

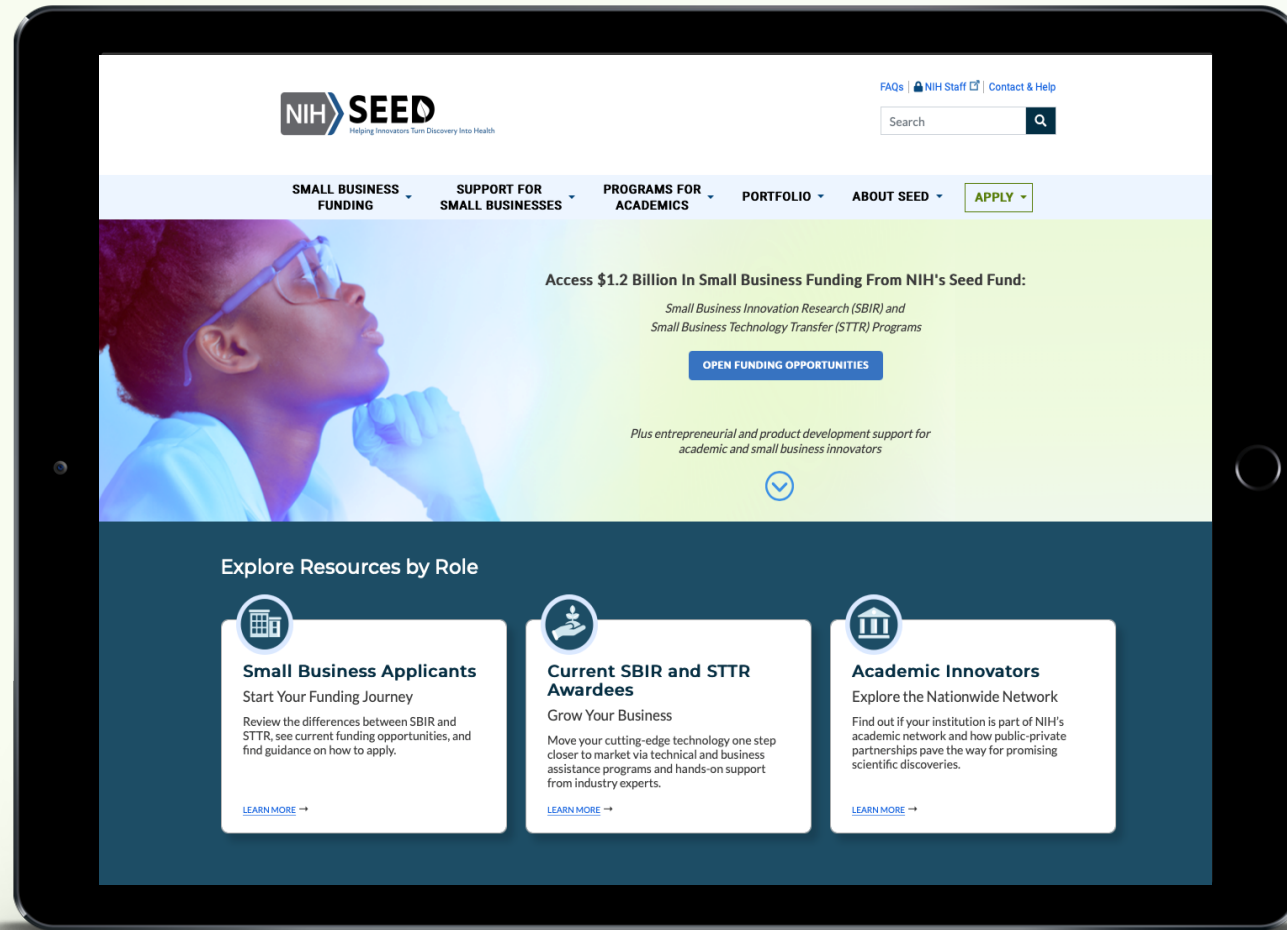
Small Business Transition Grant for New Entrepreneurs

Stephanie Fertig

Director, NIH Small Business Program

SEED (Small business Education & Entrepreneurial Development)

Small Business Program Website



<http://seed.nih.gov>

Transition Grant Website

IMPORTANT: Follow the instructions in the Notice of Funding Opportunity


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

Small Business Transition Grant

The Small Business Transition Grant for New Entrepreneurs Notices of Funding Opportunities (NOFOs) aim to support career development and the conduct of research and development under a new entrepreneur's direction.

Optimal Program Directors/Principal Investigators (PDs/PIs) for this award are early-career scientists and professionals with research, technology development, and/or healthcare delivery skills and experience, but limited entrepreneurial and independent (non-mentored) research leadership experience.

NIH is committed to [diversifying the entrepreneurial workforce](#) and encourages applications from individuals who offer unique and/or underrepresented perspectives that enrich the biomedical innovation pipeline.

- **Award Types:** [Small Business Innovation Research \(SBIR\)](#) and [Small Business Technology Transfer \(STTR\)](#), Phase I and Fast-Track
- **Eligibility:** PDs/PIs must have never been an independent PD/PI on a major research grant and must be a U.S. Citizen or Lawful Permanent Resident
- **Mentor(s):** Applicants must identify mentor(s) to:
 - Provide technical and commercial guidance to advance the proposed research project
 - Support preparing and executing a career development plan to successfully navigate the entrepreneurial process, develop and commercialize products, or operate a small business
- **Due Dates:** September 5, January 5, and April 5 (or the next business day, if falling on a weekend or [Federal holiday](#) )

View additional [Frequently Asked Questions \(FAQs\) on the Small Business Transition Grant for New Entrepreneurs](#).



FAQs

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.



Food and Drug Administration
SBIR \$2 million



National Institutes of Health
SBIR and STTR \$1.3B



Centers for Disease Control and Prevention
SBIR \$11 million



Advanced Research Projects Agency for Health
SBIR and STTR \$38 million



Administration for 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

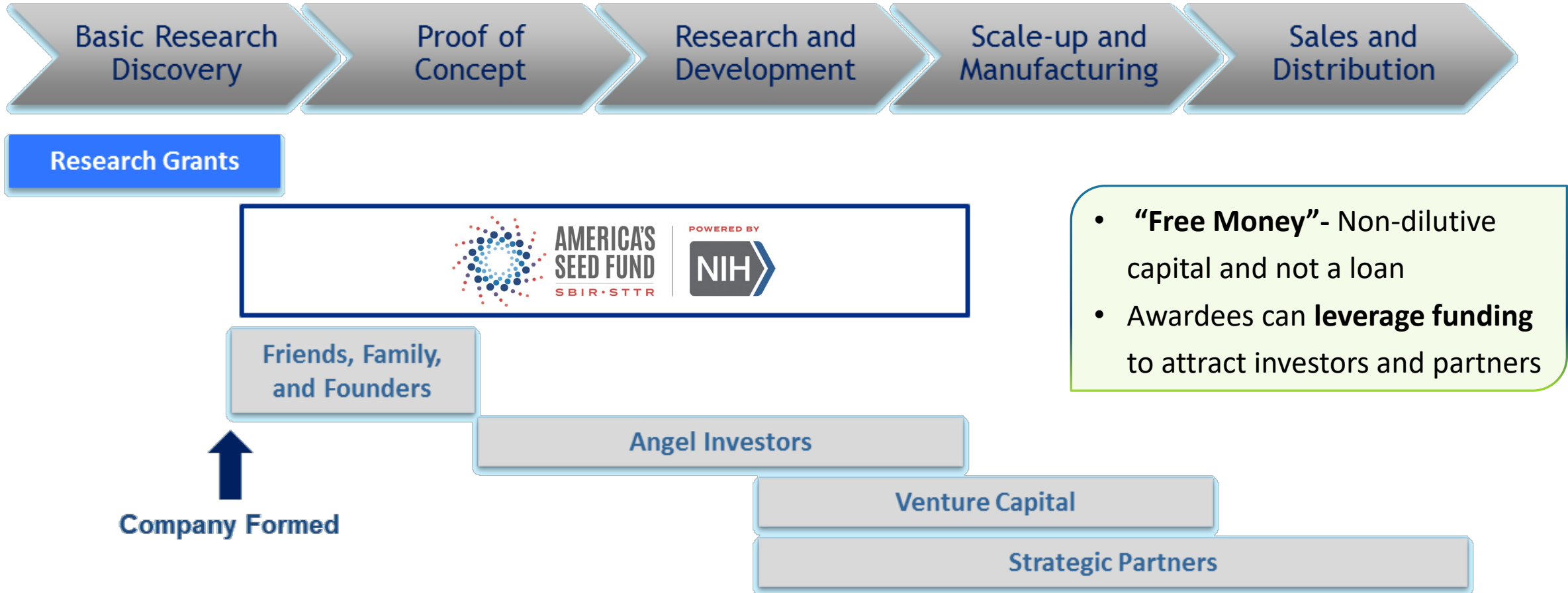
\$1.2 billion set-aside for small business concerns to engage in federal R&D -- with potential for commercialization

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



Small Business Transition Grant for New Entrepreneurs

Clinical Trial Not Allowed:
SBIR ([PAR-24-131](#)) and STTR ([PAR-24-133](#))

Clinical Trials Required:
SBIR ([PAR-24-132](#)) and STTR ([PAR-24-134](#))

Purpose: Foster early-career scientists transitioning to entrepreneurship by supporting:

- Research and development efforts at the small business *and*
- Entrepreneurial training, mentoring and career development

Investigators are expected to grow their entrepreneurial skill set while working in a small business to develop promising technologies and products

SBIR and STTR Critical Differences

Award is always made to the small business

Partnering Requirement

SBIR

Permits partnering

Work Requirement

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

Principal Investigator

Guidelines: Primary employment (>50%) 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

Employed by either the research institution partner or small business

Small Business Eligibility

*Determined at the
time of award*

- 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

Eligible Individuals

Contact Program Director/Principal Investigator (PD/PI) is limited to scientists, engineers, and health professionals who are **new to research entrepreneurship and have not independently led significant research programs.**

Per Section III:

- Contact PD/PI must have never been:
 - An independent PD/PI on an NIH or CDC research grant (R series and equivalent cooperative agreement or contract activities), *or*
 - Corresponding non-NIH peer-reviewed research grant, over \$100,000 direct costs per year, *or*
 - Project Lead on a sub-project of a program project (P01) or center (P50) grant
- Contact PD/PI must be a U.S. Citizen or Lawful Permanent Resident
- An individual may serve as the PD/PI for no more than one application

Eligible Individuals (continued)

- The Contact PD/PI should possess research skills/experience in scientific discovery or technology development.
- The Contact PD/PI may be:
 - A new employee hired for the purpose of leading the program described in the application
 - An existing employee newly elevated to a position of genuine leadership, responsibility, and authority for the purpose of directing the activities proposed in the application
- Multiple PD/PIs are allowed
 - Additional investigators can serve as MPI and provide support to the transition of the scientist to a PD/PI role
 - Transitioning scientist should be listed as the contact PD/PI on the application and have a clearly defined role that allows sufficient autonomy to exercise genuine leadership and independence that enables personal and professional growth

Clinical Trials

NIH Definition of a Clinical Trial

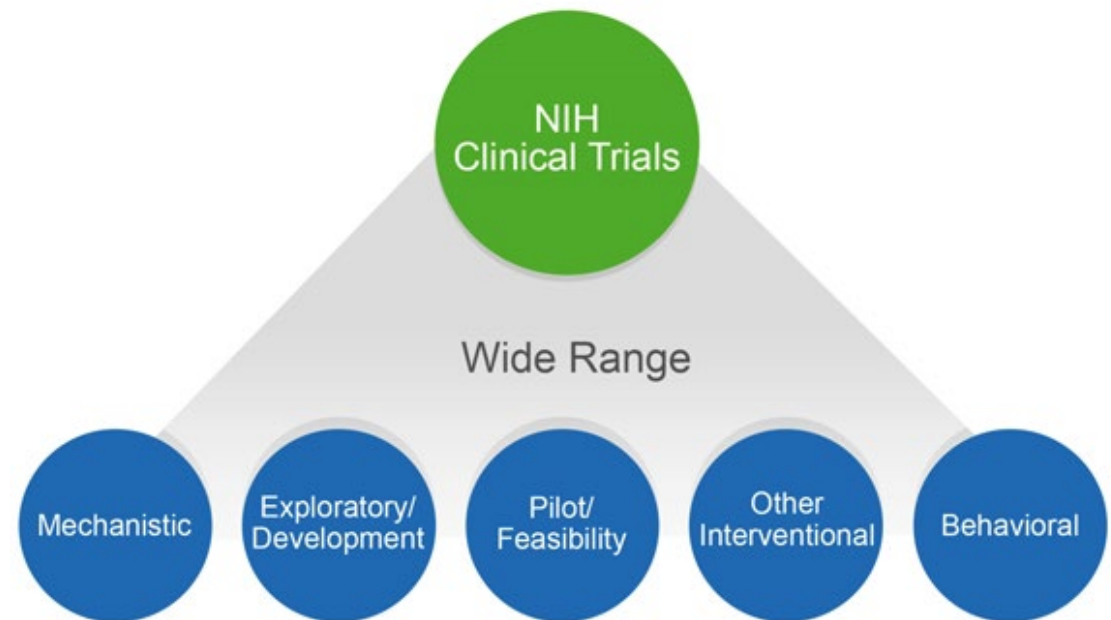
A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

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>



Participating Institutes/Centers

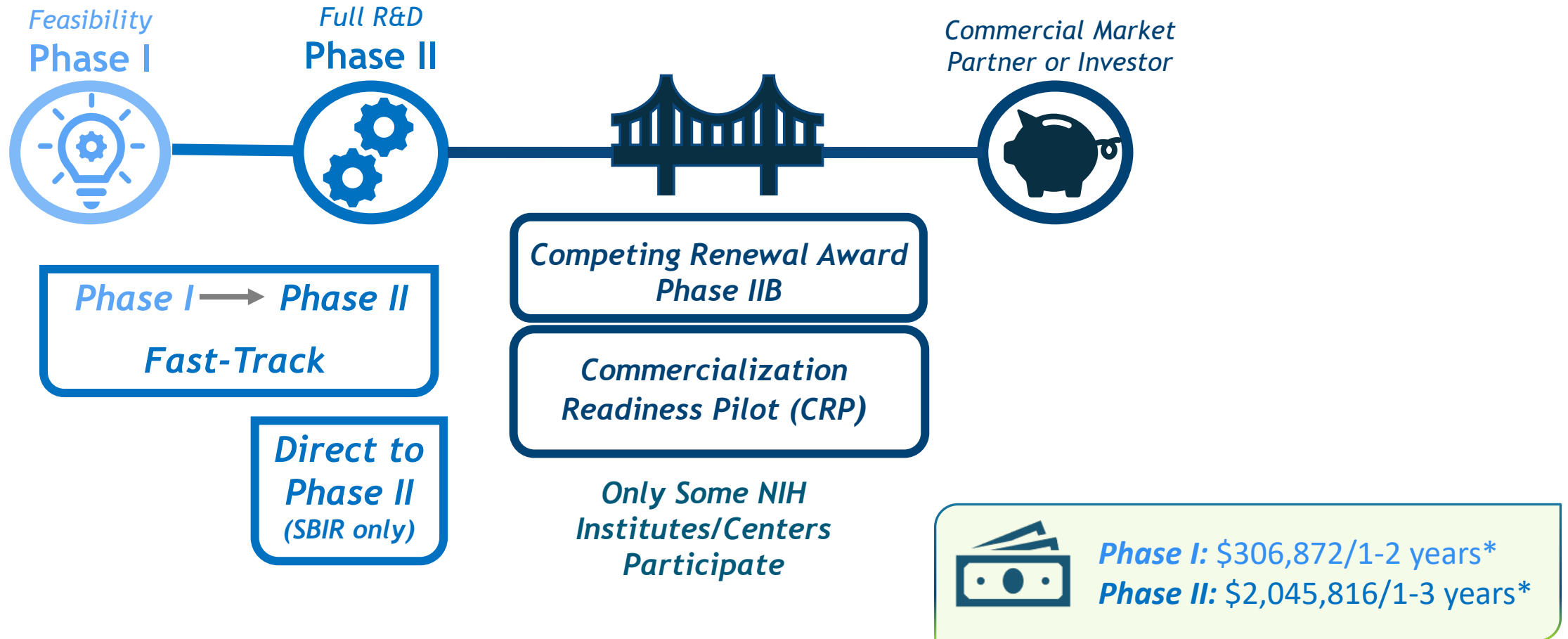
- Translational Sciences (NCATS)*
- Complementary/Integrative Health (NCCIH)
- Eye (NEI)
- Genome (NHGRI)
- Heart, Lung, Blood (NHLBI)
- Aging (NIA)
- Alcohol (NIAAA)
- Arthritis, Musculoskeletal, Skin (NIAMS)*
- Child Health (NICHD)
- Drug Abuse (NIDA)
- Deafness/Communication (NIDCD)
- Dental/Craniofacial (NIDCR)⁺
- Diabetes, Digestive, Kidney (NIDDK)^{*+}
- Environmental Sciences (NIEHS)*
- General Medicine (NIGMS)*
- Nursing (NINR)
- Library of Medicine (NLM)
- Occupational Safety/Health (NIOSH/CDC)⁺

*Does not allow for Clinical Trials

+ SBIR Only

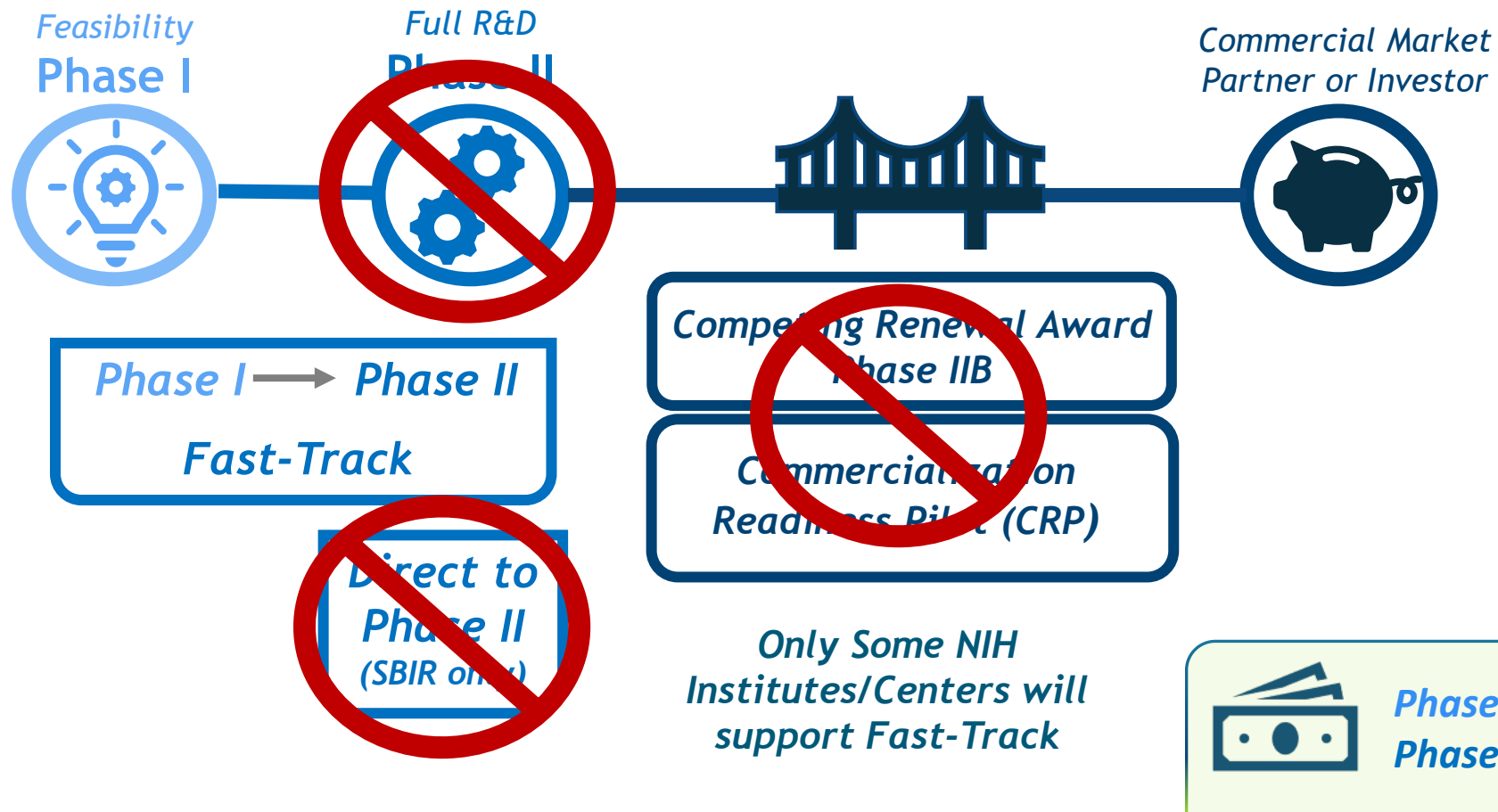
IMPORTANT: Read the Institute/Center Priorities in the Notice of Funding Opportunity!

Phased Programs



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

Allowed Phases: Transition Grant



*NIH, CDC, ARPA-H 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

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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

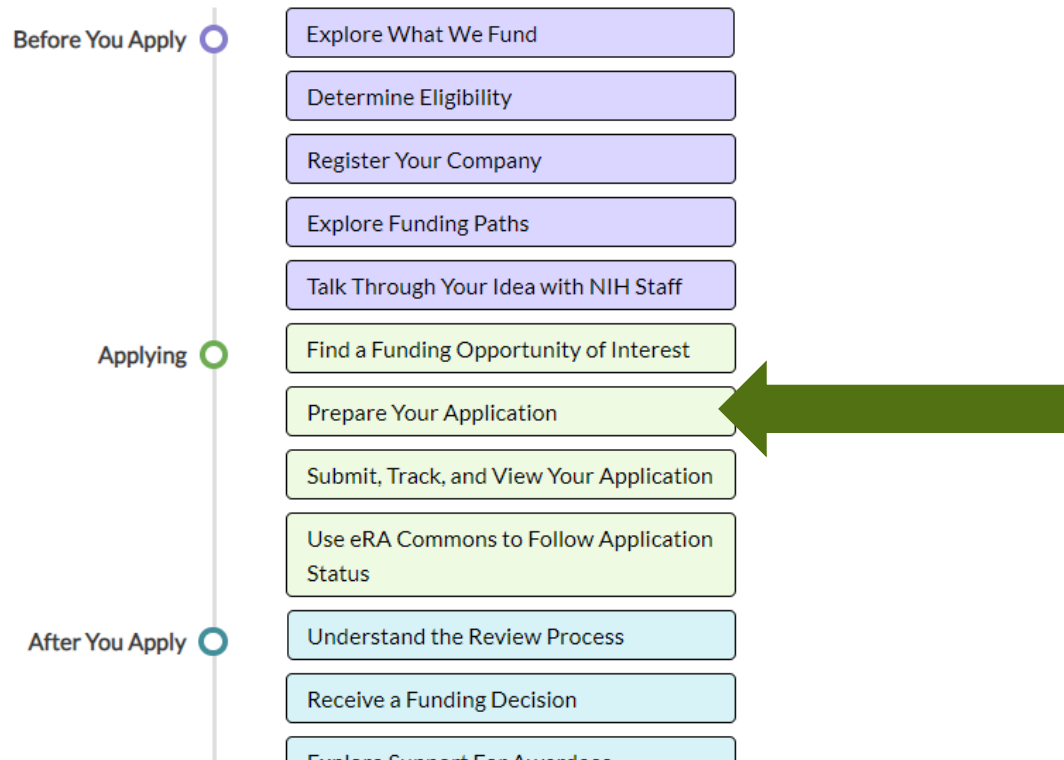
Transition Grant Uses Standard Receipt Dates

Resources

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](#)

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

Programs for Applicants:

- [State Resources through SBA FAST Program](#)
- Health Disparities Pre-Application (HDPReAPP) Program
- NIAID Applicant Assistance Program

Letter of Intent

***Not Required
Not Binding
Not Part of Application Review***

- Includes the following:
 - Descriptive title of proposed activity
 - Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
 - Names of other key personnel
 - Participating institution(s)
 - Number and title of this funding opportunity
- The letter of intent should be sent to:

NIH SEED (Small business Education and Entrepreneurial Development)
Email: SEEDinfo@nih.gov

Key Components: Mentorship

***IMPORTANT: Mentoring Letter of support is required!
Follow the instructions in the Notice of Funding Opportunity***

Applications **must** identify at least one mentor who will facilitate the successful completion of the project (both technical and commercial)

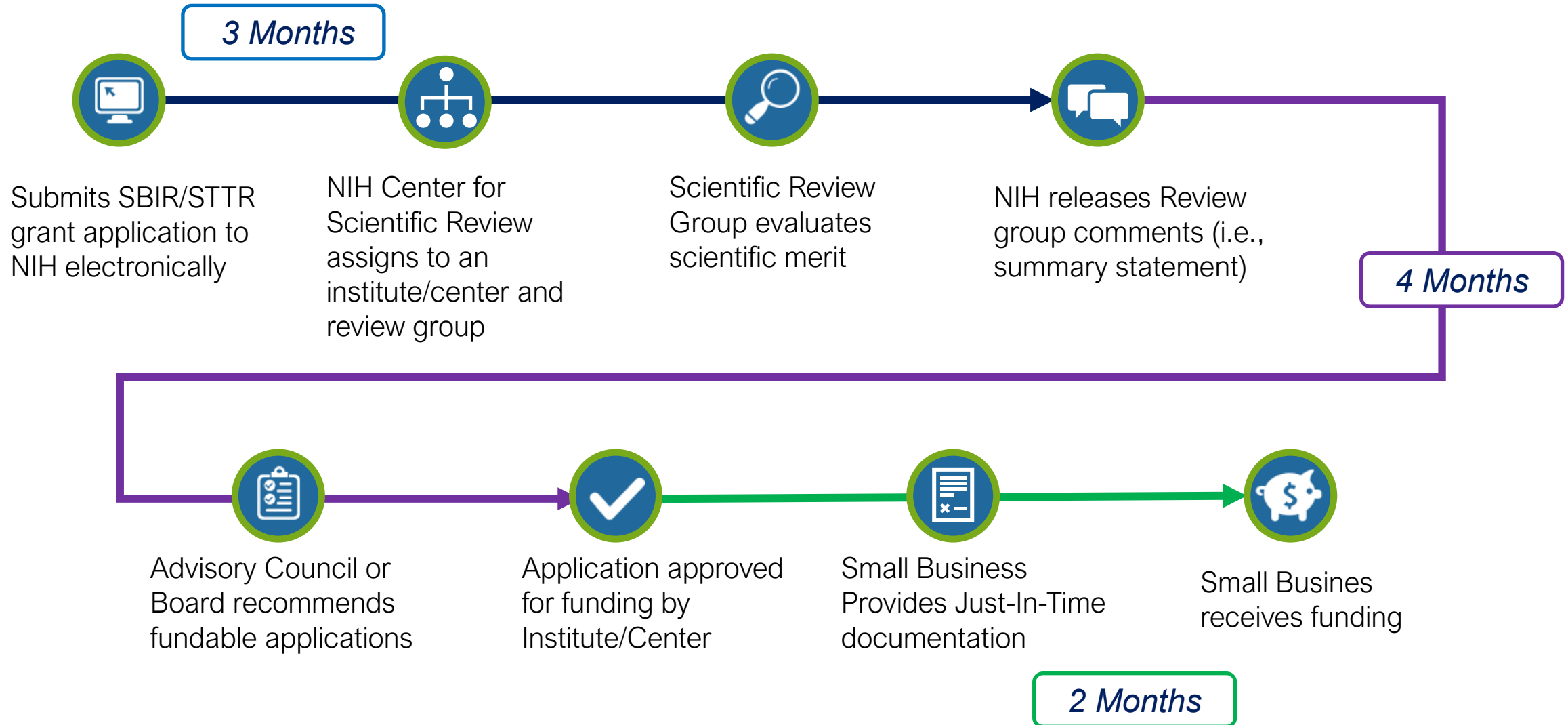
- Mentor must be committed to the goals of the transition award
- Mentor is expected to have prior experience in mentoring entrepreneurs
- Mentor must be listed as key personnel
 - Not required to be affiliated with the applicant small business
 - May not serve as a multiple PD/PI (MPI)
 - Required to commit at least 5% time or 0.6 calendar months to these obligations
- A mentoring team can be identified to meet the mentoring requirement
 - One individual must be identified as the primary mentor and fulfill the eligibility criteria above
 - Other members of the mentoring team do not need to fulfill the criteria

Key Components: Career Development Plan

IMPORTANT: A Career Development Plan is Required!
Follow the instructions for the in the Notice of Funding Opportunity

- Cannot exceed three pages
- Include clear milestones and success criteria
- Organized into the following sections:
 - Section 1: Background and Project Fit
 - Section 2: Career Objectives and Plan for Professional Growth
 - Section 3: Mentor Utilization
- Mentors should play a key role in identifying appropriate training opportunities

NIH Application & Review Process



Review Process

Scored Review Criteria

(score 1-9)

Significance:

Real Problem/Commercial Potential

Investigators:

Investigator and Team

Innovation:

Competitive Advantage

Approach:

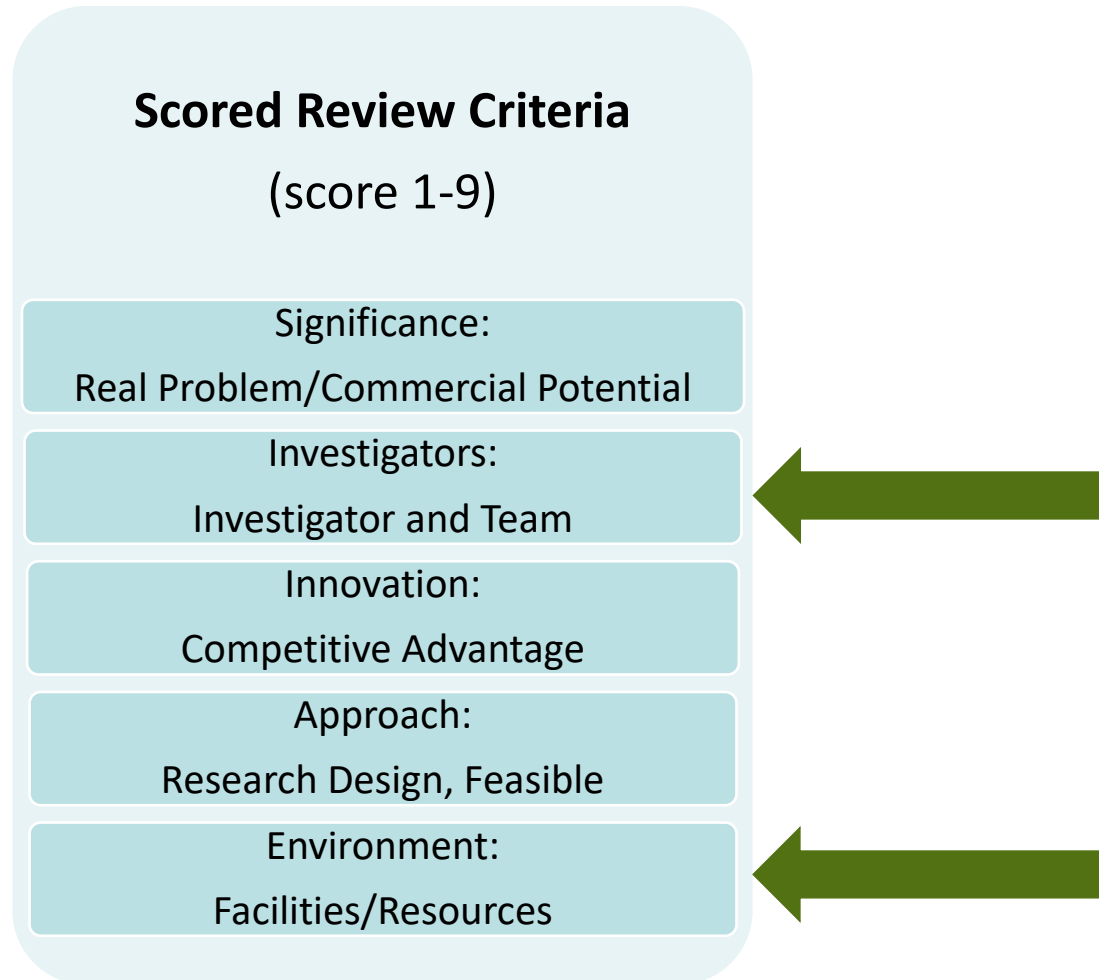
Research Design, Feasible

Environment:

Facilities/Resources

- Each application has 3 assigned reviewers
- Five Review Criteria that reviewers score individually
- 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!

Specific to this Notice of Funding Opportunity



- Evaluated for scientific/technical merit of research project *and* contribution to career development of PD/PI
- Additional Questions:
 - Investigator(s)
 - Environment
 - Additional Review Criteria:
Entrepreneurial Career Development

IMPORTANT: Read the Review Criteria (Section V) in the Notice of Funding Opportunity

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



“ 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.”

Most Important Piece of Advice

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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!

Notice of Funding Opportunity
Section VII: List of Agency Contacts
Scientific/Research Contact(s)

Not sure who to contact?

Email: SEEDinfo@nih.gov

List of SBIR Program Managers:

<https://seed.nih.gov>

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

NIH > RePORT > RePORTER

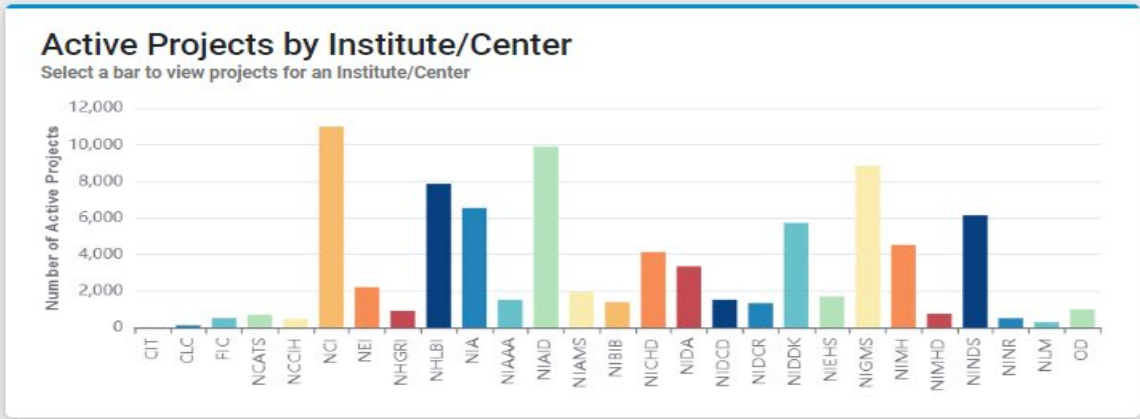
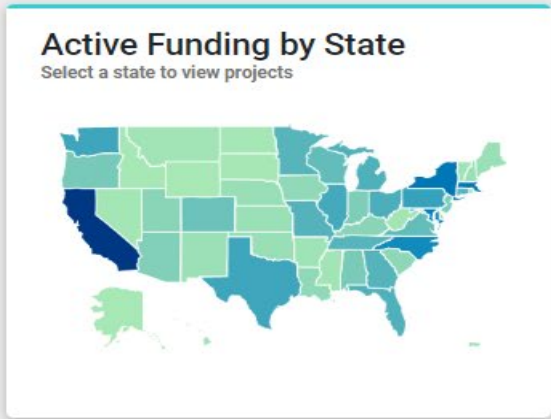
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Advanced Projects Search

Fiscal Year ?

Current FY is 2021

Principal Investigator (PI) ?

PI Names or Profile IDs, semicolon ";" separated

Organization ?

Enter at least 3 characters to search

Matchmaker

Find potential Program Officials, ICs, and review panels for your research.

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Questions?

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SEEDinfo@nih.gov



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The NIH Guide for Grants and Contracts:

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