America's Seed Fund:
How to Fund your Startup with an NIH Grant

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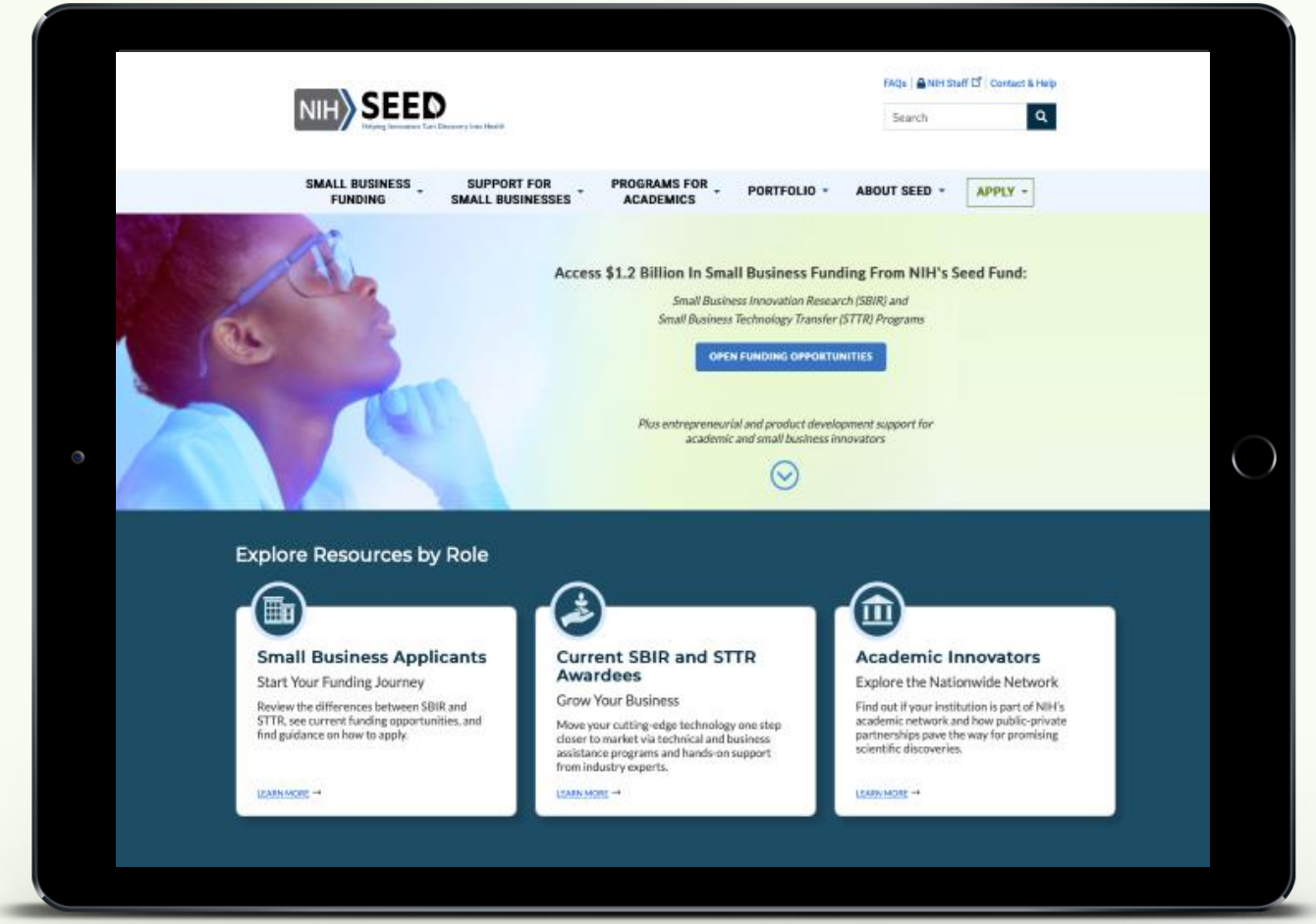
SEED (Small business Education & Entrepreneurial Development)

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

You will see this warning for potential applicant pitfalls!

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
Largest source of early-stage capital for life science in the US

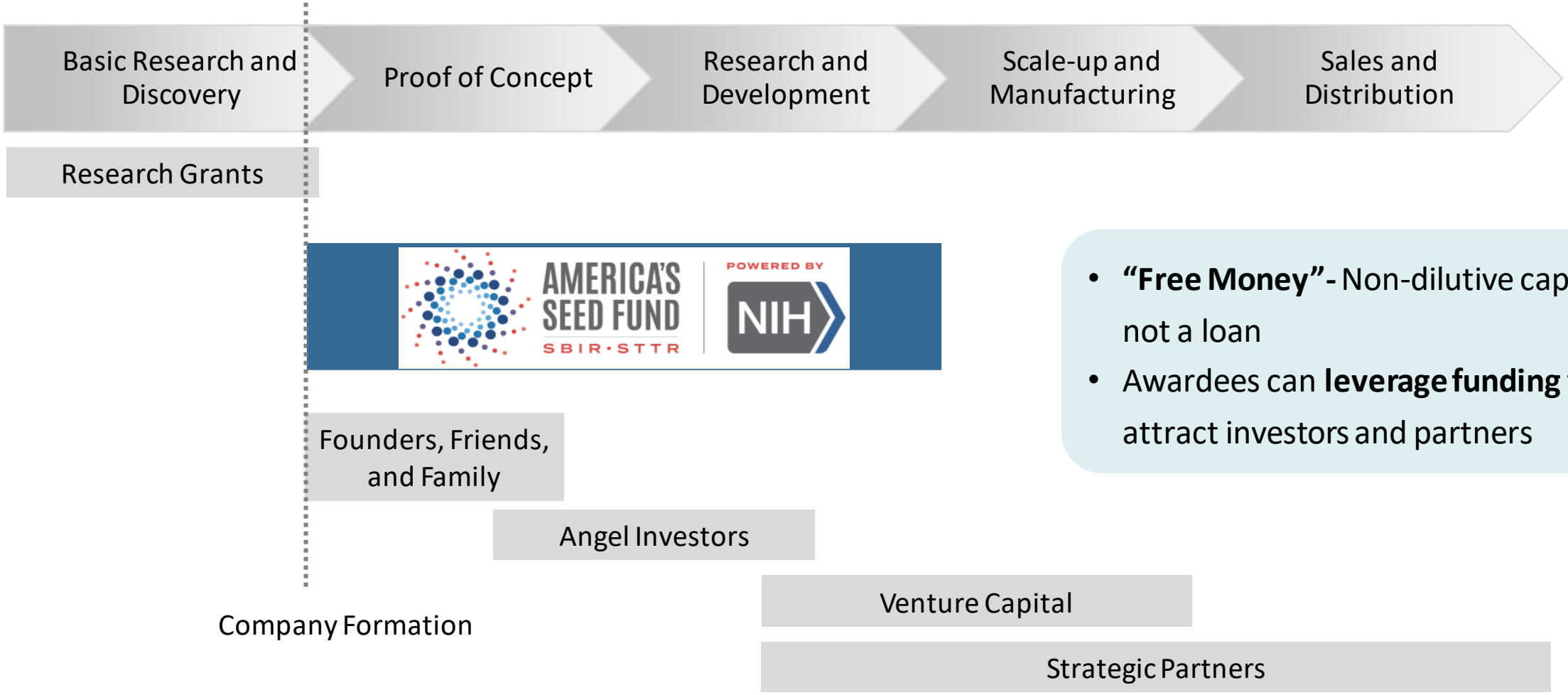
SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

For small business concerns to engage in federal R&D -- with potential for commercialization

SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM

To facilitate cooperative R&D between small business concerns and US research institutions with potential for commercialization

Benefits of NIH Funding



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

- 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

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/

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

Small Business Transition Grant for New Entrepreneurs:
PAR-24-131, PAR-24-133, PAR-24-132, PAR-24-134

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

Notice of Funding Opportunity (NOFO) Includes:

Table of Contents

Part 1. Overview Information — Participating Institutes/Centers

Key Dates — Due Dates

Part 2. Full Text of Announcement

Section I. Notice of Funding Opportunity Description — Purpose/Objectives

Section II. Award Information — Budget Guidance

Section III. Eligibility Information

Section IV. Application and Submission Information

Section V. Application Review Information — Review Criteria

Section VI. Award Administration Information

Section VII. Agency Contacts — Scientific/Research Contacts

Section VIII. Other Information

Phased Programs

Phase I → Phase II
Fast-Track

Direct to Phase II
(SBIR only)

Competing Renewal Award
Phase IIB

Commercialization Readiness Pilot (CRP)

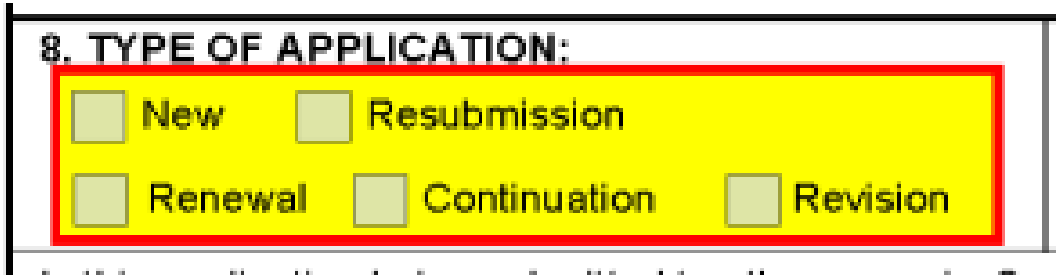
Only Some NIH Institutes/Centers Participate

Phase I: $314,363/1-2 years*
Phase II: $2,095,748/1-3 years*

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

Phase II Applications Types

First Page of Application


8. TYPE OF APPLICATION:

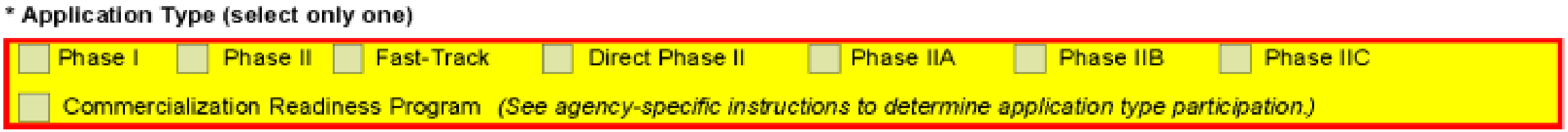
☐ New ☐ Resubmission

☐ Renewal ☐ Continuation ☐ Revision

READ the Instructions to make sure you are selecting the correct one!

SBIR/STTR Instructions for NIH and Other PHS Agencies

SBIR/STTR Information Form


* Application Type (select only one)

☐ Phase I ☐ Phase II ☐ Fast-Track ☐ Direct Phase II ☐ Phase IIA ☐ Phase IIB ☐ Phase IIC

☐ Commercialization Readiness Program *(See agency-specific instructions to determine application type participation.)*

SBIR and STTR Critical Differences

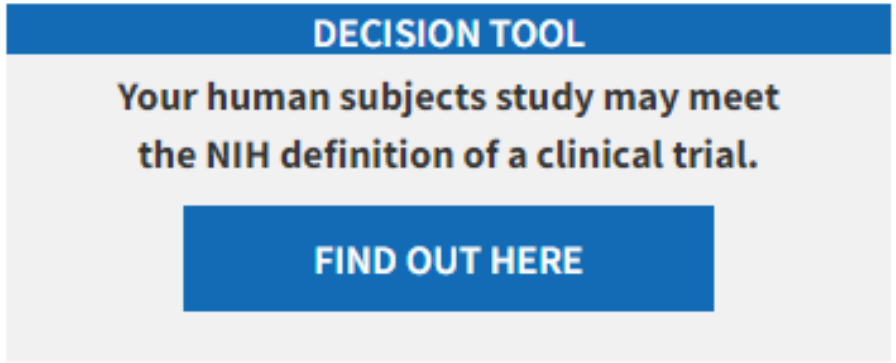
Award is always made to the small business

	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

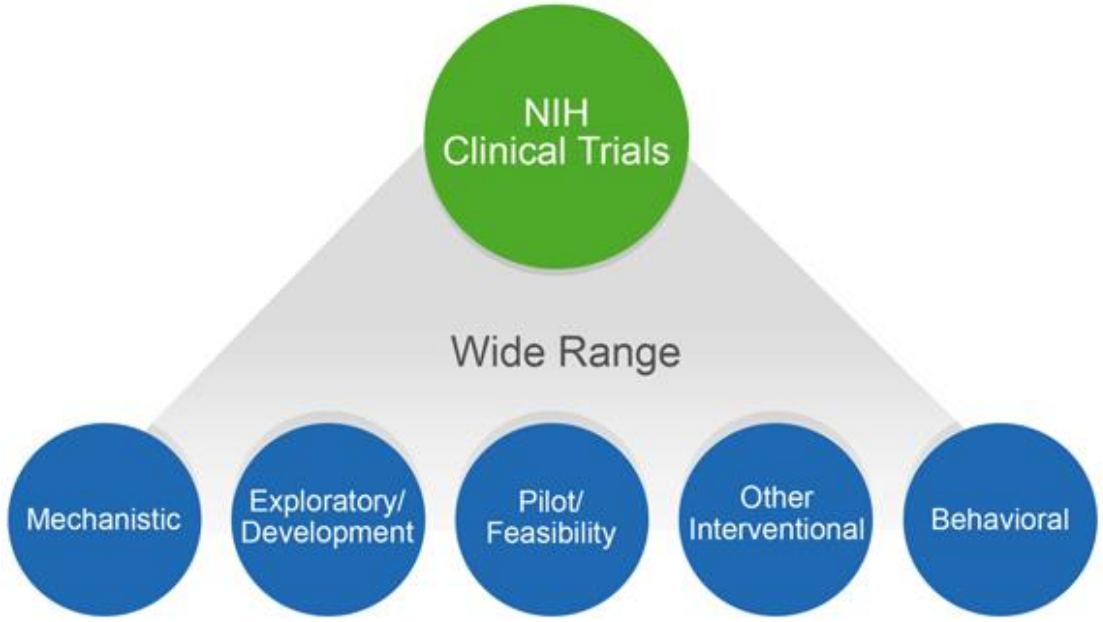
Clinical Trials

NIH Definition of a Clinical Trial

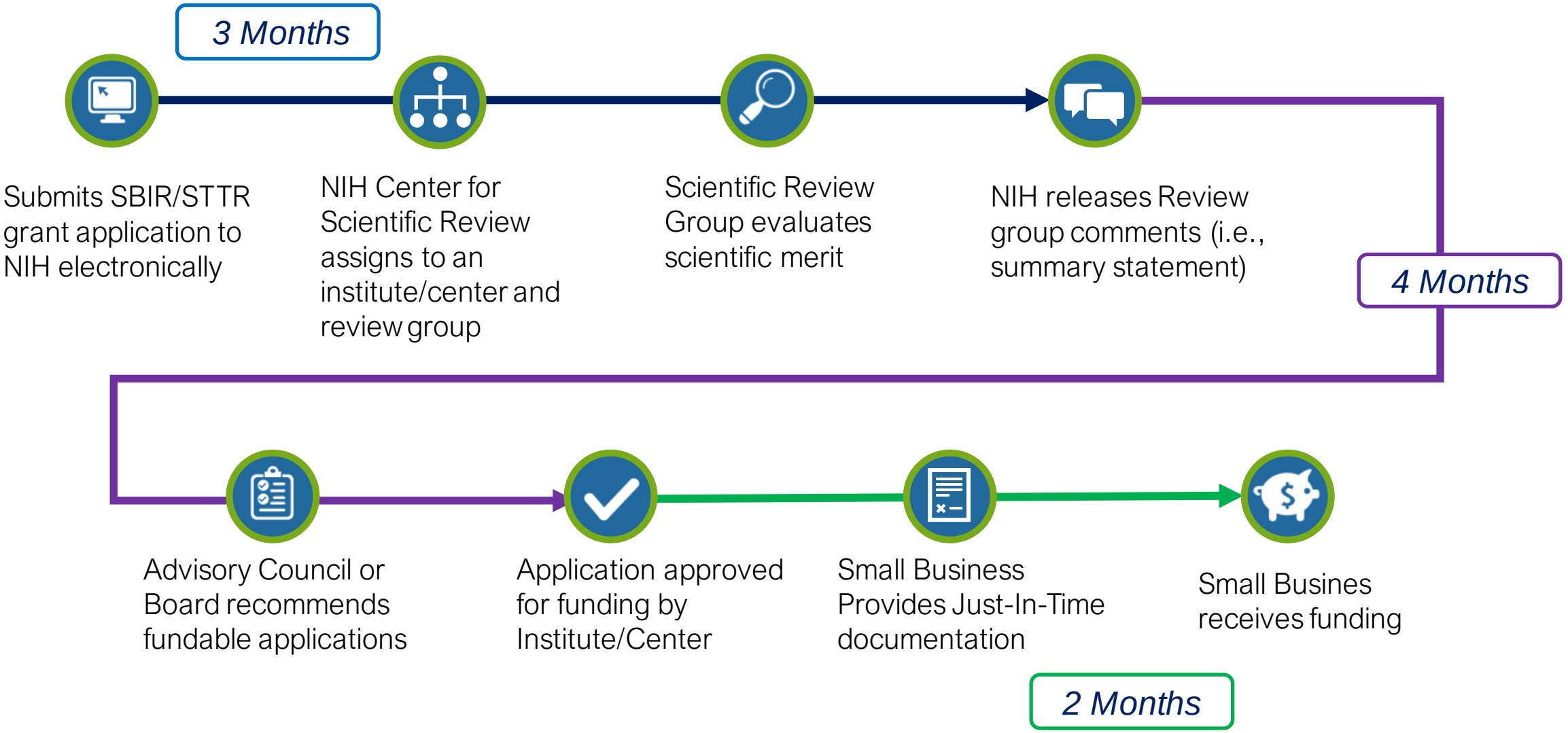
A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.



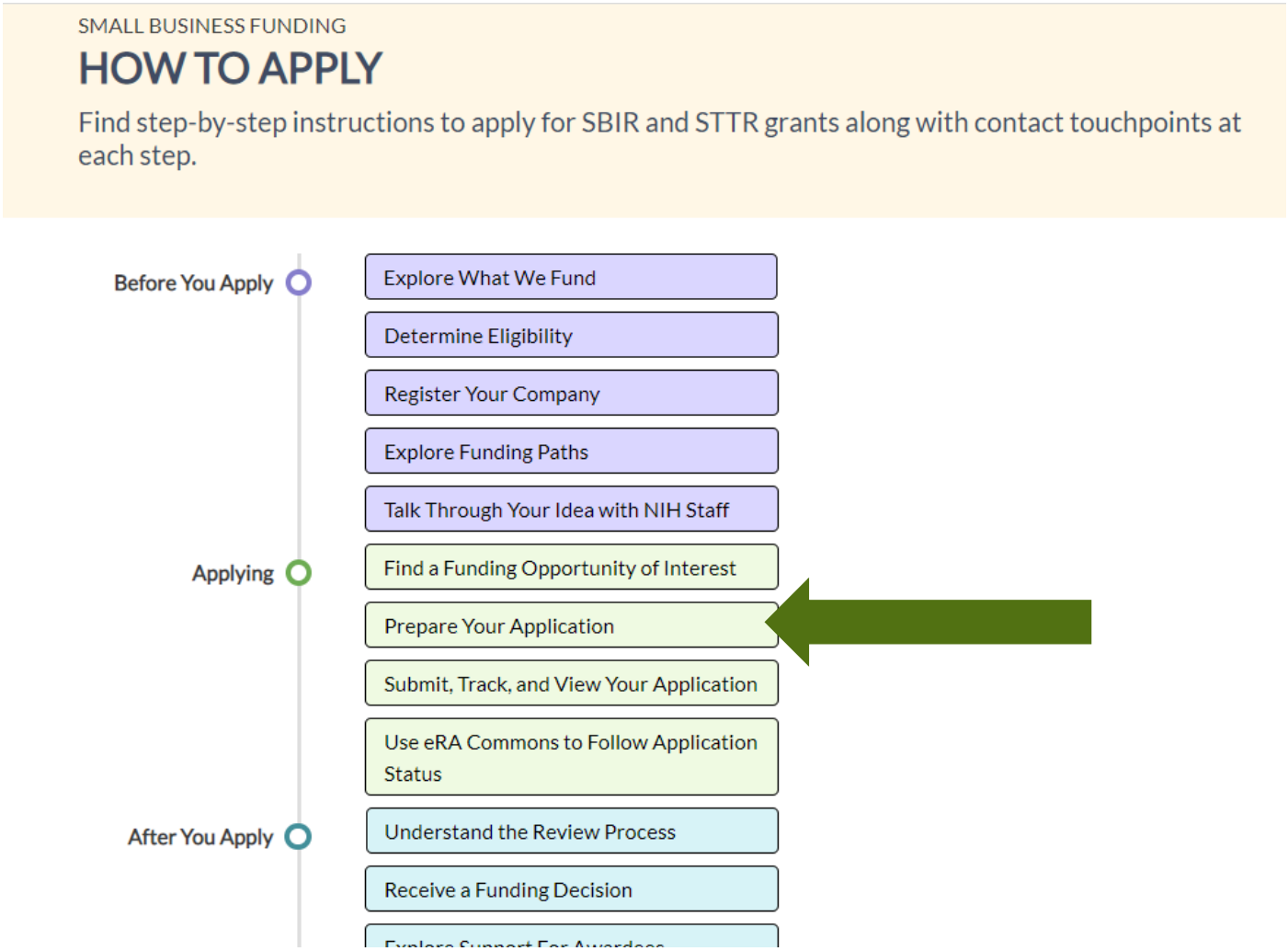
https://grants.nih.gov/policy/clinical-trials.htm



NIH Application & Review Process: Submission



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

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 Senior/Key Personnel)**
- SBIR.gov

Two-Factor Authentication is Required

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

Data Management and Sharing Plan

- Required for SBIR/STTR applications
- See Optional DMSP Format Page for help writing your DMSP
- **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

See Data Management and Sharing Plan webpage for more information and sample plans!

Use of Hyperlinks in Application

The do's and don'ts of hyperlinks in grant applications are simple:

- Do include hyperlinks when explicitly requested in application guide, funding opportunity, or NIH Guide notice instructions
- Do use hyperlinks in relevant citations and publications included in biosketches and publication list attachments
- Don't use hyperlinks anywhere else in your application

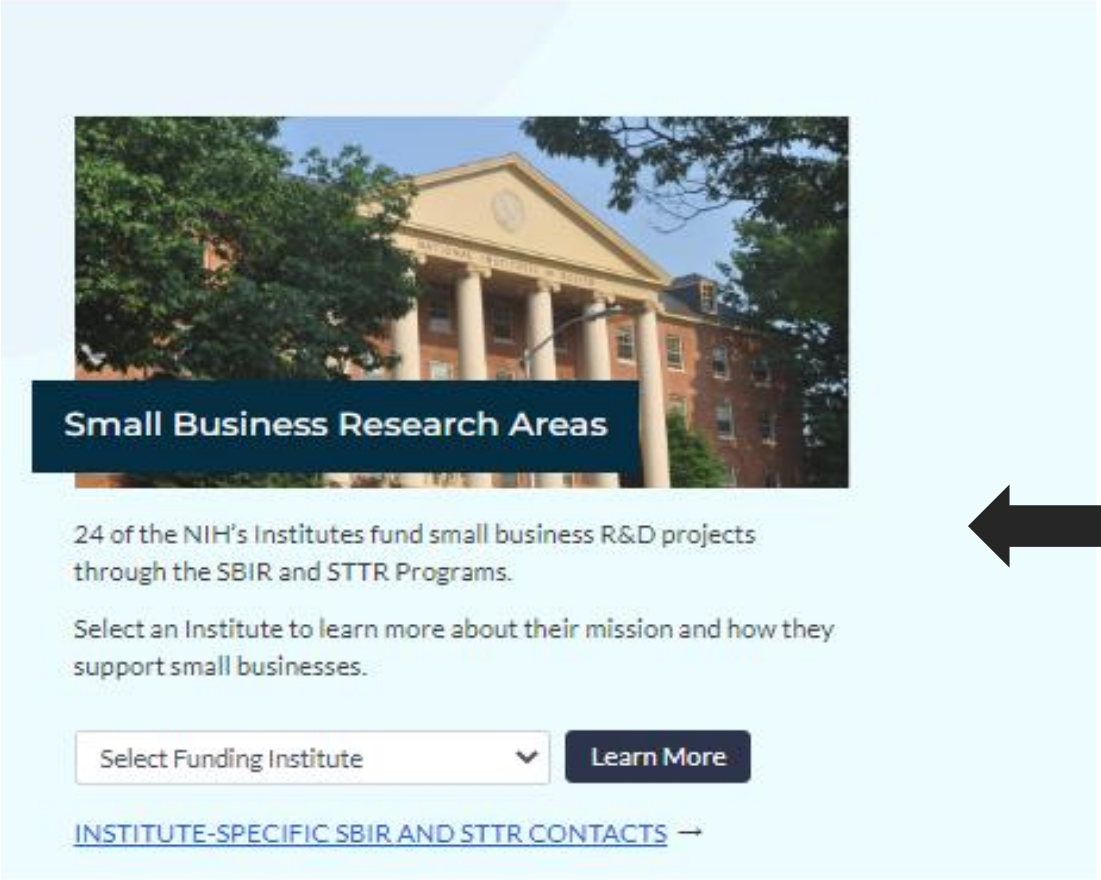
See NOT-OD-20-174 for more information

Application Tips

- Build a team
- Talk to people about your innovation- be prepared to pivot
- Read the Notice of Funding Opportunity
- Follow the instructions
- Review successful grant applications
- 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!

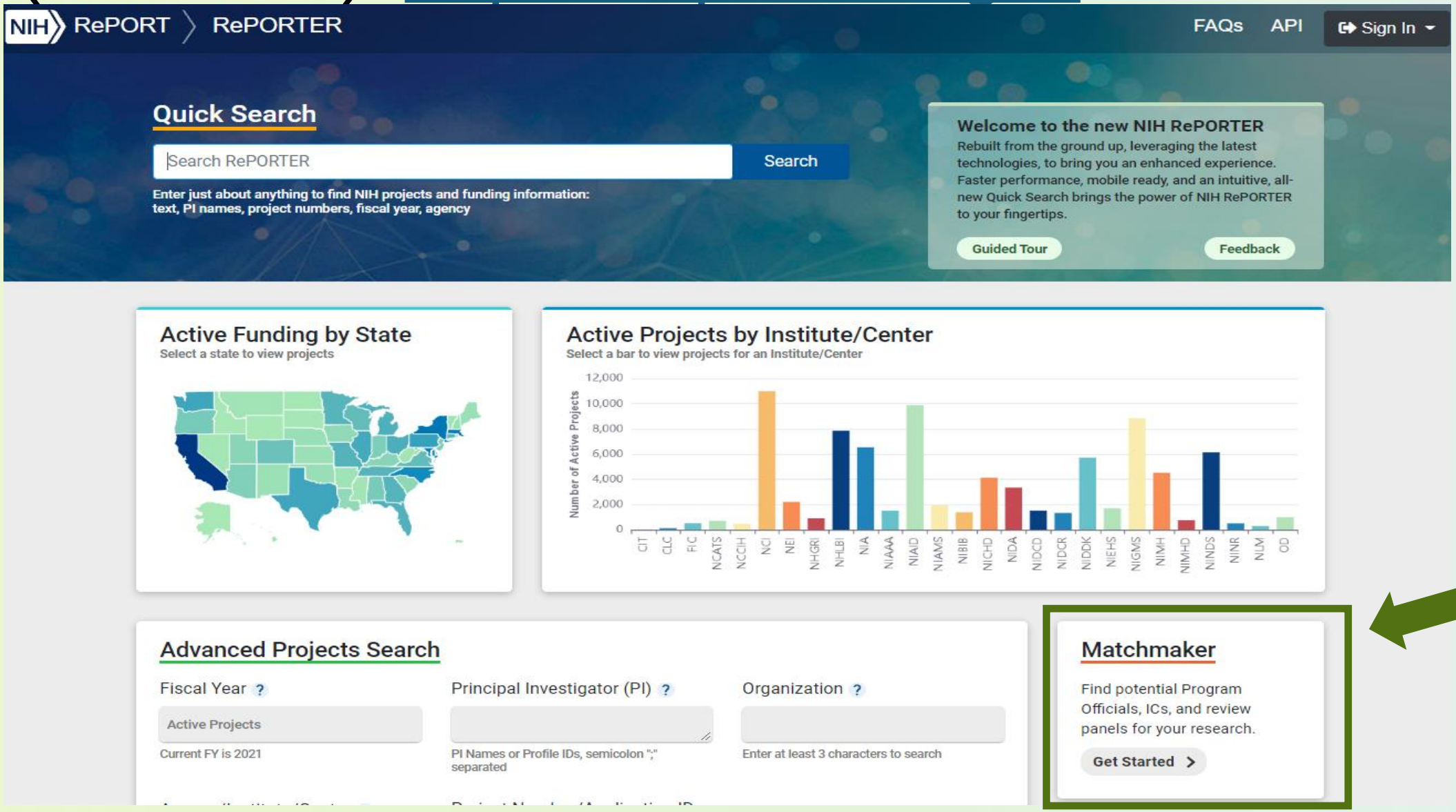
List of SBIR Program Managers
https://seed.nih.gov

Not sure who to contact?

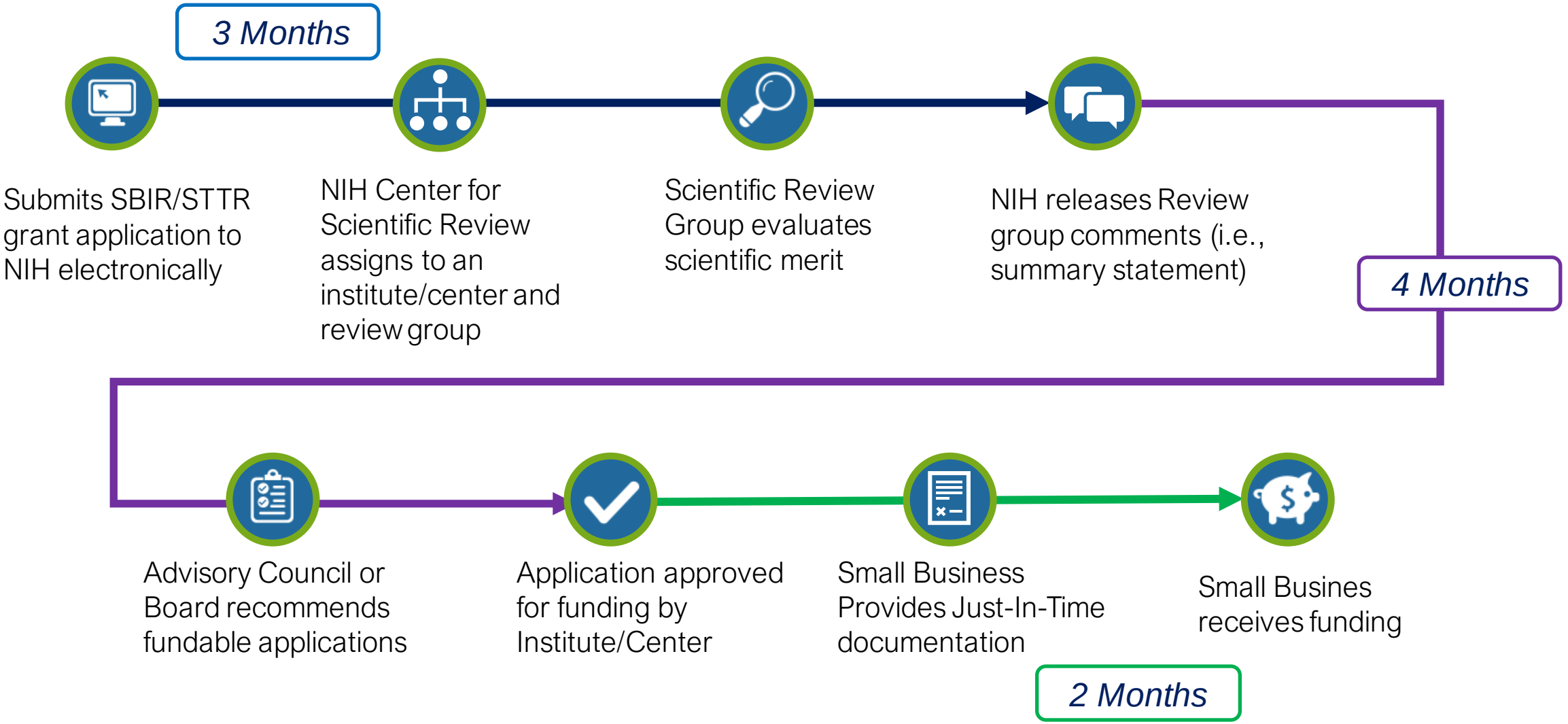
NIH RePORTER: https://reporter.nih.gov/

Email: SEEDinfo@nih.gov

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



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
  - Notice of Funding Opportunity will give specific questions in Section V.
  - Budget is not factored into the score!
- 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

- Significance: Unimportant problem, unconvincing case for commercial potential or societal impact
- Innovation: Lack of innovation or advantage over other technologies or products
- Environment/Investigators:
  - 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

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."

Technical and Business Assistance (TABA) Programs

Take Advantage of the 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

Entrepreneurial Support Programs

NIH Entrepreneurship BOOTCAMP

Pre-SBIR
Introduce teams to customer discovery & business model validation
seed.nih.gov/bootcamp

I-CORPS™ AT NIH

Phase I SBIR/STTR Awards
Support for teams to develop a business model canvas
seed.nih.gov/I-corps-at-NIH

NIH Small Business DIVERSITY Supplement

Supplements to SBIR/STTR Awards
Research and entrepreneurial experiences at NIH SBIR/STTR recipients for individuals to enhance the diversity workforce
seed.nih.gov/diversity_supp

Concept to Clinic: Commercializing Innovation (C3i)

Pre-SBIR AND SBIR/STTR Awards
Helps medical device innovators move technologies from the lab to the market
nibib.nih.gov/research-program/c3i-program

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