

New SBIR and STTR Requirements: How Does It Impact Your Company?

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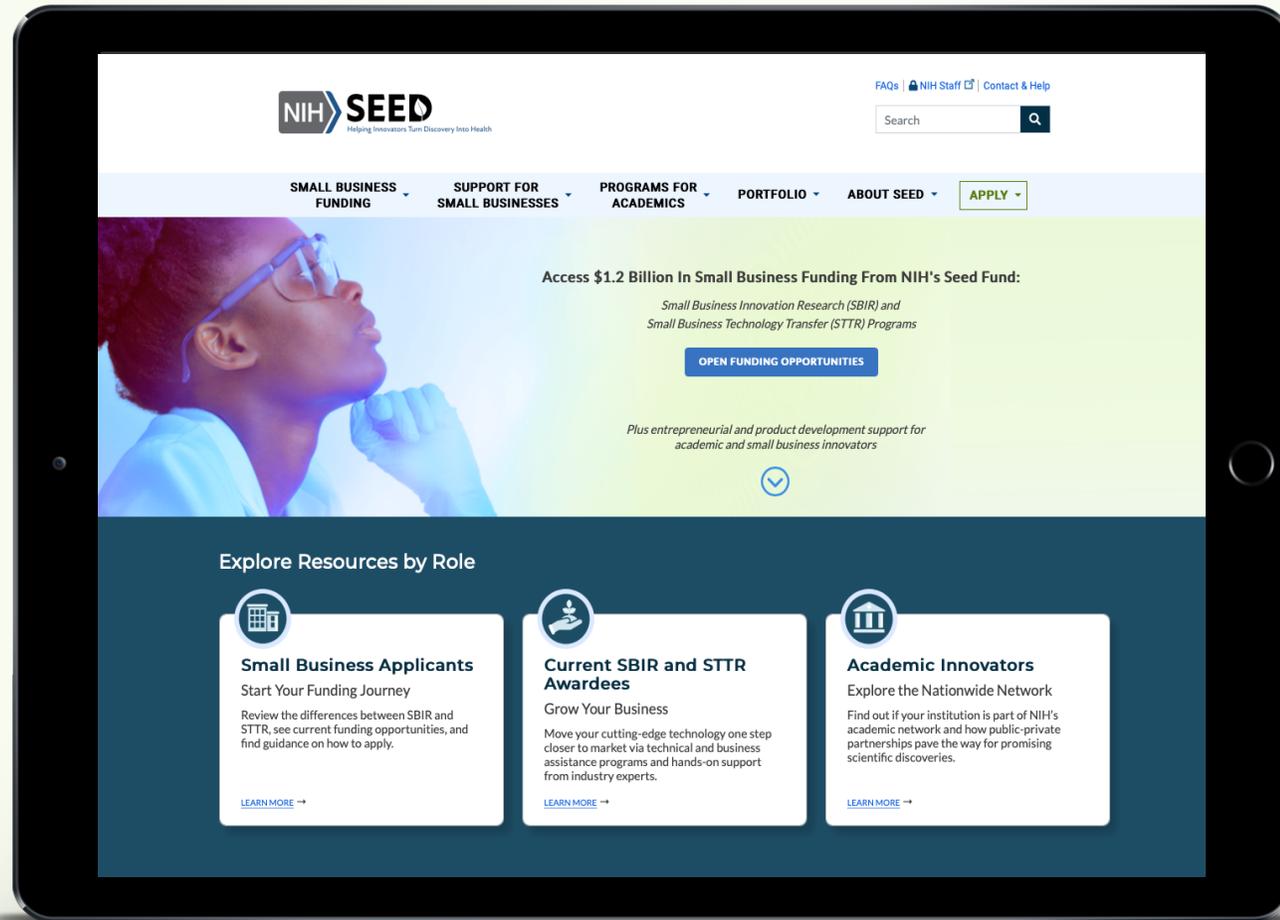
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Immediate Office of the Director*

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>

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

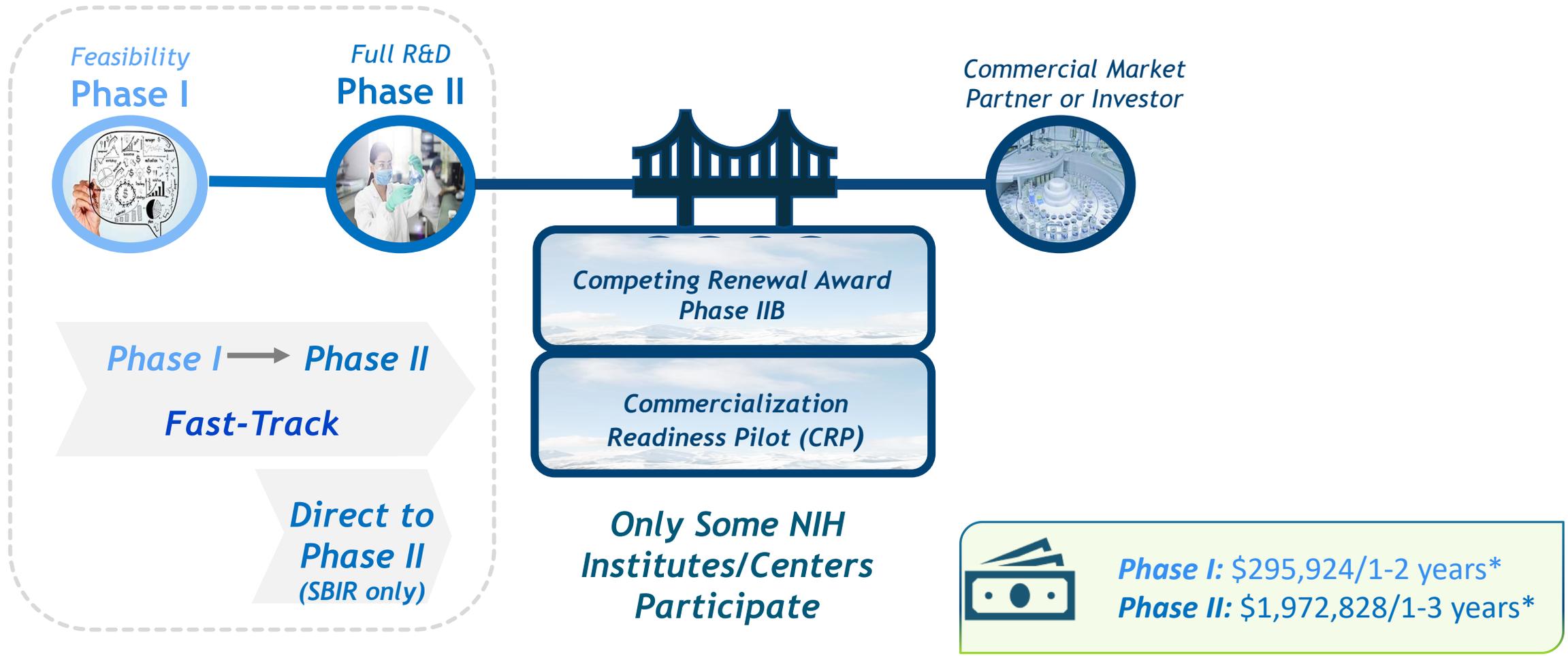
Venture Capital

Strategic Partners

Company Formed

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

Phased Programs



*NIH and CDC have a waiver from the Small Business Administration to exceed these budgets for selected [topics](#)

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:

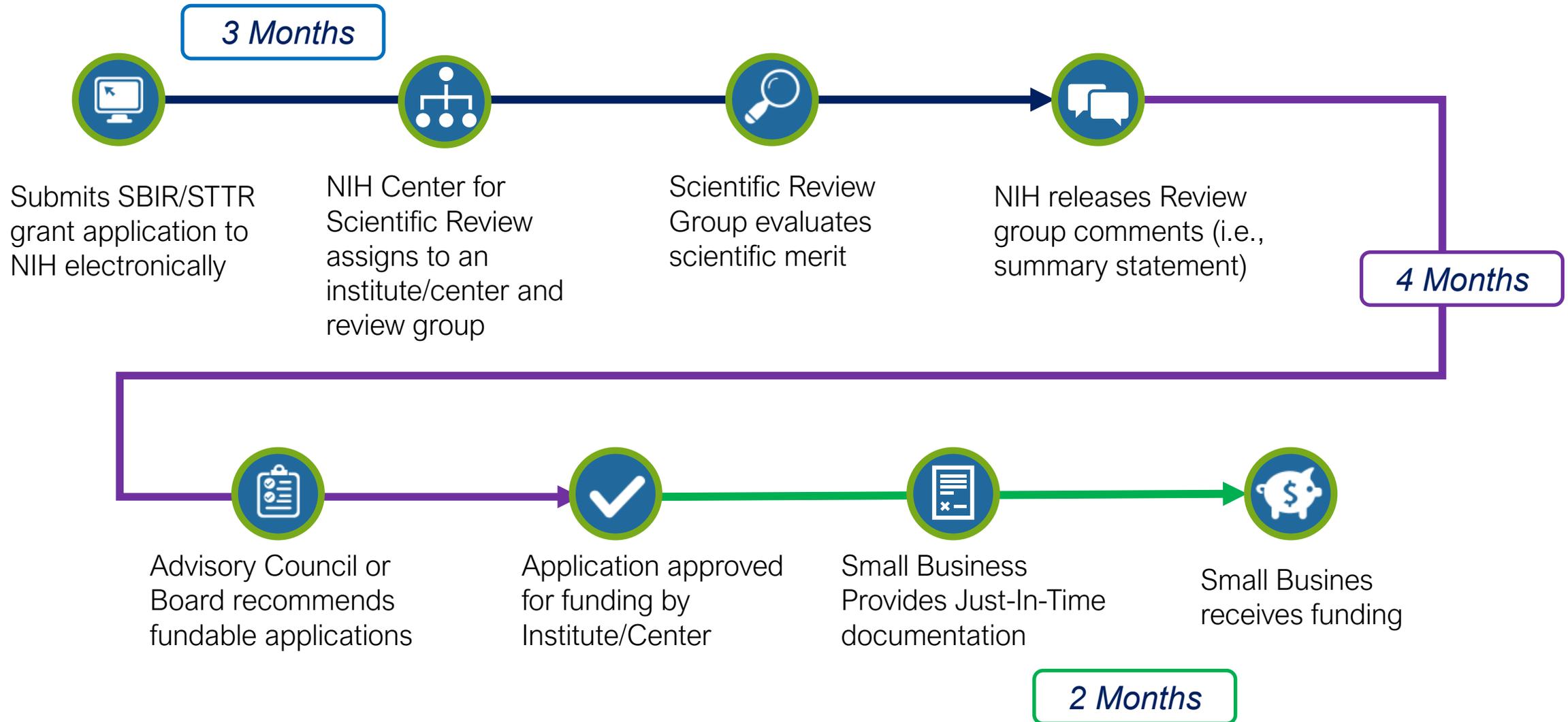
[Contract Solicitation](#) is now available!

READ CAREFULLY!

Not all Institutes/Centers participate

Not all targeted solicitations have specific set-asides or review

NIH Application & Review Process: Submission



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>

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

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**

Recipient Resources: Beyond TABA

Partnering and Investment Opportunities



Entrepreneurial Support Programs



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



**Administrative
Supplements to
Promote Diversity**

Regulatory & Business Development Consultants



Most Important Piece of Advice

NIH SEED
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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!

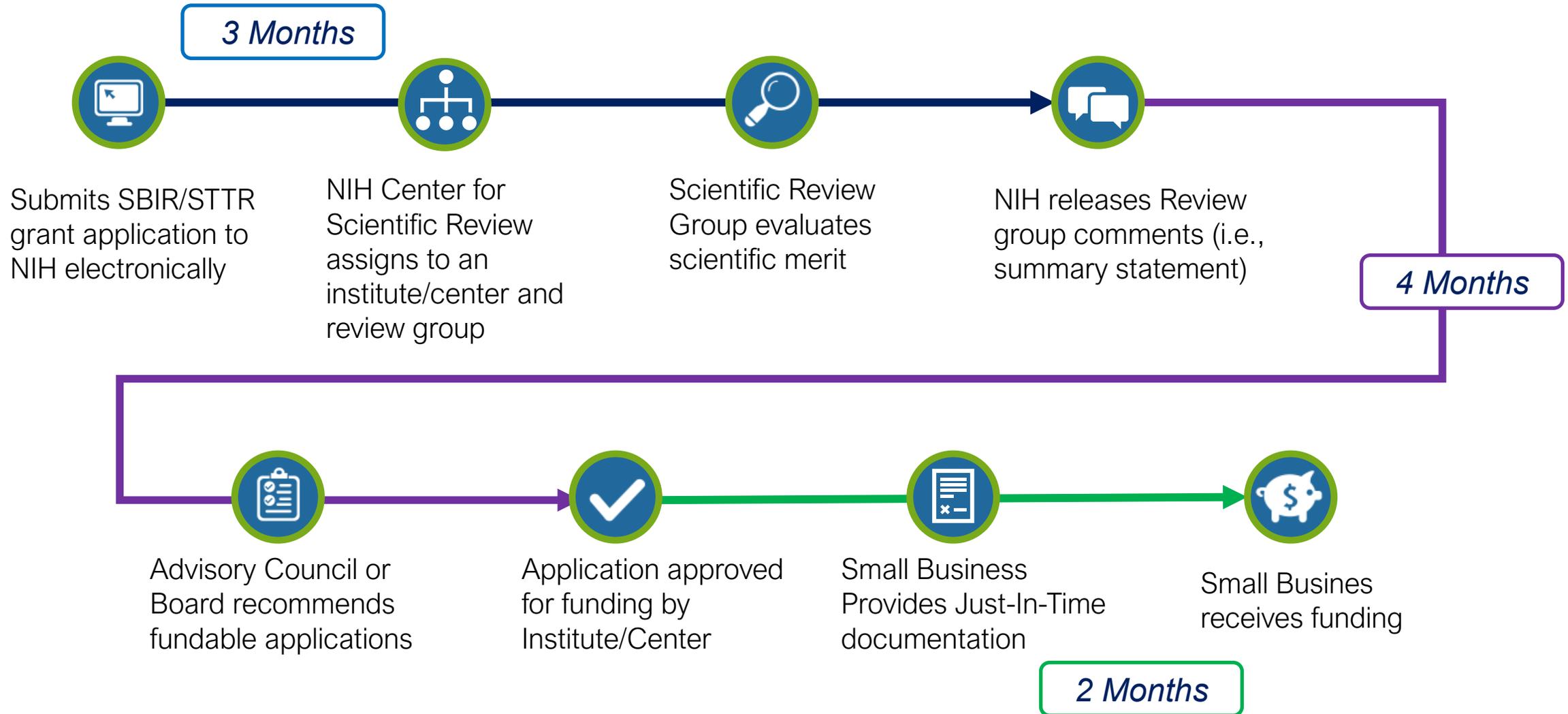
Not sure who to contact?

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

Email: SEEDinfo@nih.gov

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

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
 - *Applicants should review specific questions in the Funding Opportunity**
- 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:

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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

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

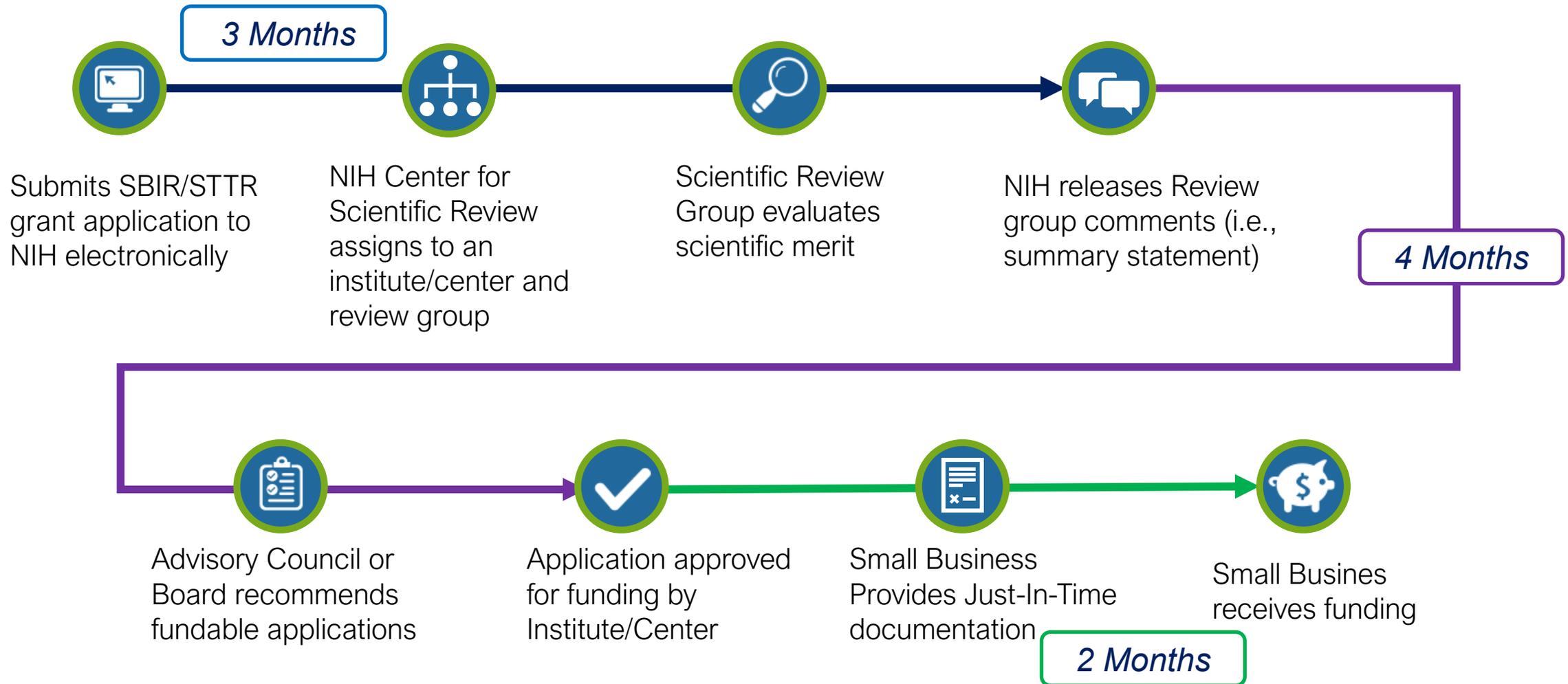
<https://www.simphotek.com/>



“ 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



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)
- 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

Due Diligence Program- Denial of Award

New Requirement from the SBIR and STTR Extension Act of 2022

- If possible, NIH will work with applicants to address security risks, but may decline to move forward with an award based on security concerns.
- Denial of award occurs when a small business
 - (i) has an owner or covered individual that is party to a malign foreign talent recruitment program;
 - (ii) has a business entity, parent company, or subsidiary located in the People's Republic of China or another foreign country of concern; or
 - (iii) has an owner or covered individual that has a foreign affiliation with a research institution located in the People's Republic of China or another foreign country of concern;**AND** the relationships and commitments above
 - (i) interfere with the capacity for activities supported by the Federal agency to be carried out;
 - (ii) create duplication with activities supported by the Federal agency;
 - (iii) present concerns about conflicts of interest;
 - (iv) were not appropriately disclosed to the Federal agency;
 - (v) violate Federal law or terms and conditions of the Federal agency; or
 - (vi) pose a risk to national security.

[Foreign Disclosure and Risk Management webpage](#)

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](#)

Connect with SEED



Online

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

The NIH Guide for Grants and Contracts:

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