Navigating NIH Small Business Grant Opportunities

STEPHANIE FERTIG, MBA

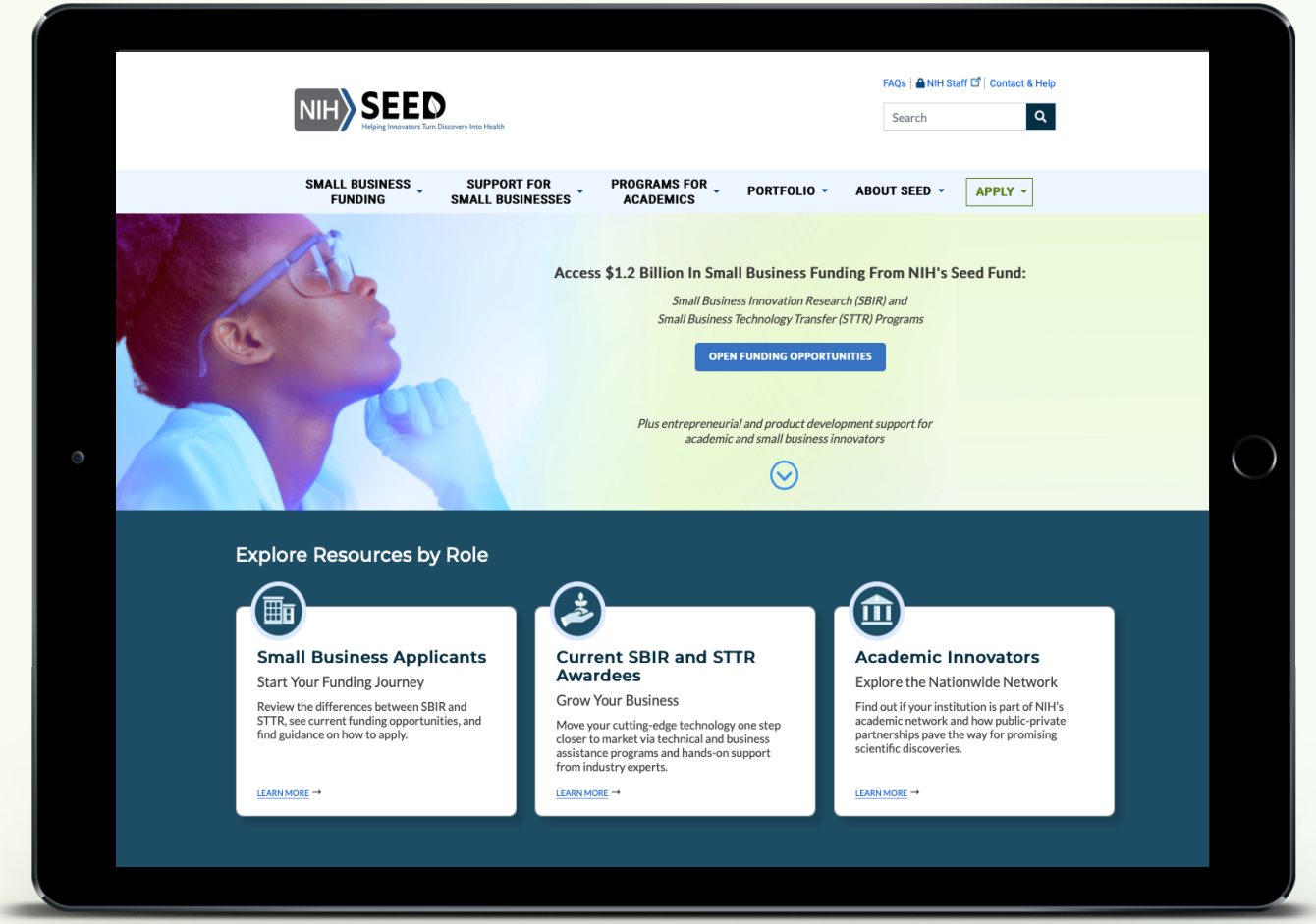
Director, NIH Small Business Program
SEED (Small business Education & Entrepreneurial Development)

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

This presentation may include presenter's notes.

NIH SEED

Small Business Program Website



http://seed.nih.gov

HHS Mission and Divisions

National Institutes of Health
Turning Discovery Into Health

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.

Food and Drug Administration
SBIR $2 million

Centers for Disease Control and Prevention
SBIR $9 million

National Institutes of Health
SBIR and STTR $1.4B

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

Administration for Community Living
SBIR $4 million

NIH Mission

National Institutes of Health
Turning Discovery Into Health

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

$1.4 Billion Dedicated Funding via Set-aside from NIH's R&D Budget

SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

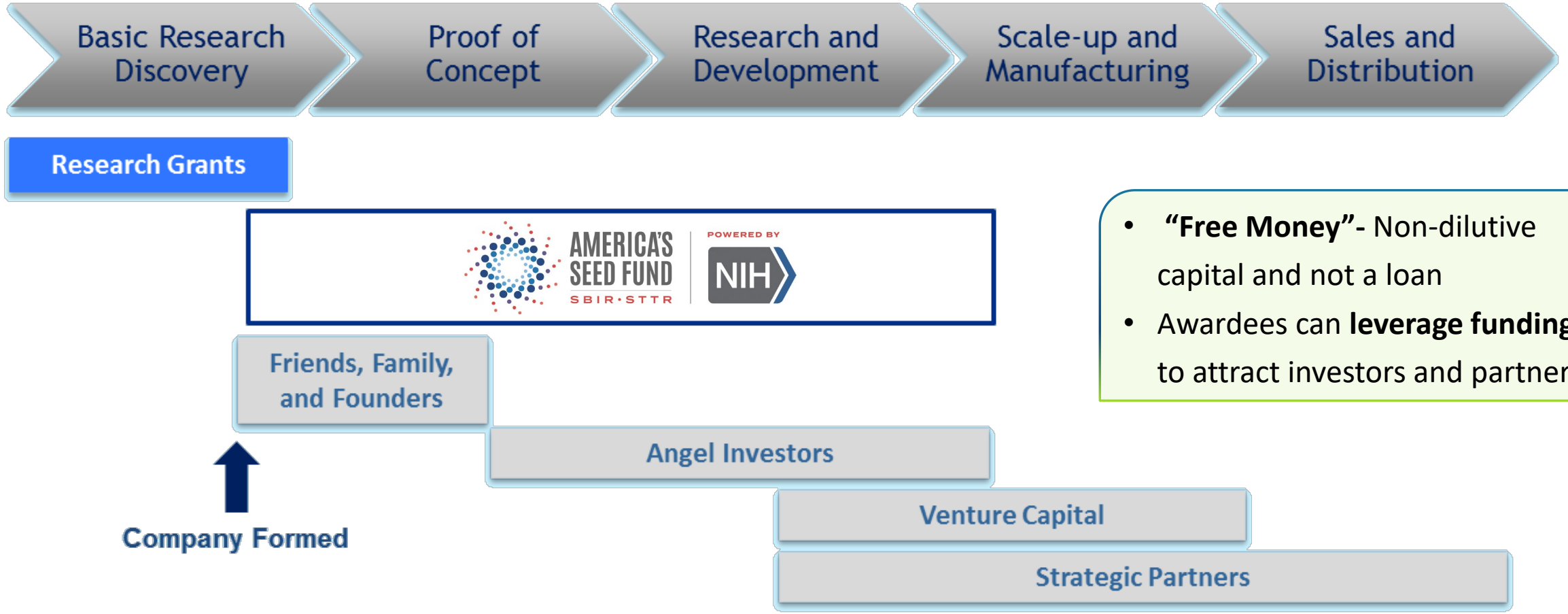
$1.25 billion set-aside for small business concerns to engage in federal R&D -- with potential for commercialization

SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM

$177 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



- **"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!

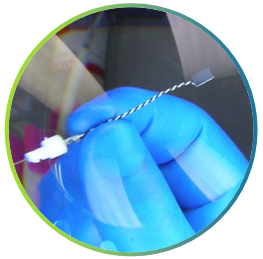
Myth Busted

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

seed.nih.gov/portfolio/stories

PINNACLE TECHNOLOGY INC

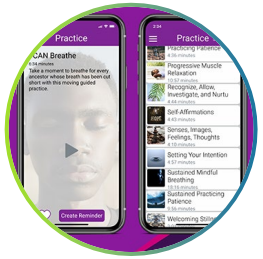


Biomedical company advances Brain Disorder Research

FHC
Neural microTargeting™ Worldwide

Rural company goes deep in the brain to treat movement disorders

trifoia®



Digital learning company supports parents, teachers, underserved communities

Eligibility Criteria

Determined at the time of award- Applicants provide either an SBIR or STTR Funding Agreement Certification

- 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

Phased Programs

Phase I → Phase II
Fast-Track

Direct to Phase II (SBIR only)

Competing Renewal Award Phase IIB

Commercialization Readiness Pilot (CRP)

Only Some NIH Institutes/Centers Participate

Phase I: $306,872/1-2 years*
Phase II: $2,045,816/1-3 years*

***NIH, CDC, ARPA-H 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

Funding Opportunities

https://seed.nih.gov

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 Trials Not Allowed:
SBIR (PA-24-245) and STTR (PA-24-247)

Clinical Trials Required:
SBIR (PA-24-246) and STTR (PA-24-248)

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

NOT-OD-24-079
Women's Health Research

SBIR NIH/CDC Contract Pre-Solicitation

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)

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

Webinar Materials and Further Information: Small Business Transition Grant Website

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	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	Guidelines: Primary employment (>50%) with the small business	Employed by <u>either</u> 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

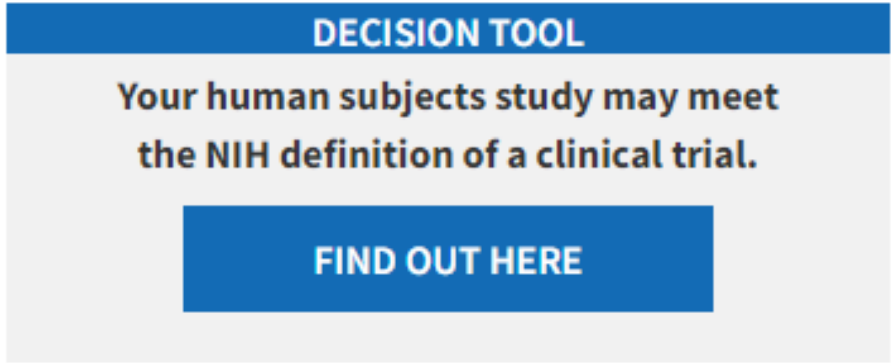
The size of the program does not correlate with the chance of getting an award.

For example, smaller programs (i.e. STTR) or NIH Institutes may have far fewer applications.

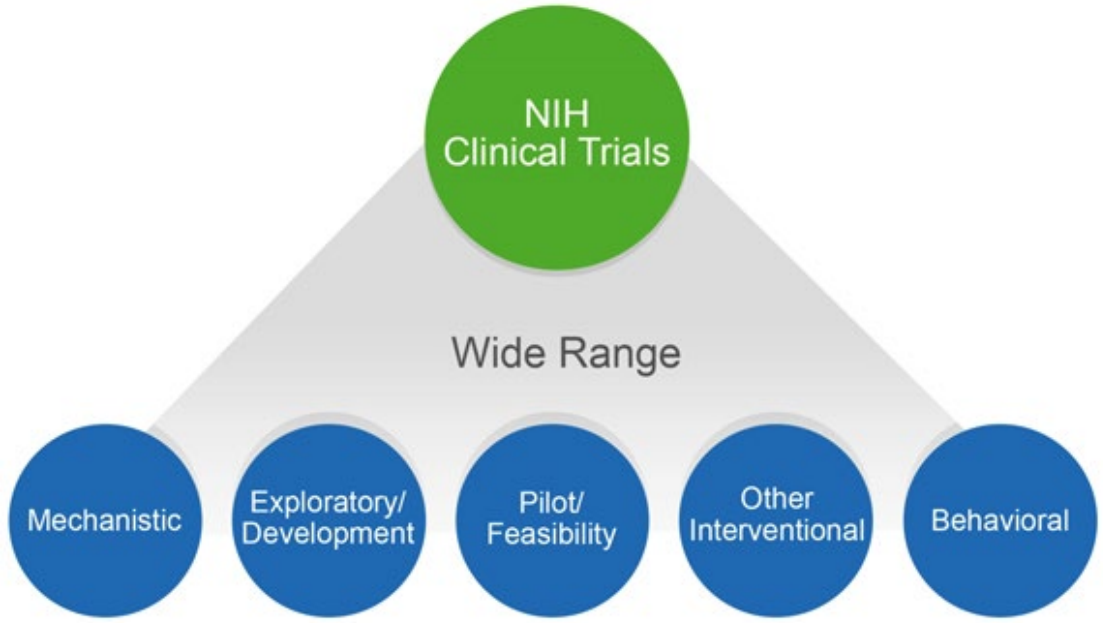
Clinical Trials

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.



https://grants.nih.gov/policy/clinical-trials.htm



Myth 5

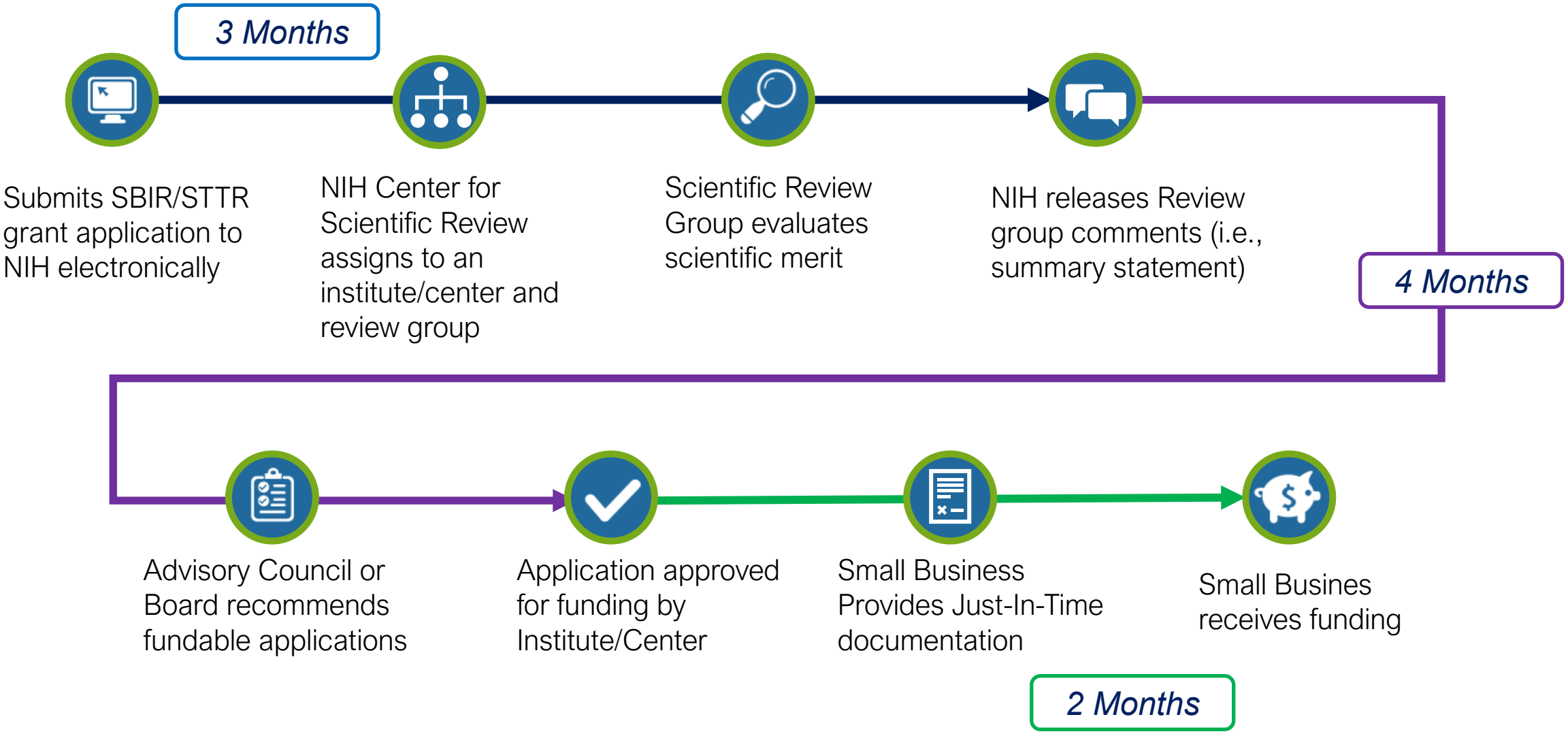
My project is low risk and only has a few human subjects, so it is not a clinical trial.

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



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 (SBC & all Sr/Key Persons)
- SBIR.gov

Two-Factor Authentication is Required

login.gov

Use the same login.gov account for all the registrations!

Myth 6

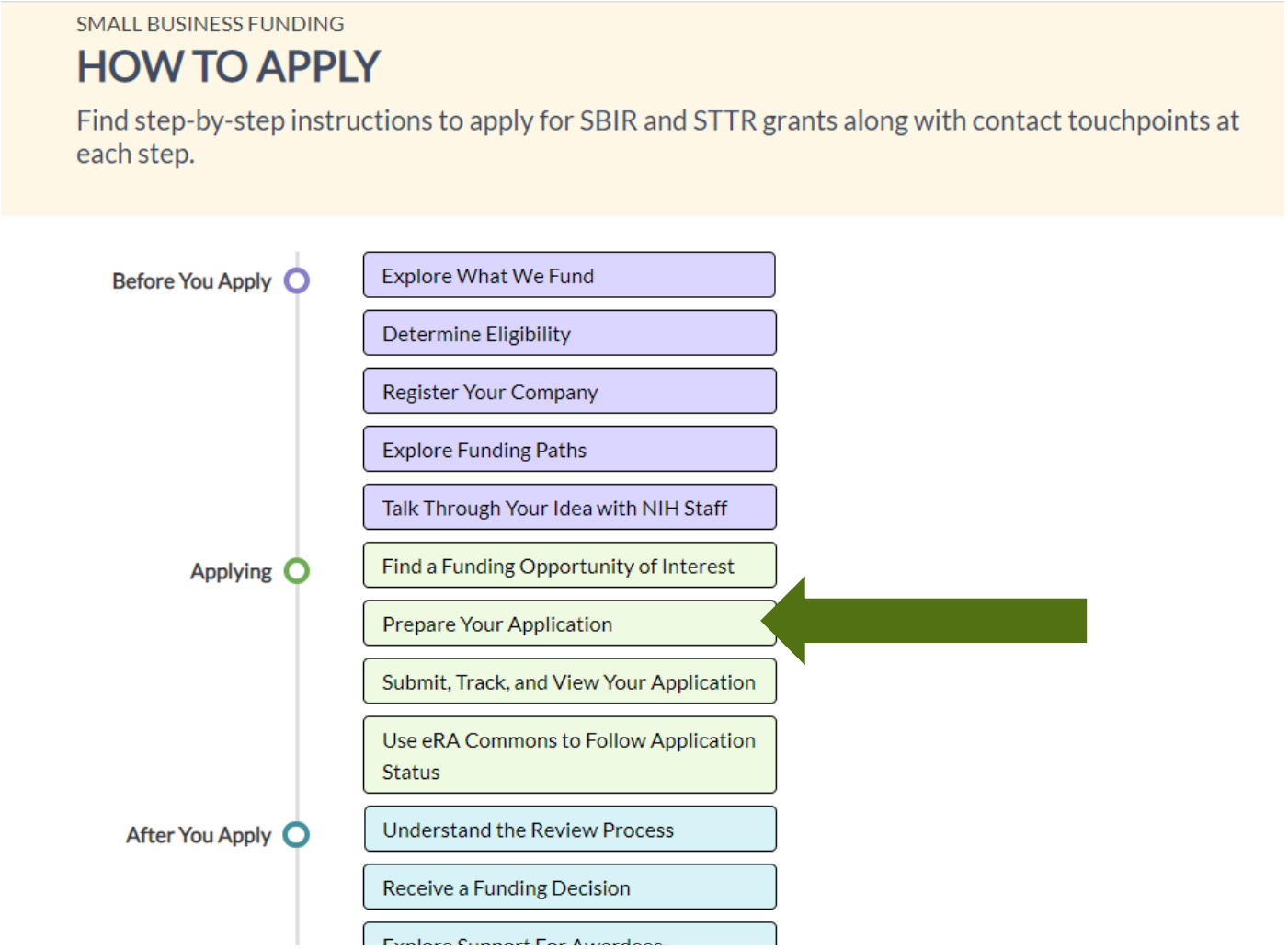
Novice applicants to the program are almost never successful at getting awards.

Myth Busted

~1/3 of the companies receiving SBIR and STTR awards go to new companies.

NIH strongly encourage new applicants!

Resources



Links to:

- **Application Instructions**
- **Annotated Form Set**
- **Sample Applications**
- **State Resources through SBA FAST Program**

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

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:

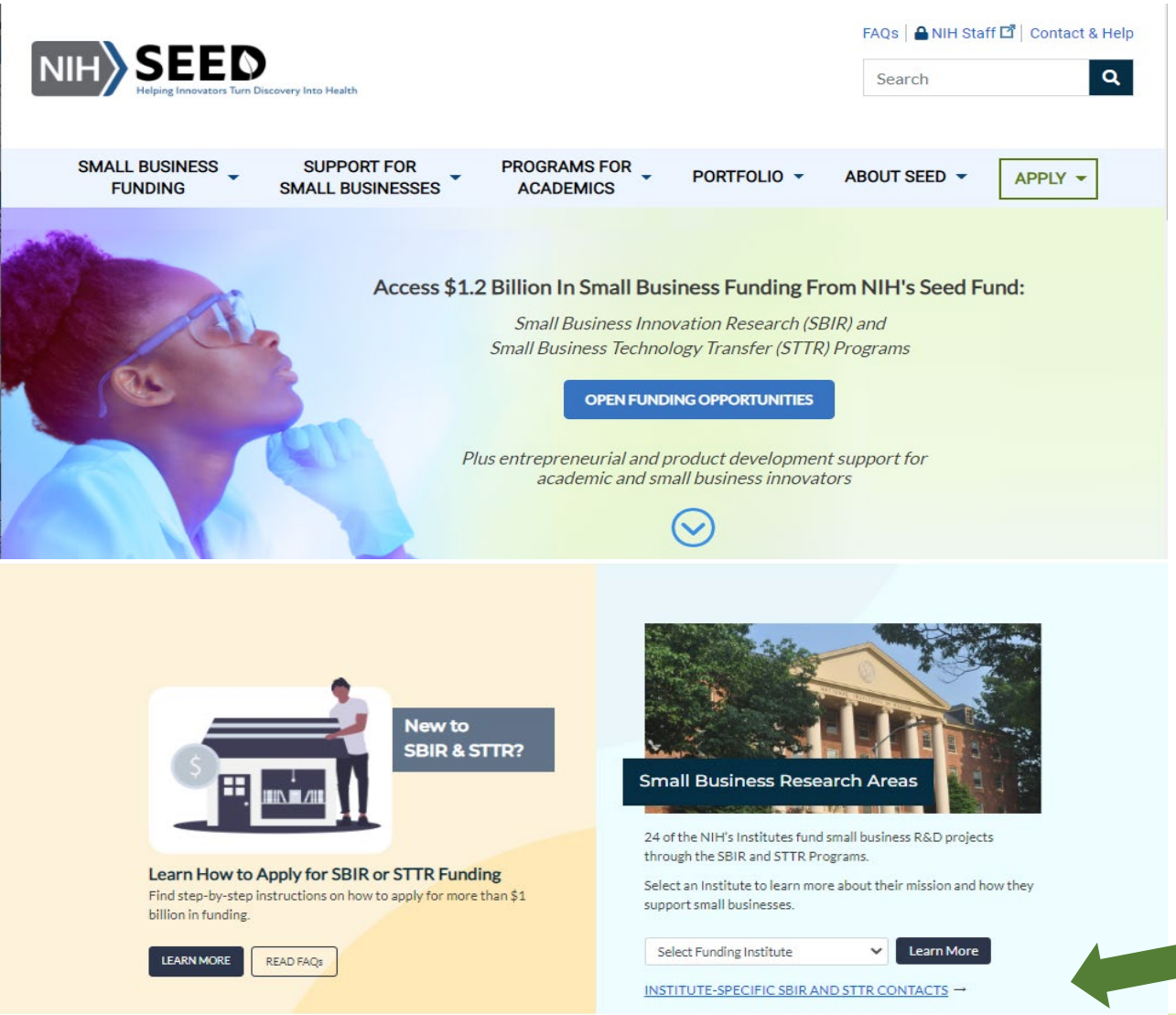
- Business environment and resources (or how you will obtain them) for completing and commercializing the product or service
- Relevant intellectual property associated with the project

Application Tips

- Build a team
- Talk to people about your innovation- be prepared to pivot
- Read the Notice of Funding Opportunity
- Review successful grant applications
- **Talk with a Program officer**
- Follow the instructions
- Write a proposal that addresses the review criteria
- Make it easy to read- Edit and Proofread!
- Write for experts and non-experts
- Let others review your application

Submit Early (Days NOT Hours)

Most Important Piece of Advice



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

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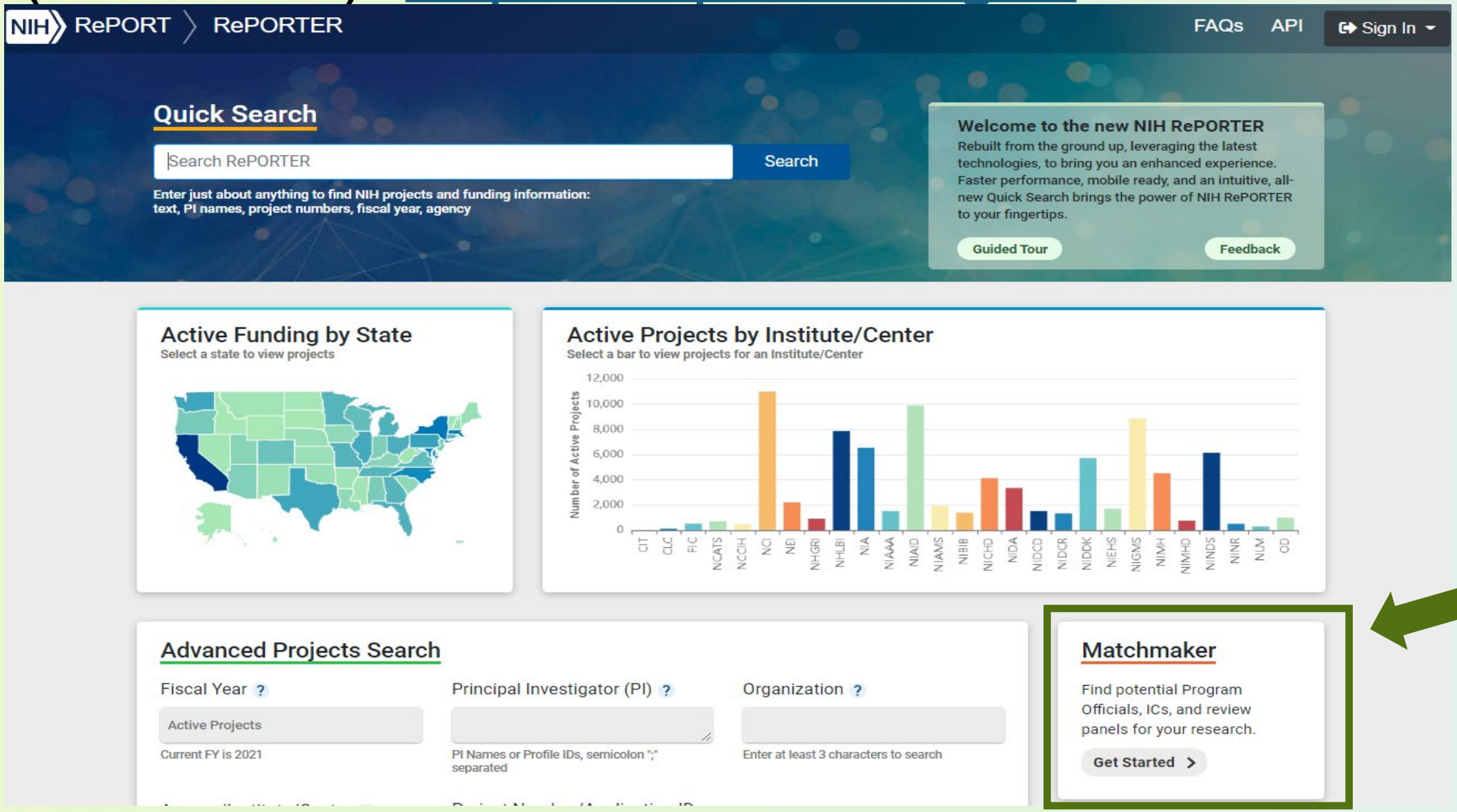


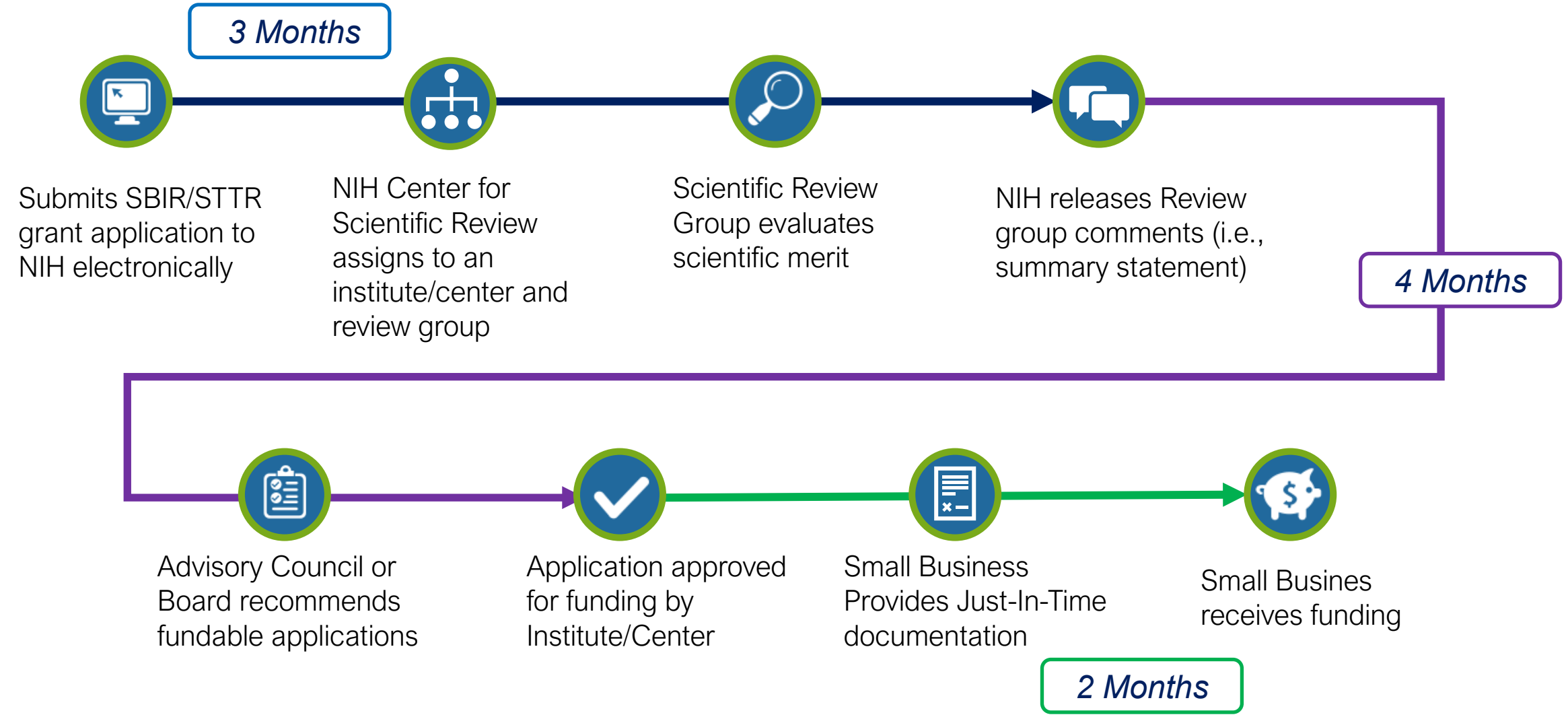
Myth 7

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

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: Competitive Advantage
- 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**

Review Process

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

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!

Common Application Problems

- No Significance: Unimportant problem, unconvincing case for commercial potential or societal impact
- Lack of innovation or advantage over other technologies or products
- Team lacks expertise/experience in a key area
- Unfamiliar with relevant published work

- Approach:
  - Inadequately defined test of feasibility
  - Diffuse, superficial or unfocused research plan
  - Questionable reasoning in experimental approach
  - Failure to consider potential pitfalls and alternatives
  - Unrealistically large amount of work proposed

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

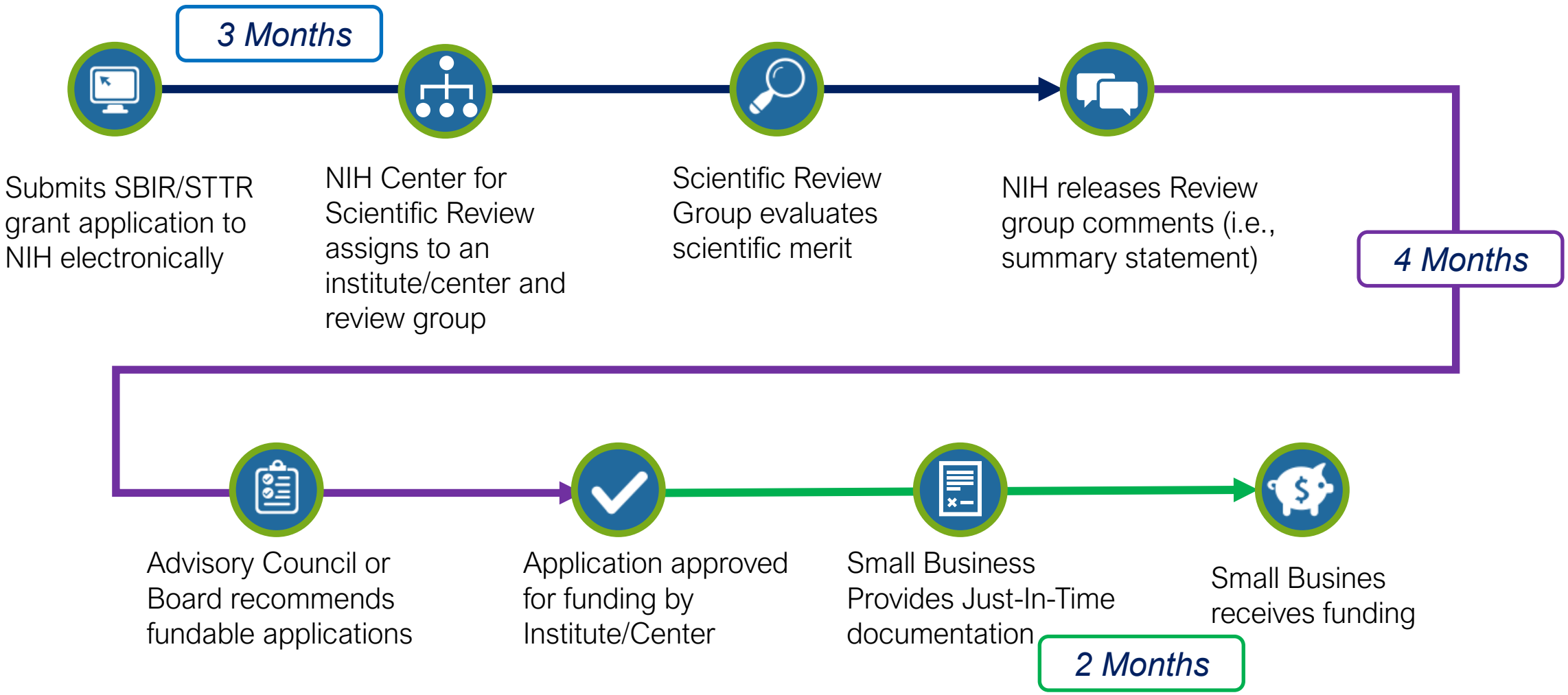
LAVERNE MORROW CARTER, PH.D.

President and Founder

REESI RESEARCH, EVALUATION & SOCIAL SOLUTIONS, INC.
INFORMATION...KNOWLEDGE...ACTION...POWER

[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 of foreign affiliations or relationships DOES NOT automatically disqualify an applicant

Foreign Risk Assessment

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, Financial Ties and Obligations

- NIH may decline to move forward with an award based on security risks as required in the legislation
  - NIH staff and applicants will not be provided details of the assessment
  - Applicants are encouraged to consider if their relationships will pose a security risk

- **For Information and Case Studies:** Foreign Disclosure and Risk Management webpage

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

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

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.

Technical and Business Assistance (TABA) Programs

Phase I: TABA Needs Assessment Request Post-Award

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

Phase II: TABA Funding Request in Application

$50,000 to hire vendor(s) for Technical and Business Assistance
(Follow Instructions to request funds in the application)

https://seed.nih.gov/TABA

Innovator Support

Partnering and Investment Opportunities

BIOTECH SHOWCASE™

LIFE SCIENCE NATION
Connecting Products, Services & Capital

BIO International Convention

LIFESCIENCES™ SUMMIT

RESI REDEFINING EARLY STAGE INVESTMENTS

4D Drugs Devices Diagnostics Digital Health MEETS AI

LONGEVITY HEALTH & INNOVATION

THE MEDTECH CONFERENCE
Powered by AdvaMed

MedTechColor

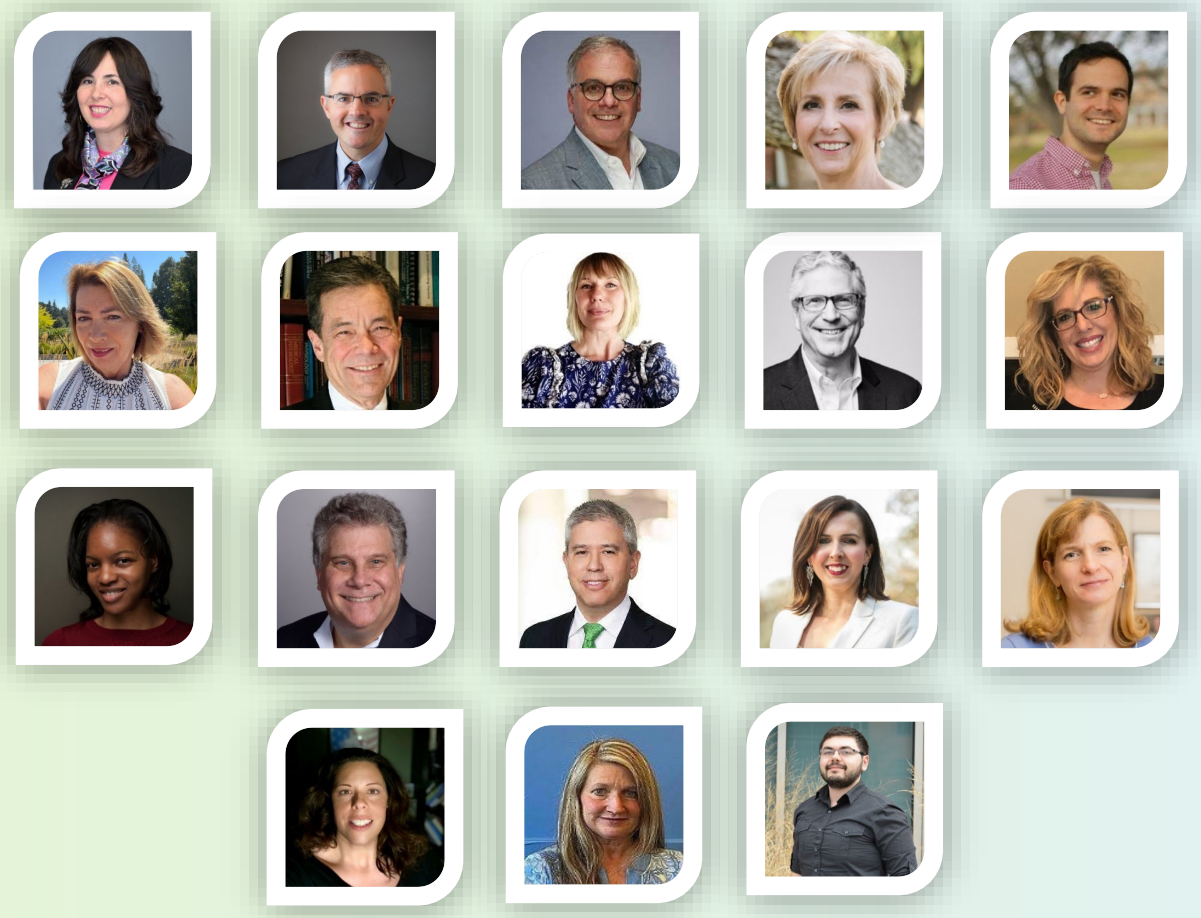
VIVE

ACA
ANGEL CAPITAL ASSOCIATION

Landmark Angels

NIH SEED

Regulatory & Business Development Consultants



Entrepreneurial Support Programs

NIH Entrepreneurship BOOTCAMP

Introduce early-stage (pre-SBIR, pre-company) innovator teams to entrepreneurship, customer discovery, and business model validation
seed.nih.gov/bootcamp

Helps medical device innovators translate biomedical technologies from the lab (concept) to the market (clinic)
nibib.nih.gov/research-program/c3i-program

Funding for Small Businesses to Diversify the Entrepreneurial Workforce

Support research and entrepreneurial experiences for individuals from diverse backgrounds by providing $5,000 to $100,000 depending on their career level
seed.nih.gov/diversity_supp

I-CORPS™ AT NIH

Phase I SBIR/STTR teams conduct 100 interviews over 8 weeks to develop a business model canvas
seed.nih.gov/I-corps-at-NIH

Bonus Myth

NIH bureaucrats are unapproachable and I shouldn't bother 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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The NIH Guide for Grants and Contracts:
http://grants.nih.gov/grants/guide/listserv.htm