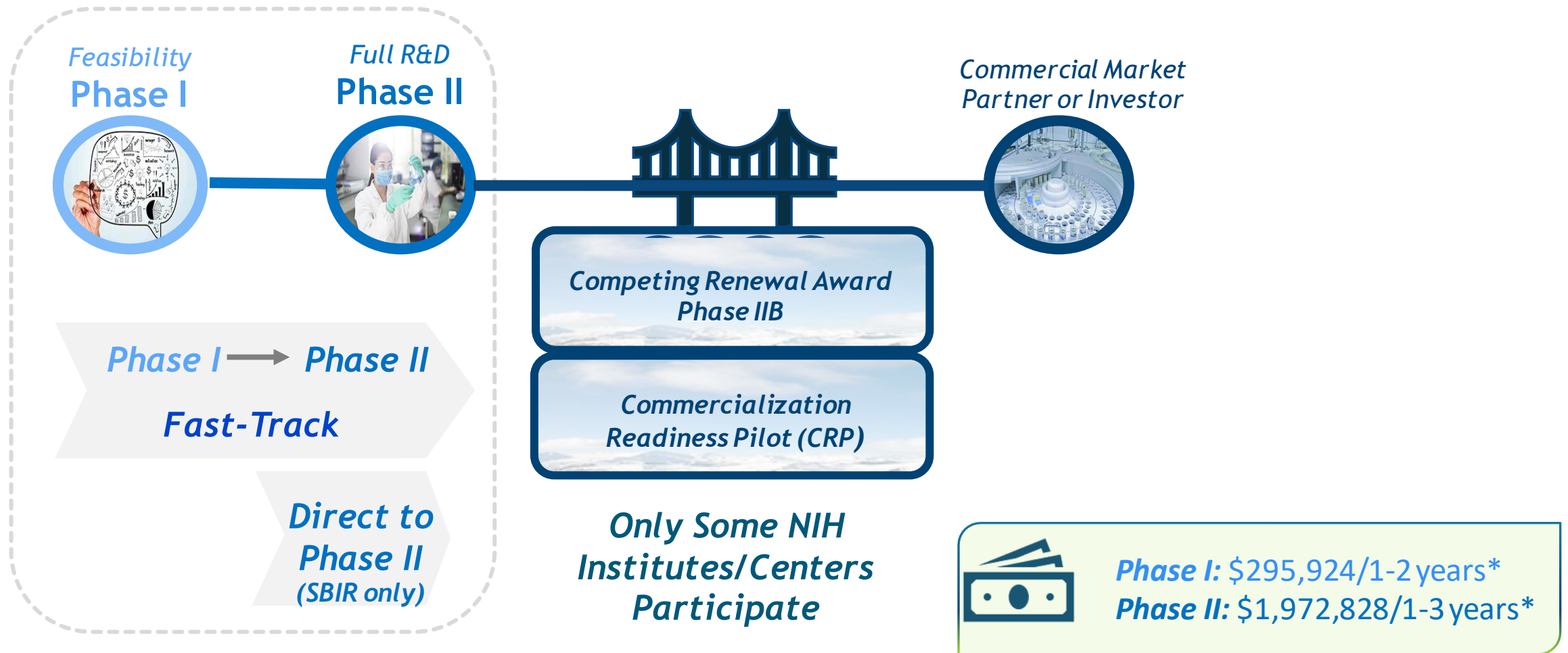


Digital Learning Company Supports Parents, Teachers, and Underserved Communities



<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 topics

Myth 2

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 (citizens or permanent residents) and independently operated <OR>
 - Greater than 50% owned and controlled by other business concerns that are greater than 50% US-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-23-230](#)) and STTR ([PA-23-232](#))

Clinical Trials Required:
SBIR ([PA-23-231](#)) and STTR ([PA-23-233](#))

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: **Expected Shortly**
<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 3

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

Myth Busted

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

SBIR and STTR Critical Differences



Award is always made to the small business

SBIR

Partnering Requirement

Permits partnering

Work Requirement

Guidelines: May outsource 33% (Phase I) 50% (Phase II)

Principal Investigator

Primary employment (>50%) must be with the small business

STTR

Requires a non-profit research institution partner (e.g., university)

Minimum Work Requirements:
40% small business
30% research institution partner

PI may be employed by either the research institution partner or small business

Myth 4

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

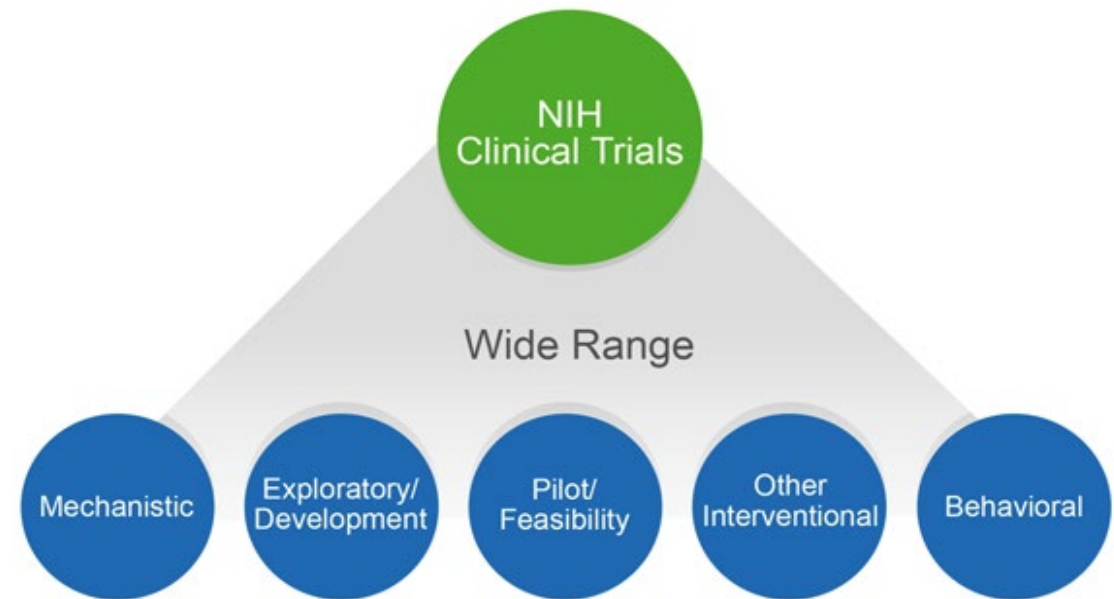
A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

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 5

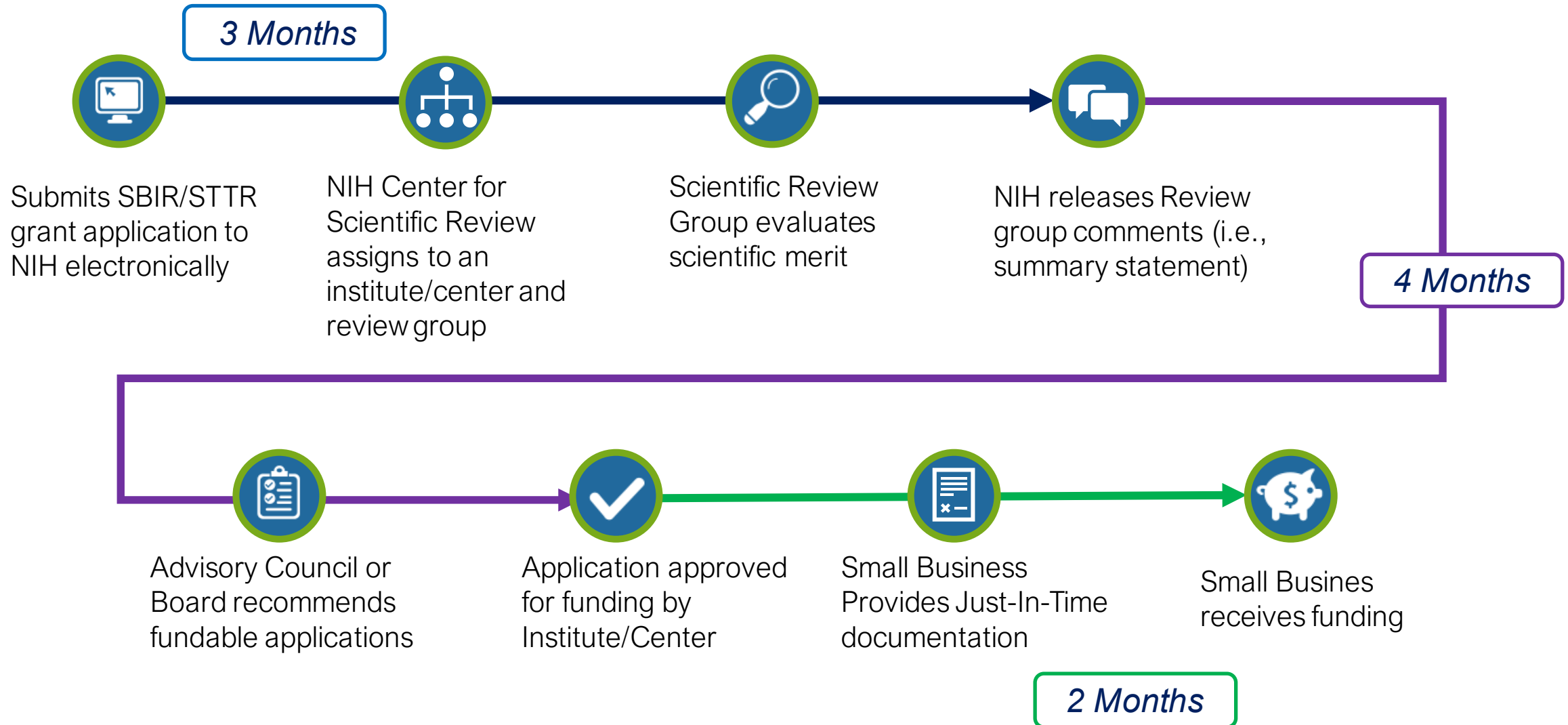
My project is low risk and only has a few human subjects, so it is not a clinical trial.

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



Myth 6

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.

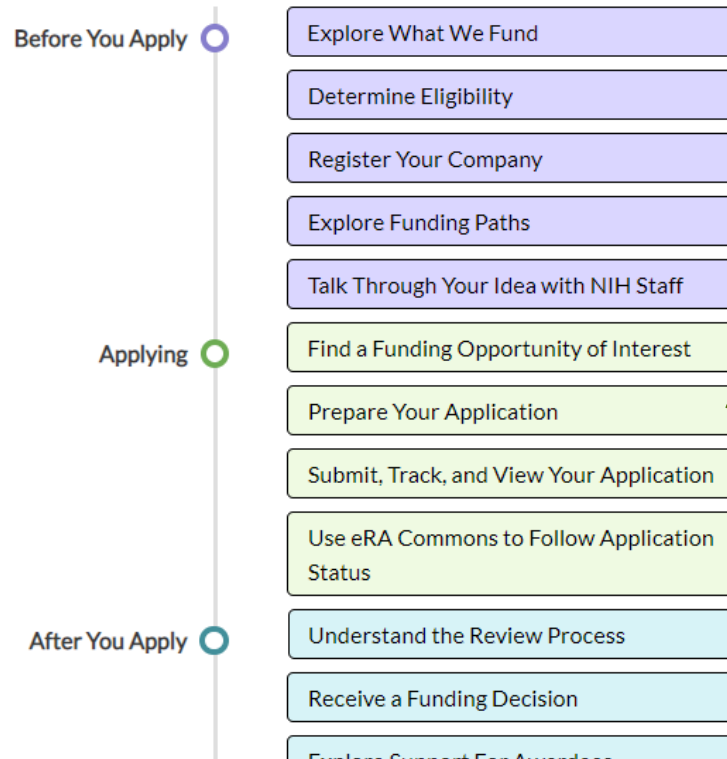
Resources

<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
- NIAID Applicant Assistance Program

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

Technical and Business Assistance (TABA) Programs

Phase I and Phase II

TABA Funding

Grant funds to use your own vendors for Technical and Business Assistance

- \$6,500 per year for a Phase I
- \$50,000 per project for a Phase II

Follow Instructions to request funds in the application

Post-Award 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**

Highlighted Recent Changes

Data Management and Sharing Plan

- Required for SBIR/STTR applications
- **May retain the rights to data generated during the performance of the award for up to 20 years after the award date**
- Acceptable plans can reference and incorporate these data rights
- NIH may make plans public- plans should not contain proprietary information

Facilities & Other Resources

Must describe:

- Business environment and resources (or how you will obtain them) for completing and commercializing the product or service
- Relevant intellectual property associated with the project

Most Important Piece of Advice

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Helping Innovators Turn Discovery Into Health

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OPEN FUNDING OPPORTUNITIES

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

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!

Not sure who to contact?

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

Email: SEEDinfo@nih.gov

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

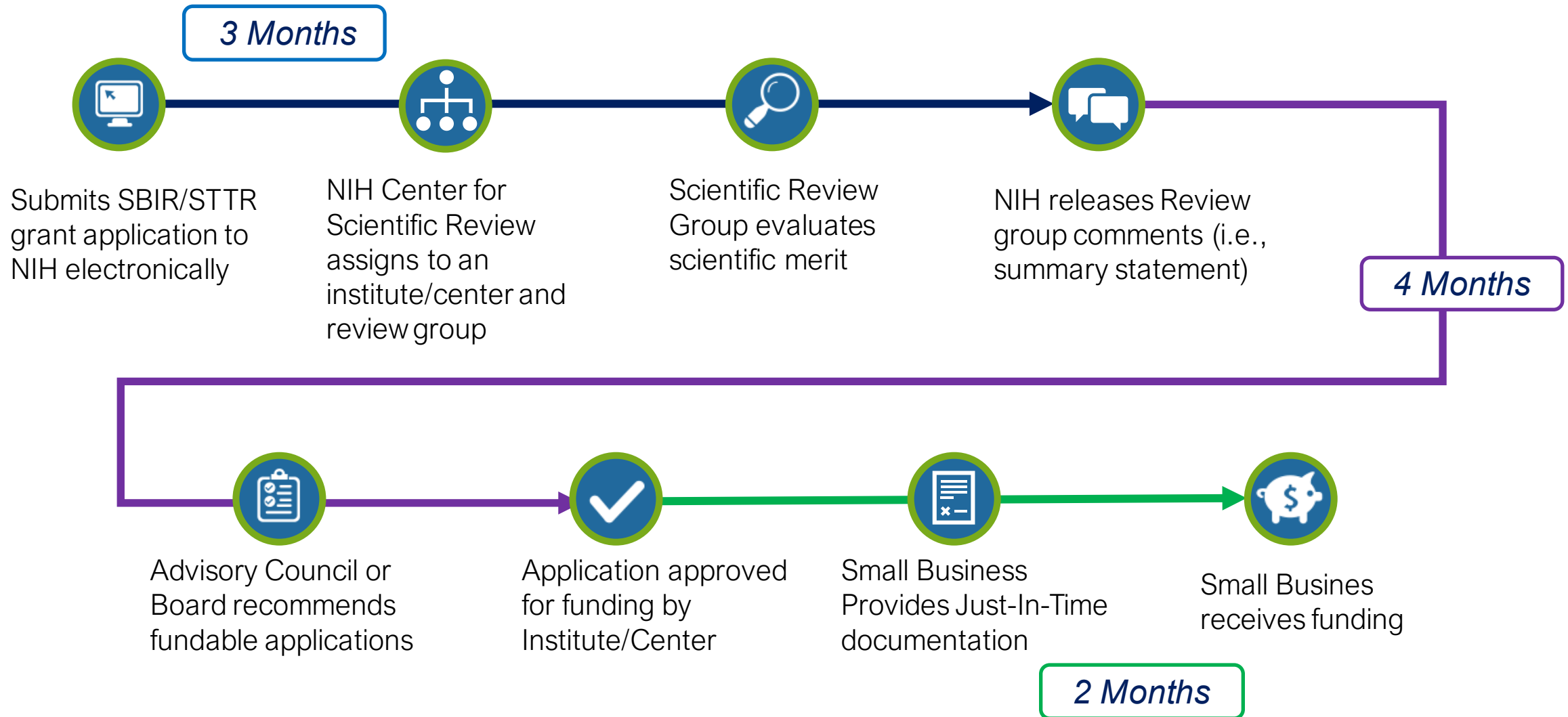
Myth 7

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



Review Criteria

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

- Each application has 3 assigned reviewers
- Five Review Criteria that reviewers score individually
Funding Opportunities contain specific questions the reviewers should consider
Applicants should review: These have changed for the Omnibus Solicitations
- Overall Impact Score is determined after discussion and scoring by the Scientific Review Group
- ~50% of applications are not discussed-
but **all** applications receive reviewer comments!

Review Criteria

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

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

Myth 8

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

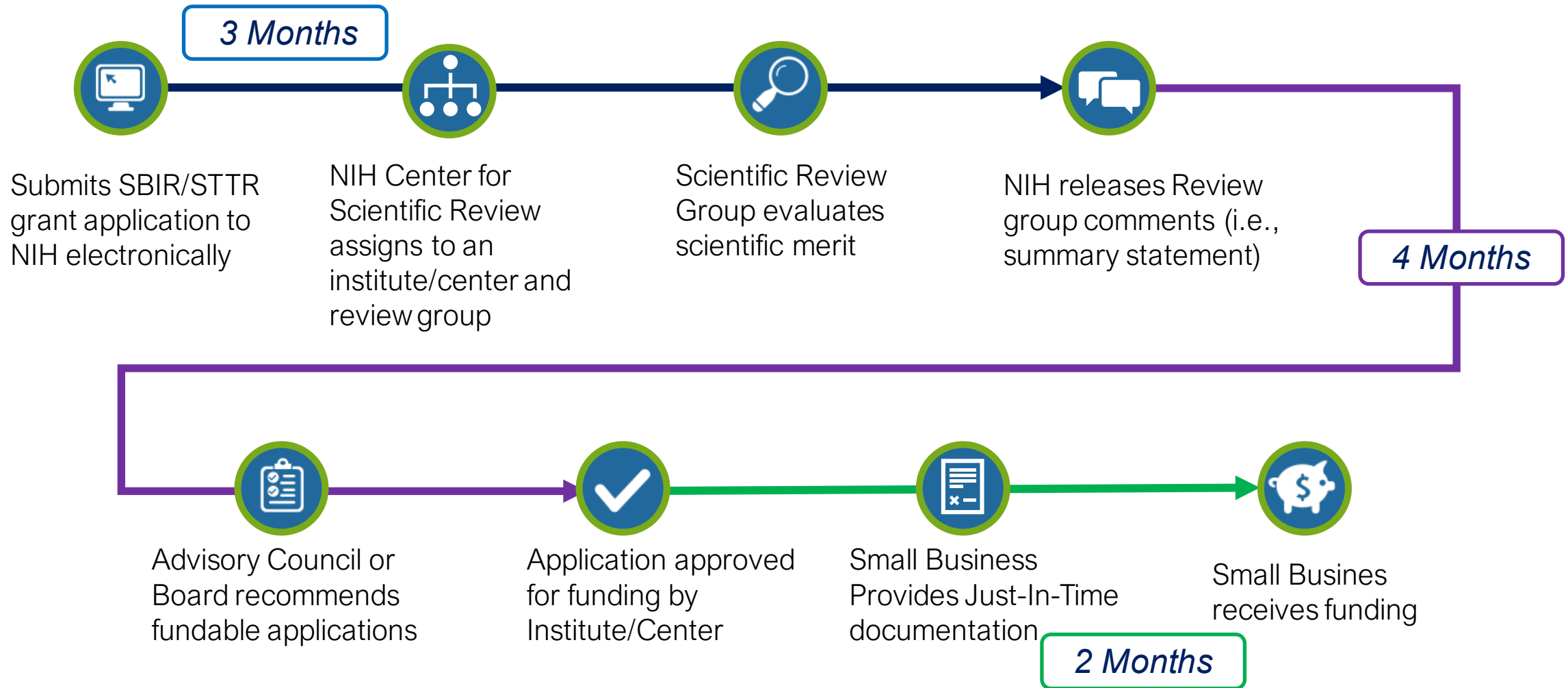
<https://www.simphotek.com/>



“ 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.”

NIH Application & Review Process: Advisory Council and Due Diligence



Myth 9

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

Foreign Disclosure: Pre-award Requirements

New Requirement from the SBIR and STTR Extension Act of 2022

Disclosure is required using the [Required Disclosures of Foreign Affiliations or Relationships to Foreign Countries Form](#)

- Submitted via the Just-In-Time (JIT) process and required for award
- Disclosure is required for all owners and covered individuals (i.e. senior key personnel)



IMPORTANT: SBIR/STTR eligibility criteria HAVE NOT changed- disclosure or finding of foreign affiliations or relationships DOES NOT necessarily disqualify an applicant

Due Diligence Program

New Requirement from the SBIR and STTR Extension Act of 2022

- Prior to award NIH will assess security risk including:
 - Cybersecurity practices
 - Patent analysis
 - Employee analysis
 - Foreign ownership (including financial obligations of small business and employees)
- If possible, NIH will work with applicants to address security risks, but may decline to move forward with an award based on security concerns
- For more information:
 - [NOT-OD-23-139: Implementation of the NIH SBIR and STTR Foreign Disclosure Pre-award and Post-Award Requirements](#)
 - [Foreign Disclosure and Risk Management webpage](#)



IMPORTANT: SBIR/STTR eligibility criteria HAVE NOT changed- disclosure or finding of foreign affiliations or relationships DOES NOT necessarily disqualify an applicant

Foreign Disclosure Post-award Requirements

New Requirement from the SBIR and STTR Extension Act of 2022

- Small Business is responsible for monitoring their relationships with foreign countries
- Submit updates to the [Required Disclosures of Foreign Affiliations or Relationships to Foreign Countries Form](#)
 - Regular updates during annual, interim and final progress reports
 - Updated forms are required within 30 days of any change in ownership, entity structure, covered individual or other substantive changes in circumstance
- If a security concern is identified NIH may withhold funding until the risk has been addressed
- For more information:
 - [NOT-OD-23-139: Implementation of the NIH SBIR and STTR Foreign Disclosure Pre-award and Post-Award Requirements](#)
 - [Foreign Disclosure and Risk Management webpage](#)

Myth 10

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.

Innovator Support

Partnering and Investment Opportunities



Entrepreneurial Support Programs



**Concept to Clinic:
Commercializing Innovation (C3i)**



**Administrative
Supplements to
Promote Diversity**

Regulatory & Business Development Consultants



NIH SBIR/STTR Diversity Supplement

PA-21-345 Administrative Supplement to Promote Diversity in Research and Development Small Businesses (NIH and CDC)

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

 Supported 100+ Individuals to Date

Career Level

- Undergraduate
- Graduate
- Degree Holders
- Postdoctoral
- Developing Independent Career

https://seed.nih.gov/diversity_supp

Bonus Myth

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/>



Email us

SEEDinfo@nih.gov



@nihseed

<https://twitter.com/nihseed>



NIH SEED

<https://www.linkedin.com/company/nihseed>

Sign up for NIH and SEED updates:

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

The NIH Guide for Grants and Contracts:

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