



2020 HHS Small Business Funding Opportunity Announcements

Stephanie Fertig, MBA

HHS Small Business Program Lead, SEED (Small business Education & Entrepreneurial Development)

Office of the Director | Office of Extramural Research | National Institutes of Health



Coronavirus 2019:

[Information for NIH Applicants and Recipients](#)
[Small Business Relief Options and Resources \(SBA\)](#)



A- | A+ Q



- SBIR/STTR HOME
- ABOUT
- FUNDING
- APPLY
- REVIEW
- POLICY
- TECHNICAL ASSISTANCE
- RESOURCES
- STATISTICS AND SUCCESSES
- ENGAGE AND CONNECT

New to SBIR/STTR

Clinical Trials & SBIR/STTR Funding

Learn how Clinical trials are changing the NIH SBIR/STTR application requirements, and find out which funding opportunity announcement (FOA) is right for you.

[MORE DETAILS](#)



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 \$1.0 billion
STTR \$146 million


Centers for Disease Control and Prevention
SBIR \$11 million

 Food and Drug Administration
SBIR \$2 million


Administration for Community Living
SBIR \$3 million



*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





“As a native Spanish-speaking curriculum designer with a background in literary and performing arts, I work as a principal investigator on a number of NIH-funded projects. The SBIR and STTR programs allow me to translate evidence-based practices into web-based multimedia programs that offer skill-building tools for improving health and educational outcomes among Latino audiences.”



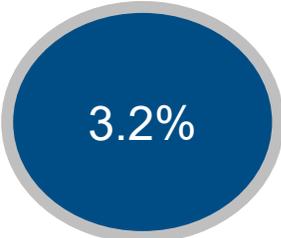
Jessie Marquez

Instructional Designer at
IRIS Educational Media
<http://www.irised.com/>



Congressionally Mandated Programs

\$1.19 Billion Dedicated Funding via Set-aside from NIH's R&D Budget



3.2%

\$1.04 billion

SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

Set-aside program for small business concerns to engage in federal R&D -- with potential for commercialization



0.45%

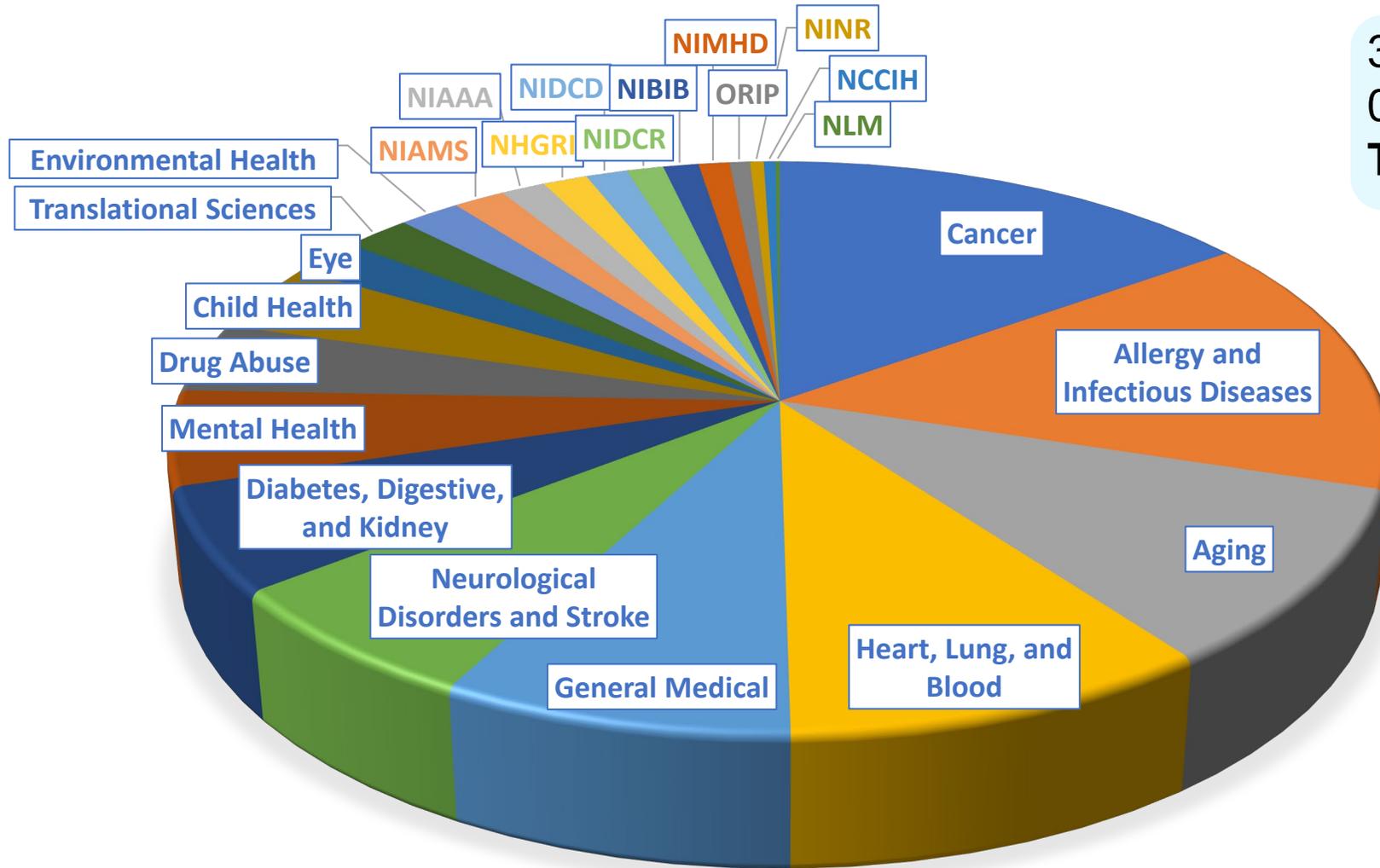
\$146 million

SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM

Set-aside program to facilitate cooperative R&D between small business concerns and US research institutions -- with potential for commercialization



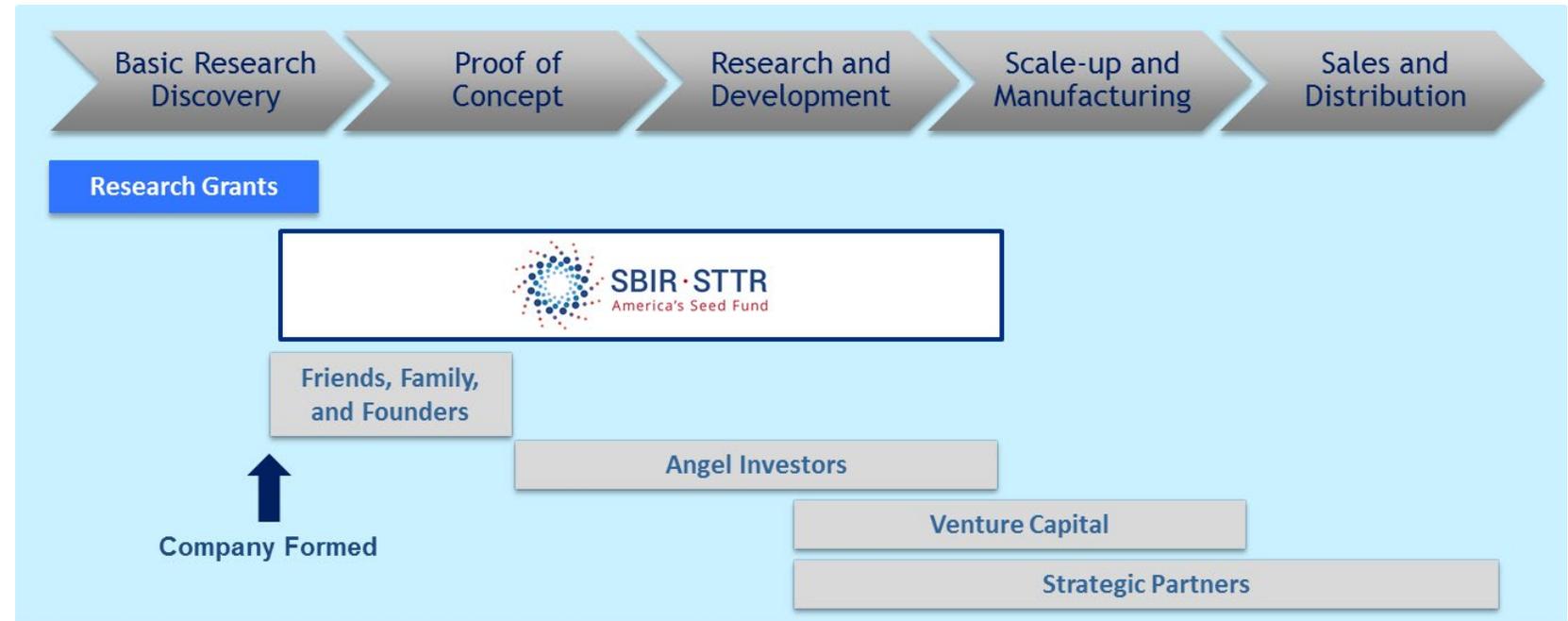
NIH SBIR/STTR Budget Allocations FY2020



3.2% SBIR \$1.04 billion
 0.45% STTR \$146 million
Total FY20 \$1.19 billion

One of the largest sources of early-stage capital for life sciences in the United States

- Not a loan and non-dilutive **capital**
- **IP/data rights** protection through Bayh-Dole Act and SBIR Policy Directive
- Awardees can **leverage funding** to attract investors and partners



Lift Labs (Acquired by Google Sept 2014)

“My PhD research centered on vibration and motion cancellation, which is basic science that could have new application areas,” said Pathak, “After graduating, I talked to neurosurgeons, did research, and found out that Parkinson’s and essential tremor effects over ten million people.”



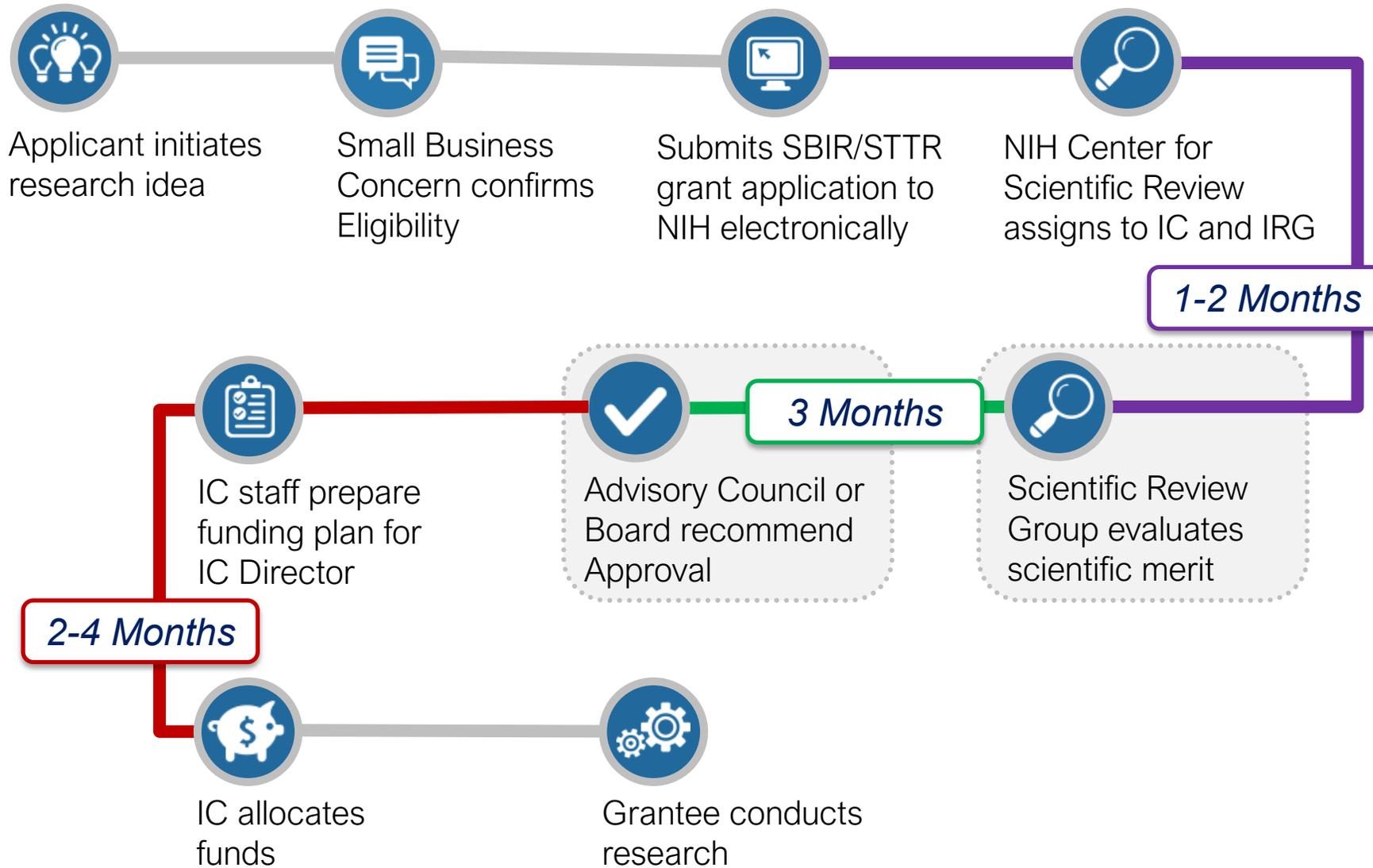
LIFT labs

Anupam Pathak, Ph.D.
Founder & CEO
NINDS SBIR Awardee

liftlabsdesign.com/



NIH Application & Review Process



- 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>
 - 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**



WOSB and SDB Definitions

What is a Women-Owned Small Business (WOSB)?

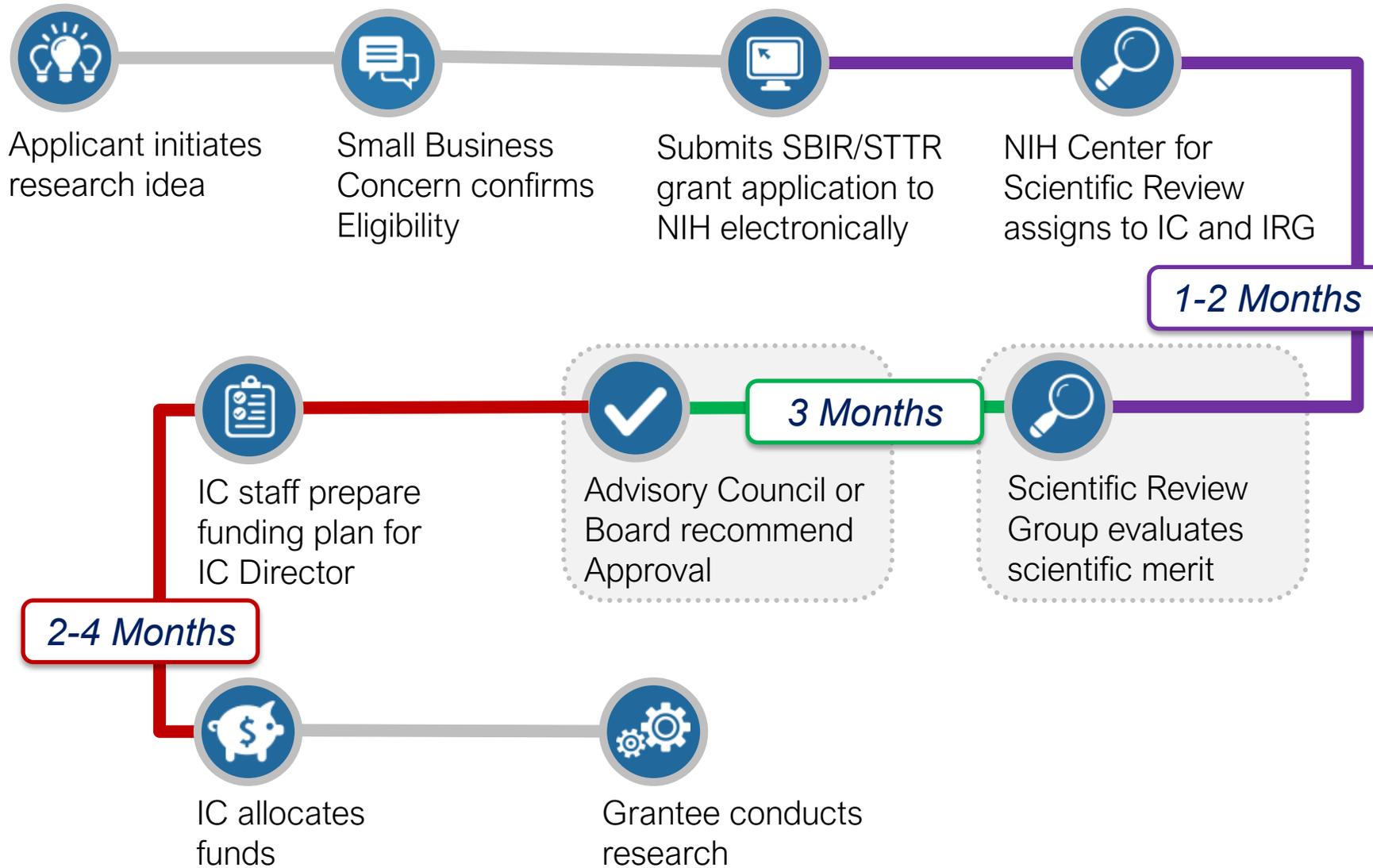
- A firm must be at least 51% owned and controlled by one or more women, and primarily managed by one or more women
- The firm must be “small” in its primary industry in accordance with SBA’s size standards for that industry
- SBCs self certify on the SF 424 (R&R) Form

What is a Socially and Economically Disadvantaged Business (SDB)?

- The firm must be 51% or more owned and control by one or more disadvantaged persons
- The disadvantaged person or persons must be socially disadvantaged and economically disadvantaged
- The firm must be small, according to SBA’s size standards
- You must self-certify by registering your business in the System for Award Management

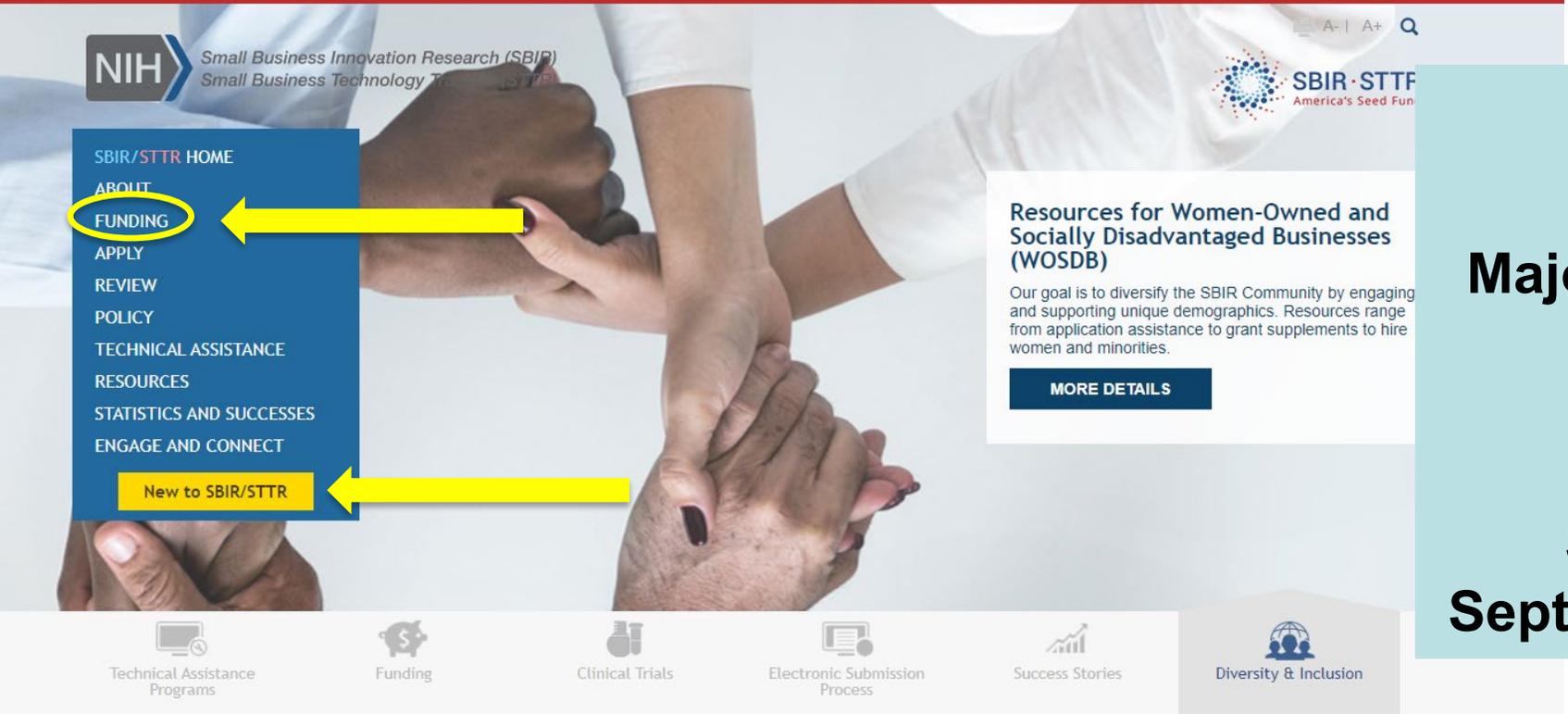


NIH Application & Review Process



Coronavirus 2019:

Information for NIH Applicants and Recipients
Small Business Relief Options and Resources (SBA)



<https://sbir.nih.gov>

Majority of the funding goes to investigator initiated applications

Standard receipt dates:
September 5*, January 5, April 5

What are SBIR and STTR Programs?

The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, also known as America's Seed Fund, are one of the largest sources of early-stage capital for technology

HHS SBIR/STTR COMPONENT PROGRAM LINKS

SBIR/STTR Grant Solicitation Funding Opportunities:

- **General Omnibus Solicitations**

- Clinical Trial Not Allowed: SBIR ([PA-20-260](#)) and STTR ([PA-20-265](#))
- Clinical Trials Required: SBIR ([PA-20-262](#)) and STTR ([PA-20-261](#))

Read the “Program Descriptions and Research Topics” Section in the Solicitation

- **Targeted Solicitations** (<https://sbir.nih.gov/funding/individual-announcements>)

*Not all of these have a separate set-aside or peer review- Read Carefully!

SBIR Contract Solicitation

- Only some Institutes/Centers participate
- [FY2021 Contract Solicitation](#) is now available
- Receipt date is **October 26th**

<https://sbir.nih.gov/funding>



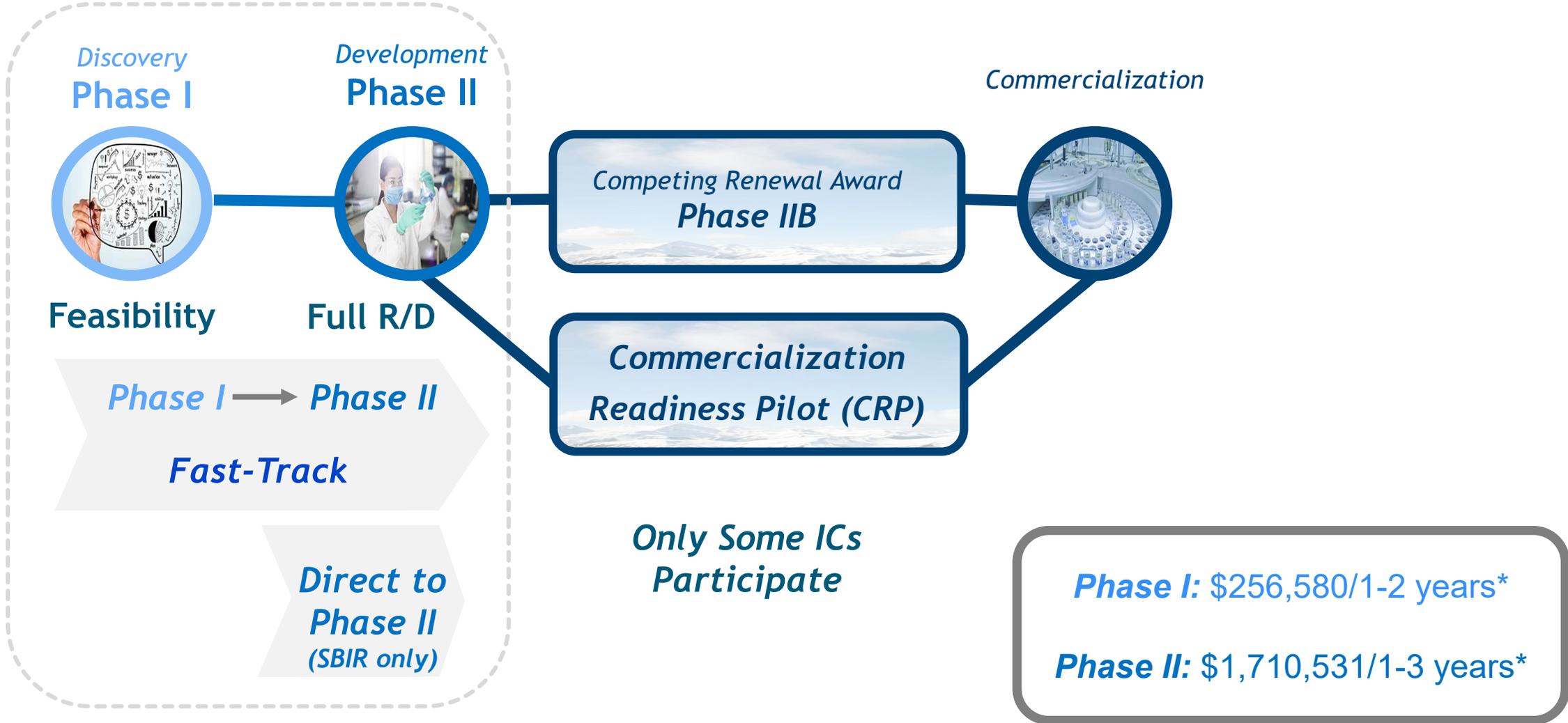
SBIR and STTR Critical Differences

	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	Primary employment (>50%) must be with the small business	PI may be employed by <u>either</u> the research institution partner or small business

Award always made to small business



Phased Programs



*NIH has a waiver from the Small Business Administration to exceed these budgets for most topics

Phase IIB

- After Phase II award
- Phase II out-sourcing guidelines
- Encourages matching funding
- Through Omnibus (IC must accept competing renewals) or specific funding opportunities

CRP

- Concurrent with or after Phase II award
- Significant out-sourcing is allowed
- Three Funding Opportunities:
 - PAR-20-128:** Technical Assistance
 - PAR-20-129:** Technical Assistance/Late Stage Development
 - PAR-20-130:** Technical Assistance/Late Stage Development (Clinical Trials)

**Only Some ICs Participate
Contact NIH Program Staff to discuss!**



Clinical Trial Requirements for Grants and Contracts

NIH is launching a series of initiatives that are rolling out in 2017-2018 to enhance the accountability and transparency of clinical research. These initiatives target key points along the whole clinical trial lifecycle from concept to results reporting. Learn more about these changes and how they will affect your research.

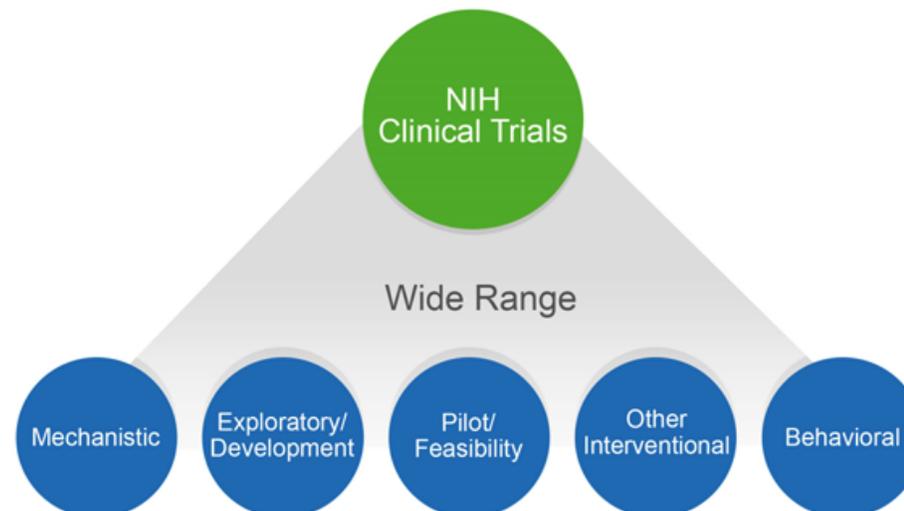
NIH Definition of a Clinical Trial

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. [Learn more](#)

DECISION TOOL

Your human subjects study may meet the NIH definition of a clinical trial.

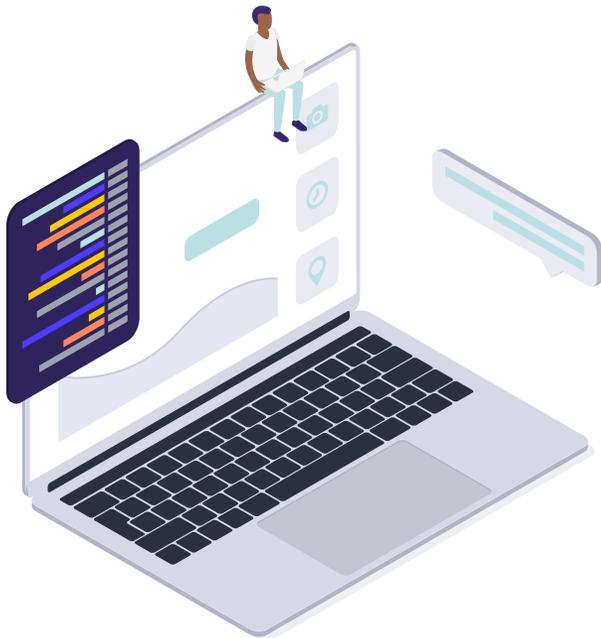
FIND OUT HERE



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



SBIR/STTR grant applications **and** SBIR contract proposals must be submitted **electronically**.



REQUIRED REGISTRATIONS

- DUNS Number (Company)
- System for Award Management (SAM)
- Grants.gov (Company)
- eRA Commons (Company and all PD/PIs)
- SBA Company Registry at SBIR.gov
- Grants submit via ASSIST or Grants.gov Workspace
- For contracts, submit proposals with [electronic Contract Proposal Submission](#) (eCPS) website



Electronic Submission

Expiration Date: 12/31/2022

**APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)**

1. TYPE OF SUBMISSION Use Application for first submission attempt for due date.

Pre-application Application Changed/Corrected Application

2. DATE SUBMITTED Applicant Identifier

Do not use Pre-application unless specifically noted in FOA. Use Changed/Corrected when submitting again to Grants.gov for a due date (e.g., to correct eRA identified errors/warnings.)

3. DATE RECEIVED BY STATE State Application Identifier

If New (box 8), leave blank. If Revision/Resubmission/ Renewal (box 8), use institute and serial # of previous NIH grant/application # (e.g., CA987654 from 1R01CA987654-01).

4. a. Federal Identifier

b. Agency Routing Identifier

c. Previous Grants.gov Tracking ID

For Notices of Special Interest, include notice number (e.g., NOT-IC-FY-XXX).

If Changed/Corrected (box 1), provide previous Grants.gov tracking #. (e.g., GRANT12345678).

5. APPLICANT INFORMATION Organizational DUNS:

Legal Name: _____

Department: _____ Division: _____

Street1: _____

Street2: _____

City: _____ County / Parish: _____

State: _____ Province: _____

Country: USA: UNITED STATES ZIP / Postal Code: _____

Must match DUNS used for System for Award Management (SAM), Grants.gov and eRA Commons registrations. Must be 9 or 13 digits; no letters or special characters.

Must provide zip+4 for all zip codes.

Person to be contacted on matters involving this application

Prefix: _____ First Name: _____ Middle Name: _____

Last Name: _____ Suffix: _____

Position/Title: _____

Street1: _____

Street2: _____

City: _____ County / Parish: _____

State: _____ Province: _____

Country: USA: UNITED STATES ZIP / Postal Code: _____

Phone Number: _____ Fax Number: _____

Email: _____ Contact e-mail is required by NIH. If not included, or improperly formatted, the AOR e-mail provided in item 19 will be used.

6. EMPLOYER IDENTIFICATION (EIN) or (TIN): Non-US organizations use 444444444.

7. TYPE OF APPLICANT: Please select one of the following

Other (Specify): _____

Small Business Organization Type Women Owned Socially and Economically Disadvantaged

Do not use these Small Business Organization Type checkboxes. NIH/CDC/FDA use SAM data to gather this information.

8. TYPE OF APPLICATION: See application guide for definitions.

New Resubmission Revision

If Revision, mark appropriate box(es). A. Increase Award B. Decrease Award C. Increase Duration D. Decrease Duration

Annotated Form Set for NIH Grant Applications FORMS-F Series



Most Important Piece of Advice

The screenshot shows the NIH SBIR/STTR website. The top navigation bar includes the NIH logo, the text 'Small Business Innovation Research (SBIR) Small Business Technology Transfer (STTR)', and the SBIR/STTR logo with the tagline 'America's Seed Fund'. A search bar is located on the right. The left sidebar contains a menu with items: SBIR/STTR HOME, ABOUT, FUNDING, APPLY, REVIEW, POLICY, TECHNICAL ASSISTANCE, RESOURCES, STATISTICS AND SUCCESS, and ENGAGE AND CONNECT (highlighted with a yellow circle). Below the menu is a 'New to SBIR/STTR' button. The main content area is titled 'SBIR/STTR Home > Engage & Connect > IC Program Contacts'. A dark blue overlay menu is open, showing 'Contact' and 'Engage' options. A yellow arrow points to 'IC Program Contacts' under the 'Contact' section. Below the overlay, there is a table of contact information for various NIH institutes.

Institute	Contact Name	Phone	Fax	Email
National Institute on Alcohol Abuse and Alcoholism http://www.niaaa.nih.gov	Megan Ryan	301-443-4225		mryan1@mail.nih.gov
National Institute of Allergy and Infectious Diseases http://www.niaid.nih.gov	Natalia Kruchinin	240-669-2919	240-627-3162	kruchininn@niaid.nih.gov
	Jeff Thurston	301-443-9801	301-443-3891	jeffrey.thurston@nih.gov
	Vandhana Khurana	240-669-2966	301-493-0597	khuranav@niaid.nih.gov

Talk to a HHS Program Officer at least a month before the application deadline!

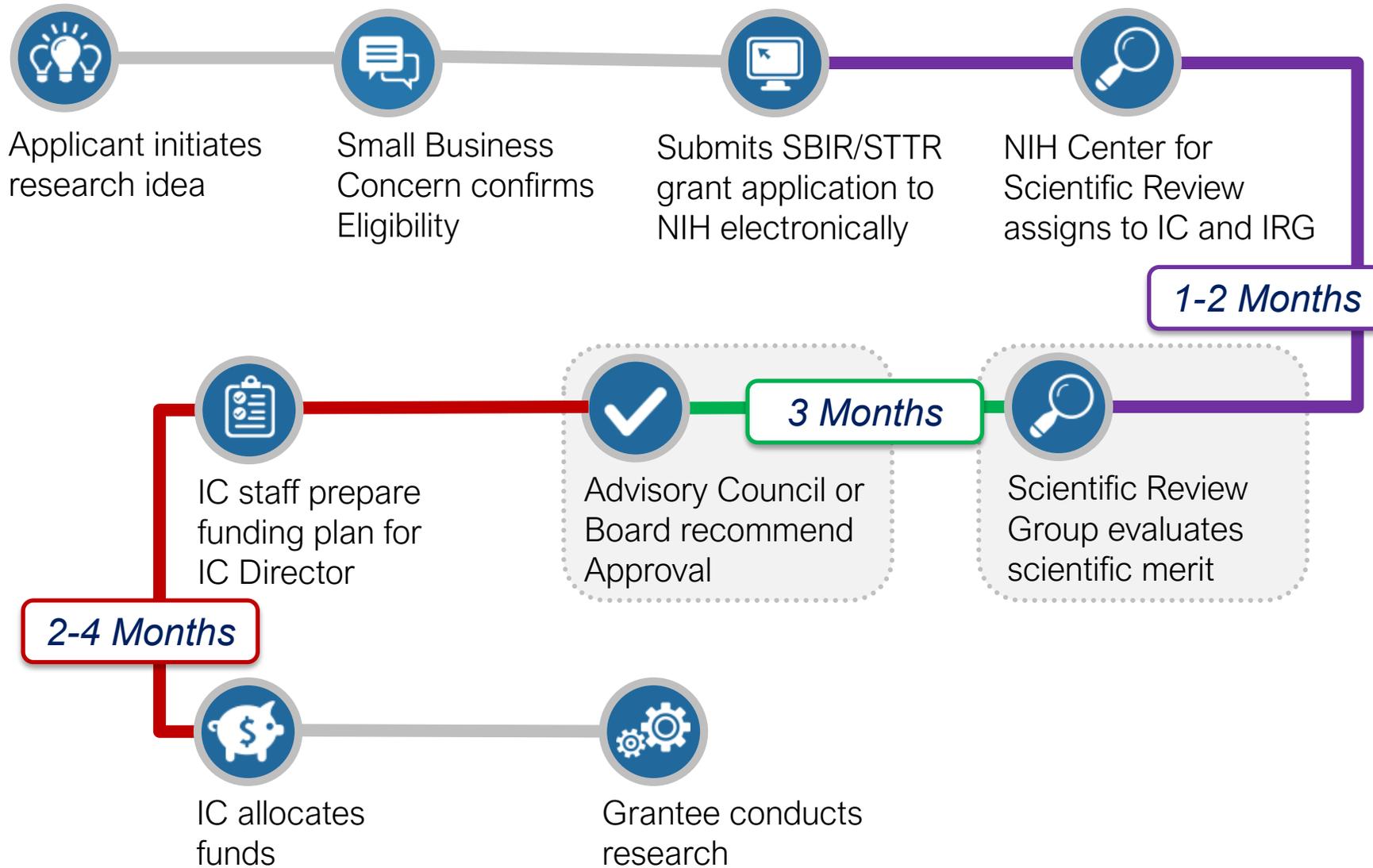
List of HHS SBIR Program Managers:
<https://sbir.nih.gov/engage/ic-contacts>

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

Not sure who to contact?
<https://public.era.nih.gov/commons/public/servicedesk/initseed.era>
or
Email: sbir@od.nih.gov



NIH Application & Review Process



Overall Impact Score

Scored Review Criteria (score 1-9)

- Significance (Real Problem/Commercial Potential)
- Investigators (PI and team)
- Innovation (New or Improved?)
- Approach (Research Design, Feasible)
- Environment (Facilities/Resources)

Additional Review Criteria (not scored individually)

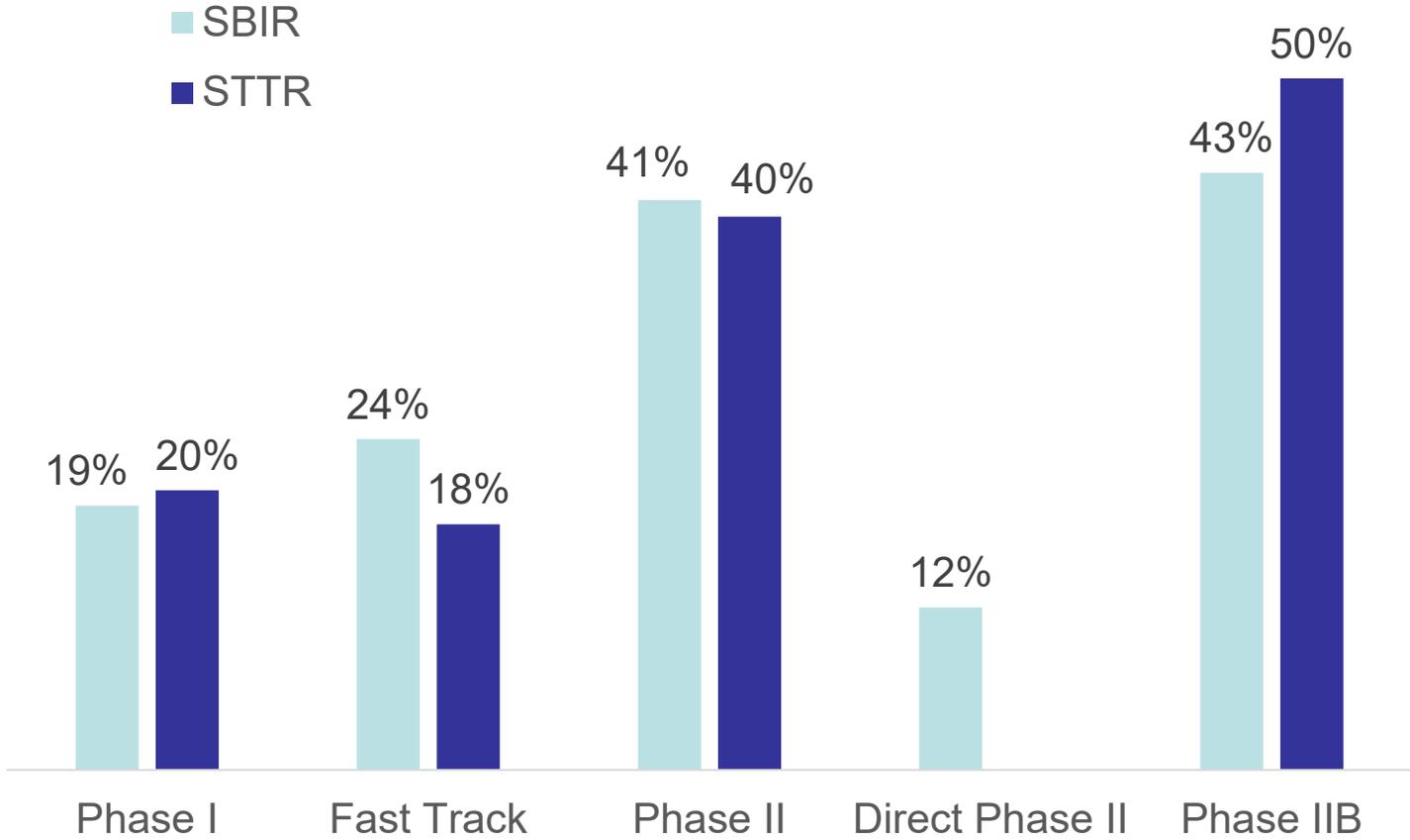
- Protection of Human Subjects
- Inclusion of Women, Minorities & Children
- Vertebrate Animals
- Biohazards

Center for Scientific Review

<https://public.csr.nih.gov/>



NIH 2019 SBIR/STTR Grants Success Rate by Phase



Be Prepared to Resubmit!

“[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.”



Laverne Morrow Carter, Ph.D.

Founder & President, REESSI

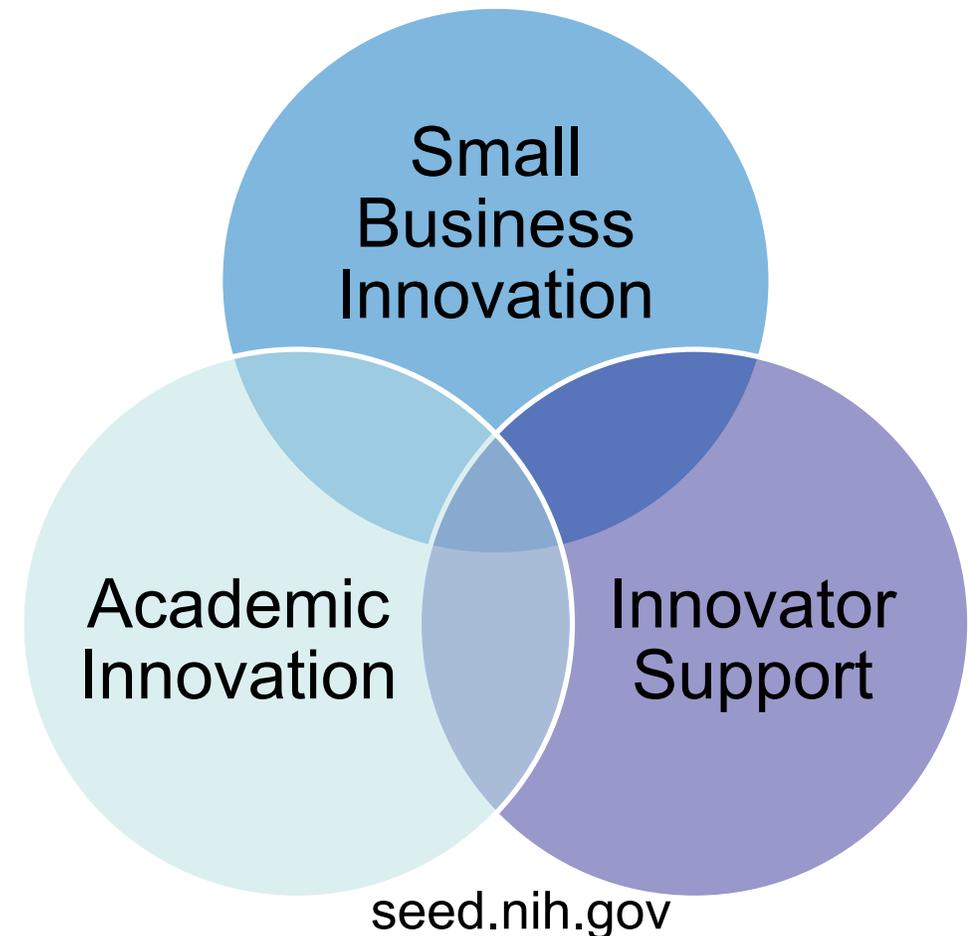
NIMHD SBIR Awardee

<http://www.reessi.com>



Small business Education and Entrepreneurial Development (SEED)

- Supports the NIH innovator community (funding and resources) to validate and advance discoveries to products that improve patient care and health.
- Develop relationships with strategic partners and build opportunities for NIH innovators to further their product development efforts.



Technical Assistance and Training

Phase I:

Technical and Business Assistance:
Coming Soon: Needs Assessment Program

Entrepreneurial Assistance/ Training:
NIH I-Corps™

Phase II/IIB:

Technical Assistance/Training:
Commercialization Accelerator Program (CAP)*

*Ending in FY2020

Phase I and Phase II/IIB:

Entrepreneurial Assistance/ Training:
NIH C3i

Entrepreneurial Training:
Diversity Supplement ([PA-18-837](#))

Technical Assistance Budget Allowance

Phase I- \$6,500/year

Phase II- \$50K

Request in Application

If requested, cannot participate in NIH centralized TABA programs (e.g. Needs Assessment Program)

Available Technical Assistance/Training:

<https://sbir.nih.gov/tap>



Strategy, Finance & Commercialization Experts:

<https://sbir.nih.gov/resources/entrepreneurs-in-residence/index.htm>



Sr. Regulatory Specialist
Innovator Support Team Lead
Chris Sasiela, PhD



Ethel Rubin, PhD



John Sullivan, MBA



Steve Wolpe, PhD

Entrepreneurs-in-Residence



Partnering Opportunities and Pitch Coaching:



ANGEL CAPITAL ASSOCIATION



21st Annual HHS Small Business Program Conference

April 27-29, 2021 | Las Vegas, Nevada

<https://www.unlv.edu/econdev/hhsconf2021>



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(weekly notification)



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