

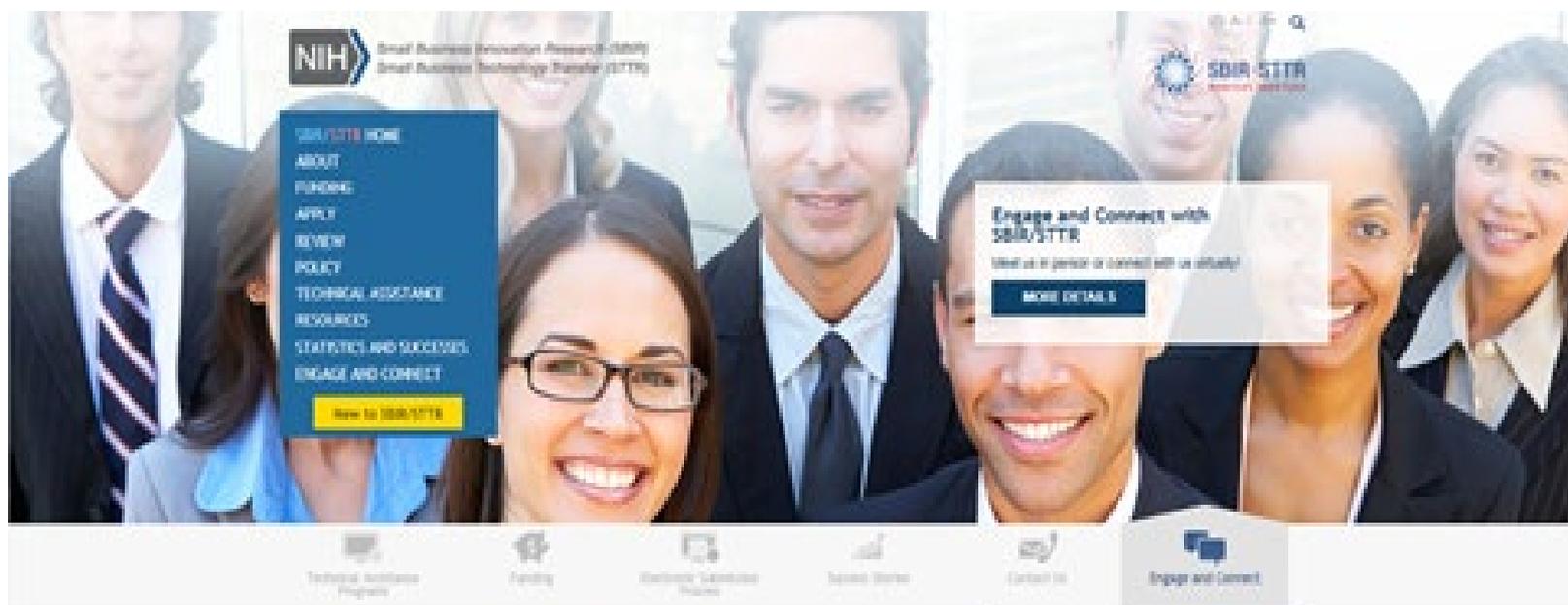


HHS SBIR/STTR PHS 2019-2 GRANT OMNIBUS/PARENT WEBINAR

May 29, 2019

Matthew Portnoy, Ph.D.
SBIR/STTR Program Coordinator
Office of Extramural Research, NIH

<https://sbir.nih.gov>



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 Funds, are one of the largest sources of early-stage capital for technology commercialization in the United States. These programs allow US-owned and operated small businesses to engage in federal research and development that has a strong potential for commercialization.

In Fiscal Year 2017, NIH's SBIR and STTR programs will invest over \$25 million dollars into health and life science companies that are creating innovative technologies that align with NIH's mission to improve health and save lives. A key objective is to translate promising technologies to the private sector and enable the ensuing innovations to

[Webinars & Conferences - Previous Years](#)

NEWS



Registration Open for the 18th Annual Health and Human Services SBIR/STTR Conference in the heartland of Biotech Innovation - Indianapolis, IN [View](#)
June 8, 2017



Just Released - 2017 FY15 SBIR and STTR Funding Award Solicitations



Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

Mission of the SBIR and STTR Programs

To support scientific excellence and technological innovation by providing investment of Federal R&D funds into small businesses to work on critical national priorities and build a stronger economy.

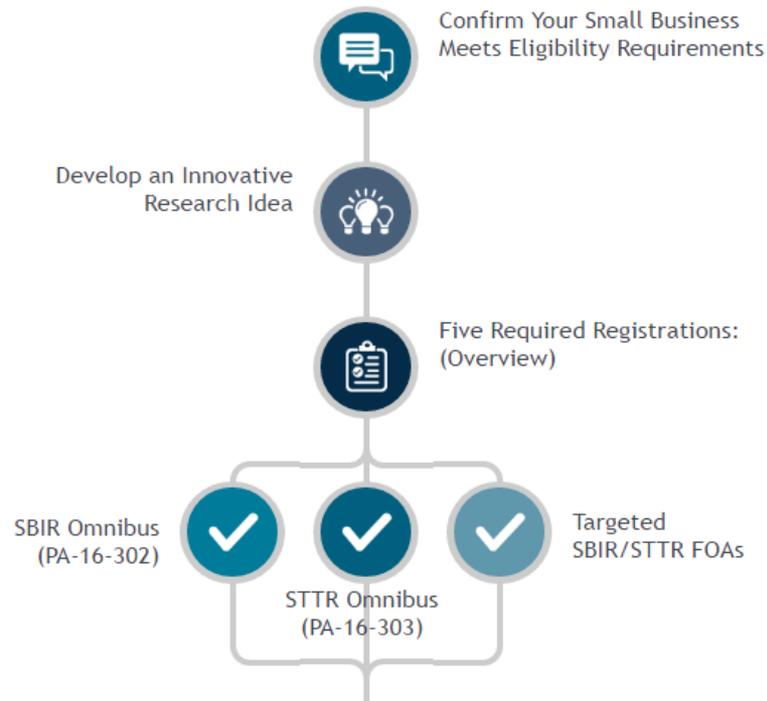




SBIR/STTR Application Process Infographic

Use this interactive chart that contains helpful information to guide you through the NIH SBIR/STTR application process. Click through the chart for answers to your related questions.

START THE SBIR/STTR
APPLICATION PROCESS
INFOGRAPHIC



<http://sbir.nih.gov/infographic>





SET ASIDE



SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

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



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





- Stimulate technological innovation
- Use small business to meet federal R&D needs
- Foster and encourage participation by minorities and disadvantaged persons in technological innovation
- Increase private-sector commercialization innovations derived from federal R&D

Small Business Innovation Development Act of 1982

P.L. 114-328 Re-Authorizes program through FY2022





- Stimulate and foster scientific and technological innovation through **cooperative research** and development carried out *between* **small business concerns** and **research institutions**
- Foster **technology transfer** between small business concerns and research institutions

*Small Business Research and Development
Enhancement Act of 1992*

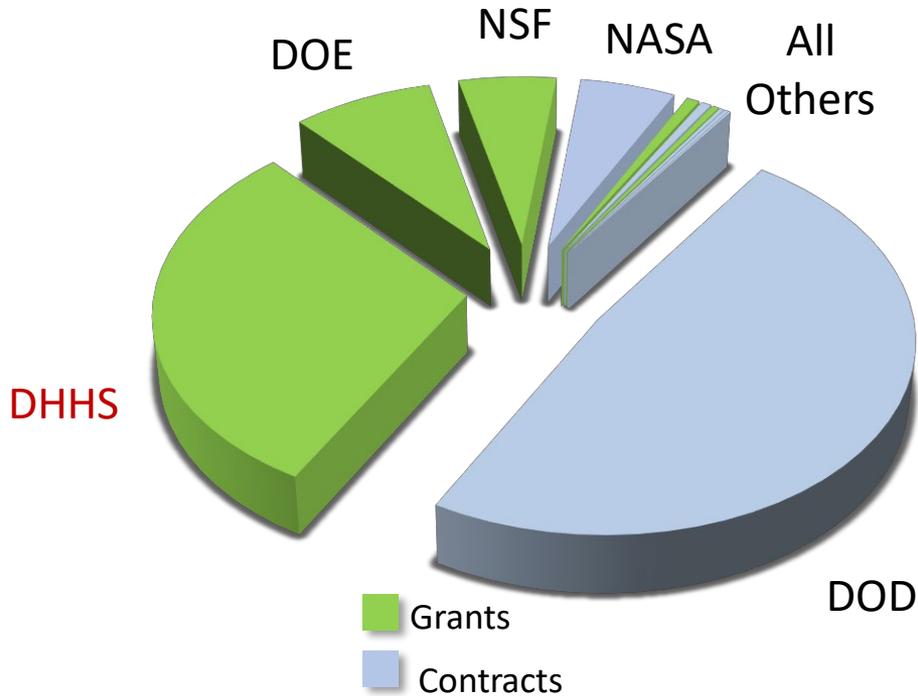
P.L. 114-328 Re-Authorizes program through FY2022





- **Non-Dilutive Capital** – The funding agency cannot take an equity position or ownership of your firm (pros and cons to this)
- **IP/Data Rights** protection – Government can't share reports or data with anyone outside of the federal government for 5 years (DoD) or 4 years (other agencies)
- **Direct follow on Phase III** awards – No need for further competition, which benefits both the government and small businesses

SBIR/STTR Budgets by U.S. Agency, FY2018



~ \$3.6 Billion in FY2018
across all agencies



5 AGENCIES WITH SBIR & STTR PROGRAMS	APPROX BUDGET
Department of Defense (DOD)	\$ 1.750 B
Department of Health and Human Services (DHHS), including the National Institutes of Health (NIH)*	\$1.088 B
Department of Energy (DOE), including Advanced Research Projects Agency – Energy (ARPA-E)	\$291.7M
National Science Foundation (NSF)	\$ 202.4 M
National Aeronautics and Space Administration (NASA)	\$198.0 M
6 AGENCIES WITH ONLY SBIR PROGRAMS	APPROX BUDGET
Department of Agriculture (USDA)	\$27.0M
Department of Homeland Security (DHS): Science and Technology Directorate (S&T) & Countering Weapons of Mass Destruction Office (CWMD)	\$20.8 M
Department of Commerce: National Oceanic and Atmospheric Administration (NOAA) & National Institute of Standards and Technology (NIST)	\$14.2M
Department of Transportation (DOT)	\$8.5 M
Department of Education (ED)	\$7.5 M
Environmental Protection Agency (EPA)	\$4.2 M

**DHHS also issues contracts*



- SBIR/STTR programs reauthorized for 5 year FY18 through FY22
- Pilot programs extended through 2022
 - SBIR Direct Phase II
 - Commercialization Readiness Pilot Programs
 - 3% Agency SBIR Admin funds
 - NIH Phase 0 Proof of Concept Centers
- Expand Technical Assistance
 - Phase I \$6,500/year (up from \$5,000/year)
 - Phase II \$50,000/**project** (up from \$5,000/year)
 - SBC hire own vendor or use agency vendor





- To provide small business concerns engaged in SBIR or STTR projects with technical and business assistance services, such as access to a network of scientists and engineers engaged in a wide range of technologies, product sales, IP protections, market research, market validation, development of regulatory plans, manufacturing plans, or access to technical and business literature available through on-line data bases, for the purpose of assisting such concerns in:
 - making better technical decisions concerning such projects;
 - solving technical problems which arise during the conduct of such projects;
 - minimizing technical risks associated with such projects; and
 - developing and commercializing new commercial products and processes resulting from such projects, including intellectual property protections.

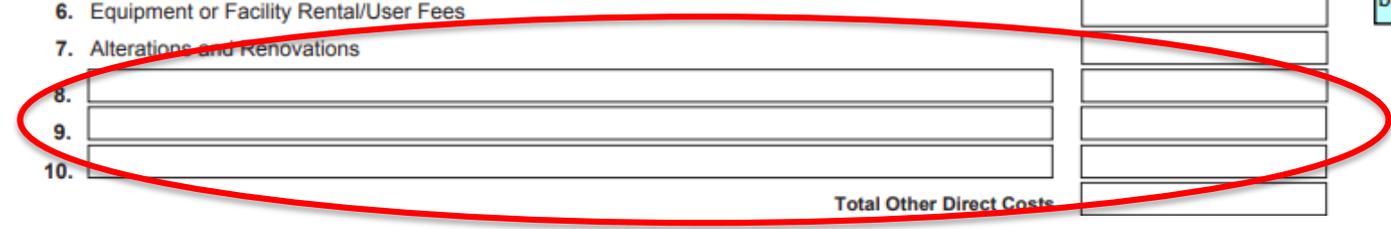




- Increase Technical & Business Assistance
 - Up to \$6,500 per year per Phase I (up from \$5K/year)
 - Up to \$50,000 per Phase II **project** (up from \$5K/year)
 - Request at time of APPLICATION
 - Request in F. Other Direct Costs lines 8-10 on SBC budget
 - Label as “Technical Assistance”

F. Other Direct Costs	Funds Requested (\$)
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8.	
9.	
10.	
Total Other Direct Costs	

Subaward/Consortium/Contractual Costs are not pre-populated. Include both Direct and Indirect costs.



HHS Program Funding

2019 Budget	SBIR	STTR
NIH	\$1B	\$141M
CDC	~\$12M	N/A
ACL (NIDILRR)	~\$3M	N/A
FDA	~\$1M	N/A



- 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 concern/s that is/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 (For some agencies)

Determined at Time of Award





- Applicant is a Small Business Concern
- Formal Cooperative R&D Effort
 - Minimum 40% by small business
 - Minimum 30% by US research institution
- US Research Institution
 - College or university; other non-profit research organization; Federal R&D center
- Intellectual Property Agreement
 - Allocation of rights in IP and rights to carry out follow-on R&D and commercialization



*Discovery*Phase
I

Phase I Feasibility Study

Budget Guide: \$150K for SBIR and STTR

Project Period: 6 months (SBIR); 1 year (STTR)

*Development*Phase
II

Phase II Full Research/R&D

\$1M for SBIR and STTR, over two years

Phase
IIB

Phase IIB Competing Renewal/R&D

Clinical R&D; Complex Instrumentation/to FDA
Many, but not all, IC's participate
Varies~\$1M per year; up to 3 years

*Commercialization*Phase
III

Phase III Commercialization

NIH, generally, not the “customer”

Consider partnering and exit strategy early



- SBA adjust budget for inflation (total costs = Direct, indirect, fee)
 - Phase I cap = \$252,131
 - Phase II cap = \$1,680,879

Total funding support (direct costs, indirect costs, fee) normally may not exceed \$252,131 for Phase I awards and \$1,680,879 for Phase II awards. NIH has received a waiver from SBA, as authorized by statute, to exceed these total award amount hard caps for specific topics. The current list of approved topics can be found at <https://sbir.nih.gov/funding#omni-sbir>. Navigate to the “Program Descriptions and Research Topics” document, Appendix A or the “2019 SBA approved topics list for budget waivers”.

Each participating component may also set their own budget limit (higher or lower than the above) in the “Limited Amount of Award Section” of their respective topics section. Applicants are strongly encouraged to contact program officials prior to submitting any application in excess of the hard caps listed above and early in the application planning process. In all cases, applicants should propose a budget that is reasonable and appropriate for completion of the research project.





NIA

For topics listed in APPENDIX A: National Institutes of Health SBA-Approved SBIR/STTR Topics for Awards over Statutory Budget Limitations, the NIA generally will not fund Phase I applications greater than \$300,000 total costs or project periods greater than 2 years; or Phase II applications greater than \$2,000,000 total costs or project periods greater than 3 years. For all other topics, the NIA does not generally fund Phase I applications greater than \$225,000 total costs or project periods greater than 2 years; or Phase II applications greater than \$1,500,000 total costs or project periods greater than 3 years.

NIAMS

Generally, NIAMS does not fund Phase I applications with a total cost greater than \$252,131 or a project period greater than 2 years and Phase II applications with a total cost greater than \$1,680,879 or a project period greater than 3 years.

CDC will not fund:

- Phase I applications greater than \$150,000 total costs.
- Phase II applications greater than \$1,000,000 total costs

Bottom line: Call a Program Officer to discuss your budget of any size.





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 either the research institution partner or small business

Award is always made to the small business





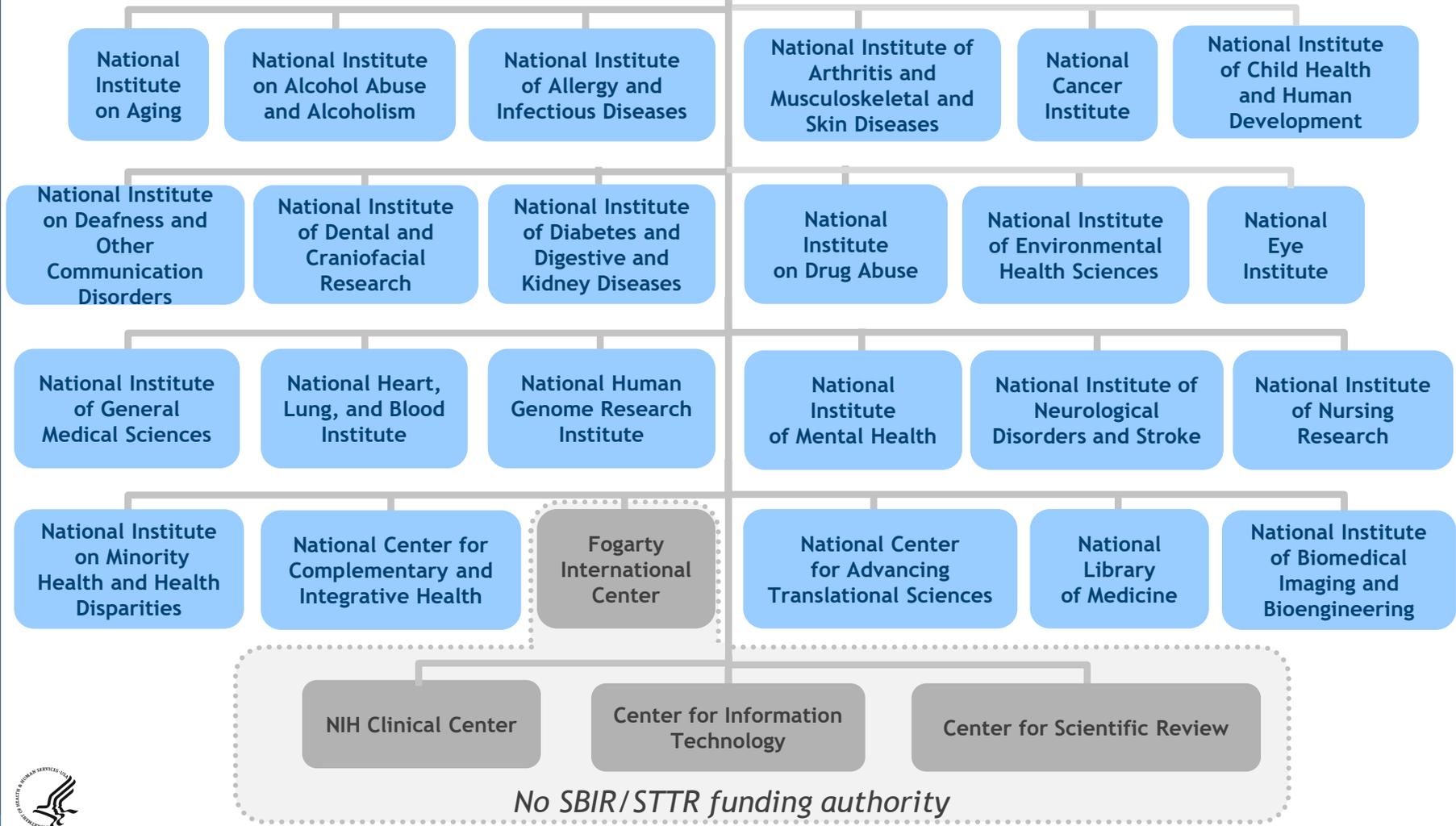
Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

National Institutes of Health

<http://www.nih.gov/icd>

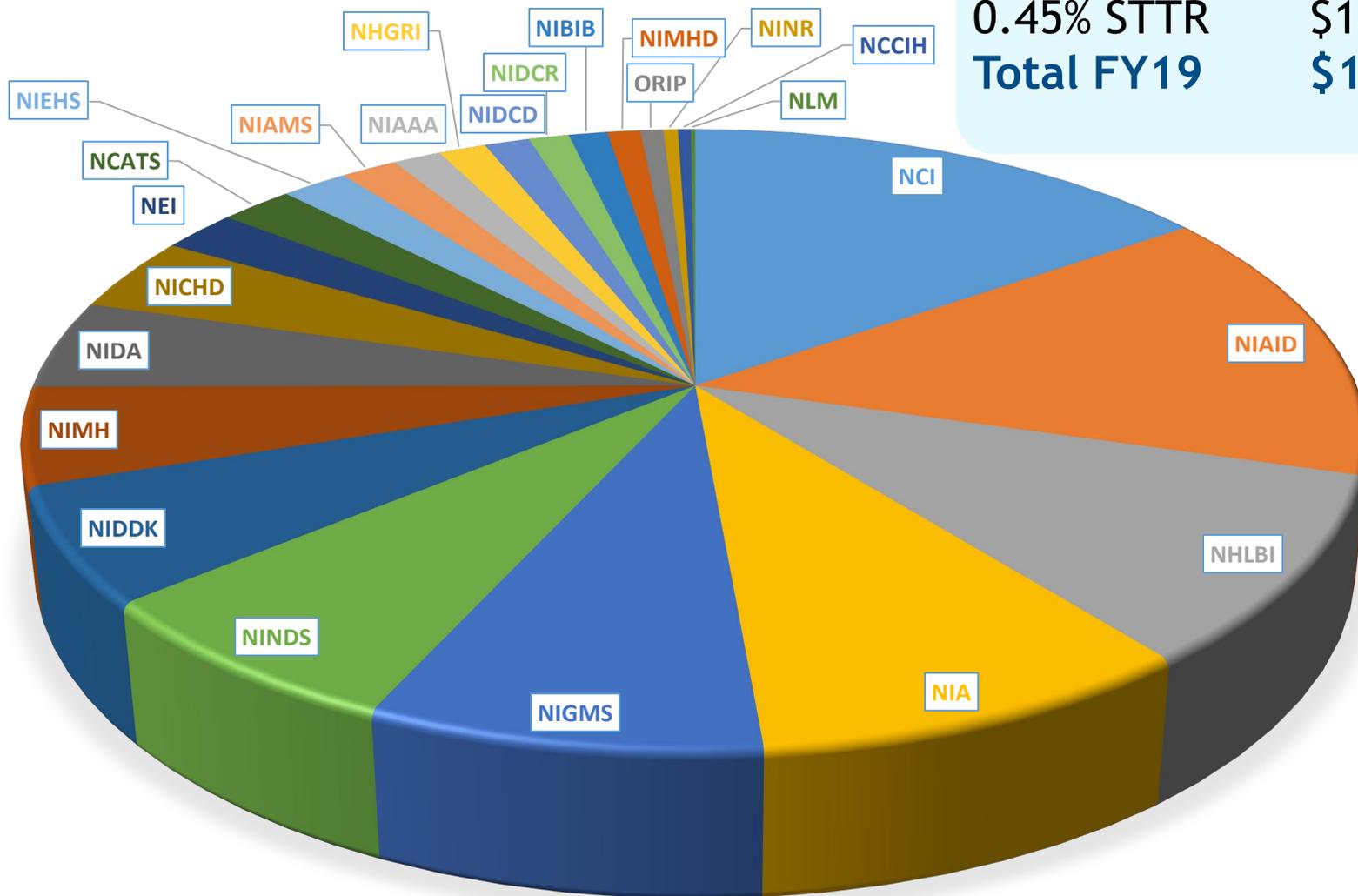
Office of the Director

Office of Research Infrastructure Programs

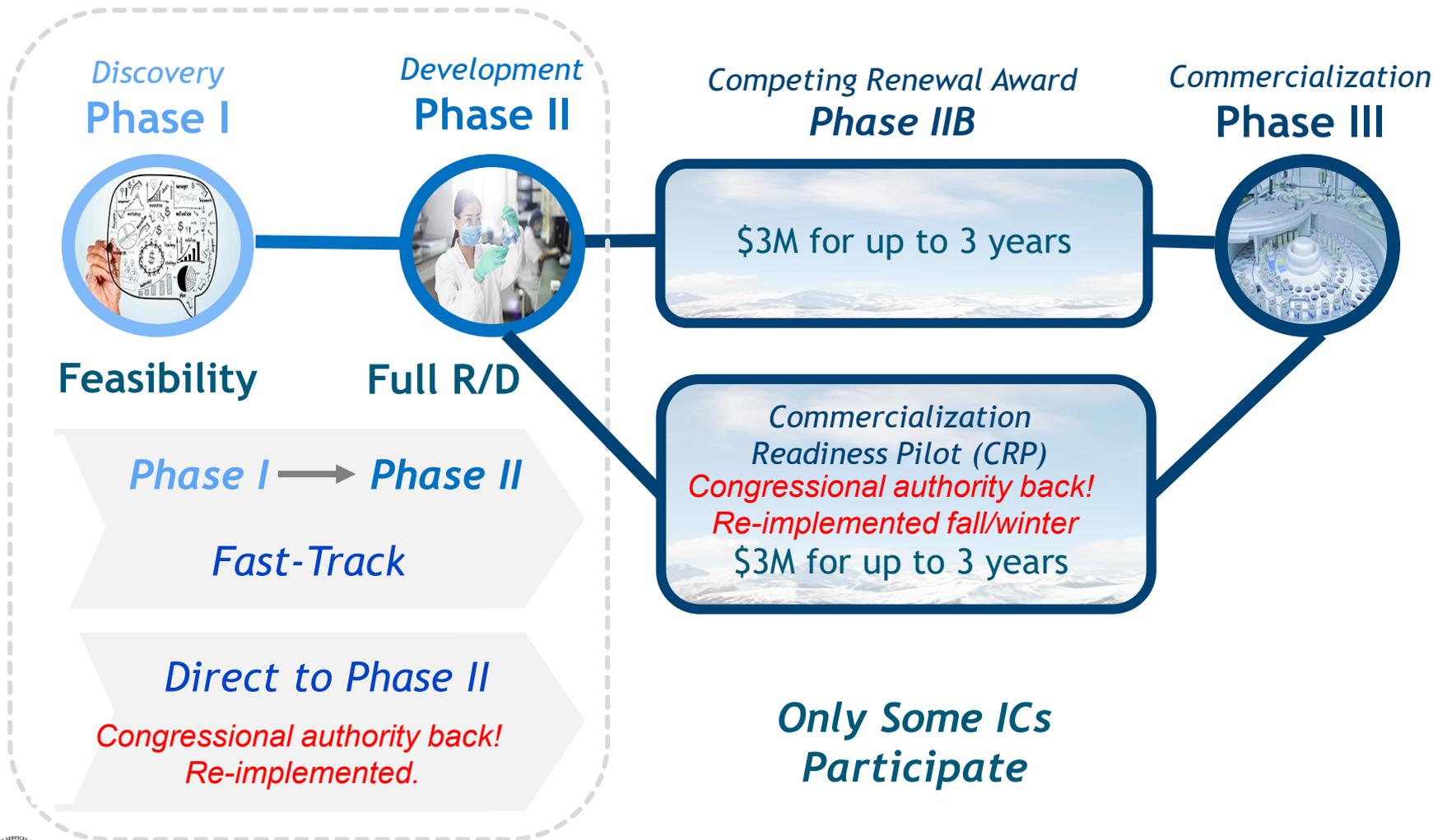


NIH SBIR/STTR Budget Allocations FY2019

3.2% SBIR \$1B
 0.45% STTR \$141M
Total FY19 \$1.145B

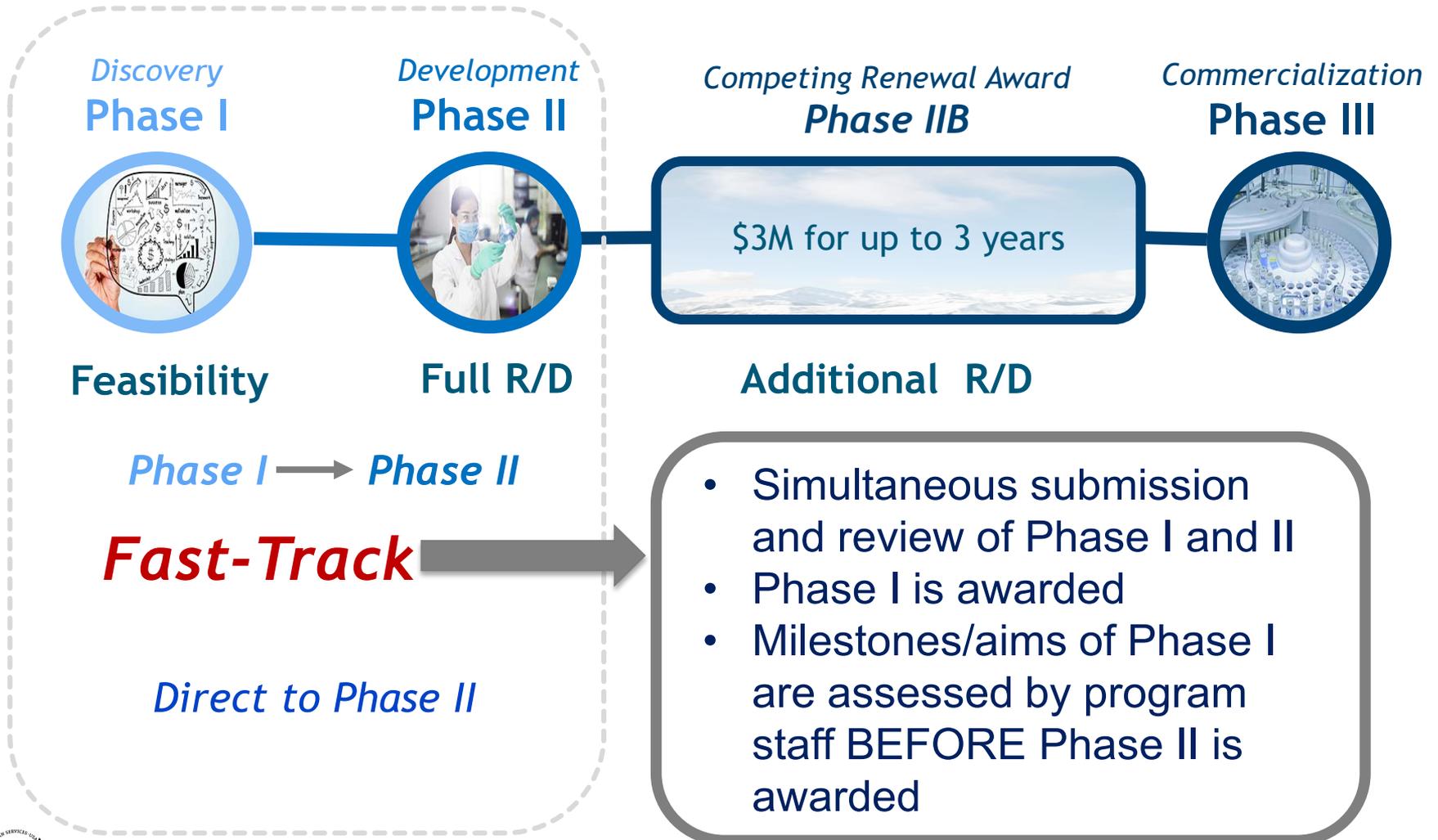


NIH SBIR/STTR 3-Phase Program

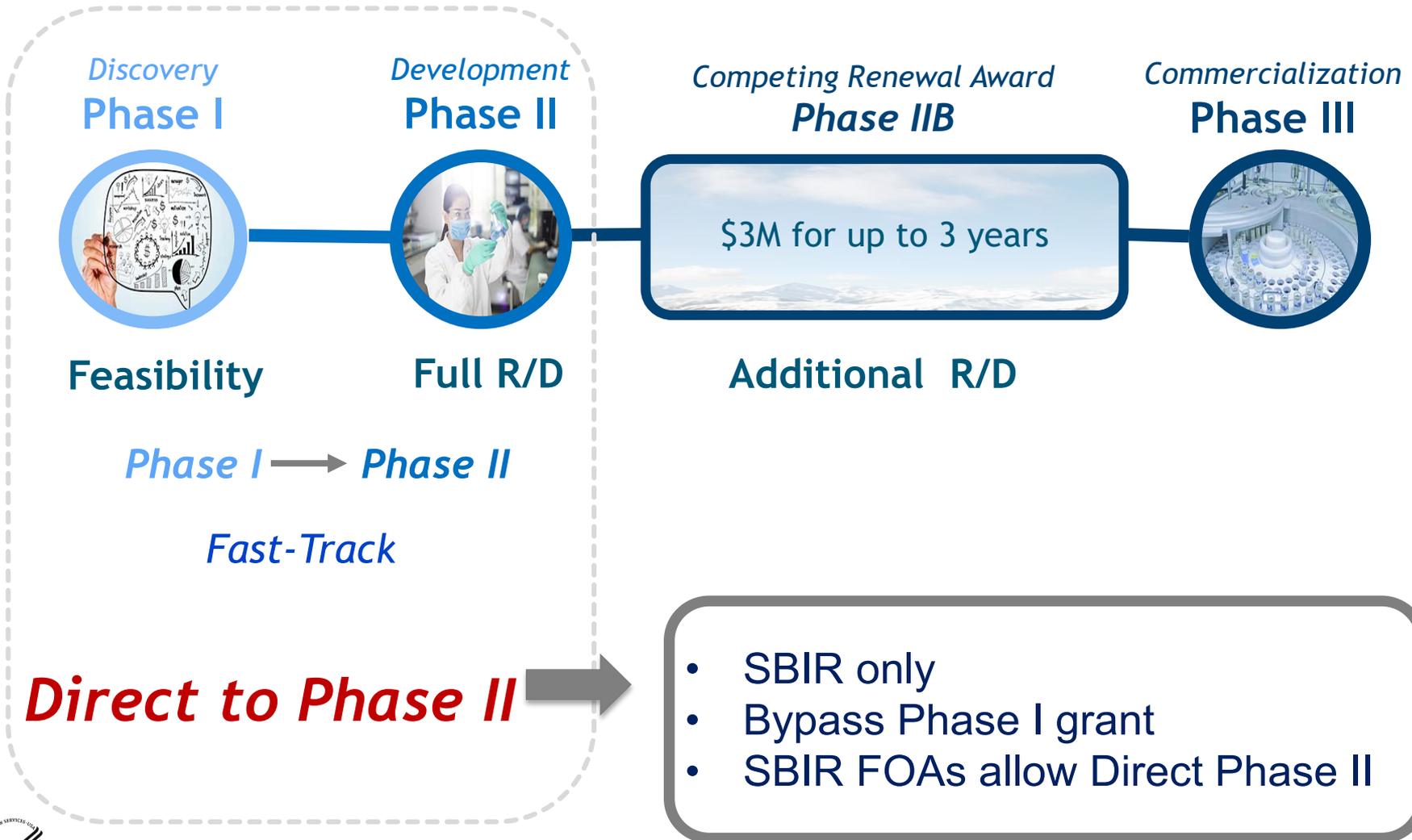




NIH SBIR/STTR Fast-Track



NIH SBIR/STTR Direct to Phase II



Phase IIB Competing Renewal Award

Discovery
Phase I



Development
Phase II



**Competing Renewal
Phase IIB**

**\$3-4M for up to 3
years**

Commercialization
Phase III



- SBIR/STTR Phase II awardee
- Technologies that require extraordinary time/effort to develop, and often require FDA regulatory approval
- Awards up to **\$1M/year for up to 3 years**
- IC must accept Competing Renewal applications (NIA, NIAAA, NIAID, NICHD, NIDA, NIDCD, NIDDK, NEI, NIGMS NHLBI, NIMH, NINDS, NCATS, ORIP, NCI, NHLBI, NINDS)

Contact NIH Program Staff to discuss!

Funding Opportunities Announcements (FOAs)

a publicly available document by which a federal agency makes known its intentions to award discretionary grants or cooperative agreements, usually as a result of competition for funds.

2019 SBIR and STTR Omnibus/Parent Grant Solicitations for the NIH, CDC, and FDA, Clinical Trial Not Allowed and Clinical Trial Required

- SBIR Omnibus/Parent Clinical Trial Not Allowed Funding Opportunity Announcement (PA-19-272)
 - STTR Omnibus/Parent Clinical Trial Not Allowed Funding Opportunity Announcement (PA-19-270)
 - SBIR Omnibus/Parent Clinical Trial Required Funding Opportunity Announcement (PA-19-273)
 - STTR Omnibus/Parent Clinical Trial Required Funding Opportunity Announcement (PA-19-271)
 - 2019 Program Descriptions and Research Topics Document
 (2.31 MB)  (614 KB)
 - 2019 SBA approved topics list for budget waivers
 (554 KB)  (72 KB)
-  NIH SBIR/STTR Grant Forms

Standard Due Dates:

-  January 5
-  April 5
-  September 5

NIH SBIR Direct to Phase II

The Congressional authority for SBIR Direct Phase II is reinstated until FY2022. See individual SBIR solicitations.

New – Direct Phase II will be added as an allowable Application Type either by Notice or in the solicitation in Part II Section II if SBIR Direct Phase II will be accepted.

See the current list of Notices that have added Direct Phase II to SBIR solicitations:
<http://bit.ly/2P0Im1H>

Standard Due Dates:

-  January 5
-  April 5
-  September 5

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



Omnibus vs Targeted FOAs

	Omnibus	Targeted
Due Dates	Standard Due Dates	Standard or Customized Due Dates
Review	SBIR/STTR panels at CSR	SBIR/STTR panels at CSR <OR> SBIR/STTR panel at IC
Application Instructions	Follow SF424 R&R SBIR/STTR Application Guide & Annotated Form Set	Follow SF424 R&R SBIR/STTR Application Guide & Annotated Form Set <AND> any additional instructions in FOA

Read FOA very carefully!





NIH, CDC, & FDA SBIR/STTR Grant Solicitation “Parent” FOAs:

<https://sbir.nih.gov/funding#omni-sbir>

Clinical Trial Required

SBIR: [PA-19-273](#)

STTR: [PA-19-271](#)

Clinical Trial Not Allowed

SBIR: [PA-19-272](#) STTR: [PA-19-270](#)

Release: May 7, 2019

Standard Due Dates: **September 5th (2019)**

January 6th, April 6th (2020)





Contracts

SBIR Contract Solicitation (NIH, CDC) - **CLOSED**

Closing Date: October XX, 2019

Program Solicitation [PHS 2019-1](#) (SBIR Only) - **Last year's**

R&D Contract Solicitation:
SBIR Phase I, Fast-Track
Contract Solicitation, PHS
2019-1

Closing Date: October 22, 2018, 5:00PM EDT - **Solicitation Closed**

- PHS 2019-1 (PDF - 1 MB)
- PHS 2019-1 (MS Word - 373 KB)
- Amendment 1 - CDC CGH Topic Added
- Amendment 2 - Q&A and CDC Contact Updates
- Contract Proposal Forms

[NIH Guide for Grants and Contracts](#)

Release: Weekly receipt dates specified in each FOA

- NIH Guide Notice: [NOT-OD-18-123](#)





New Reforms & Initiatives

All Research Involving Human Participants

- ✓ New forms to collect human subjects information
- ✓ Use of a single Institutional Review Board (IRB) for domestic multi-site studies

Research that Meets the NIH Definition of a Clinical Trial

- ✓ Training in Good Clinical Practice (GCP)
- ✓ Clinical trial-specific Funding Opportunity Announcements (FOAs)
- ✓ New review criteria
- ✓ Expanded registration and results reporting in ClinicalTrials.gov





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**.

- **Prospectively Assigned:** a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.
- **Intervention:** a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints.
- **Health-related Biomedical or Behavioral Outcome:** the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life.





Determine if Your Study is an NIH-defined Clinical Trial

Does your study...

1. Involve one or more **human participants**?
2. **Prospectively assign** human participant(s) to intervention(s)?
3. Intend to **evaluate the effect of an intervention** on human participants
4. Have a **health-related biomedical or behavioral outcome**?

If “yes” to ALL of these questions, your study is considered a clinical trial

Clinical Trial Interactive Decision Tree: <https://grants.nih.gov/ct-decision/index.htm>



Clinical Trial-Specific Funding Opportunities

Applications/proposals involving clinical trials (due dates on or after January 25, 2018) **must** be submitted to an FOA/RFP that accepts clinical trials

NOT-OD-16-147:

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-147.html>

NOT-OD-17-043:

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-043.html>

3 Types of FOAs

- ✓ Clinical Trials Not Allowed – only accepting applications **not** proposing clinical trial(s)
- ✓ Clinical Trials Required – only accepting applications proposing clinical trial(s)
- ✓ Clinical Trials Optional – accepting applications that either propose or do not propose clinical trial(s)



Public Website on Clinical Trial Requirements

- HOME
- ABOUT GRANTS
- FUNDING
- POLICY & COMPLIANCE
- NE

Home » Policy & Compliance » Clinical Trial Requirements for Grants and Contracts

Policy & Compliance

- NIH Grants Policy Statement
- Notices of Policy Changes
- Compliance & Oversight

Select Policy Topics

- Animal Welfare
- Application Submission Policies

Clinical Trial Requirements

- Clinical Trial Definition
- Why the Changes
- Good Clinical Practice
- Specific Funding Opportunities
- New Form
- Single IRB Policy
- Protocol Template
- Registration and Reporting

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

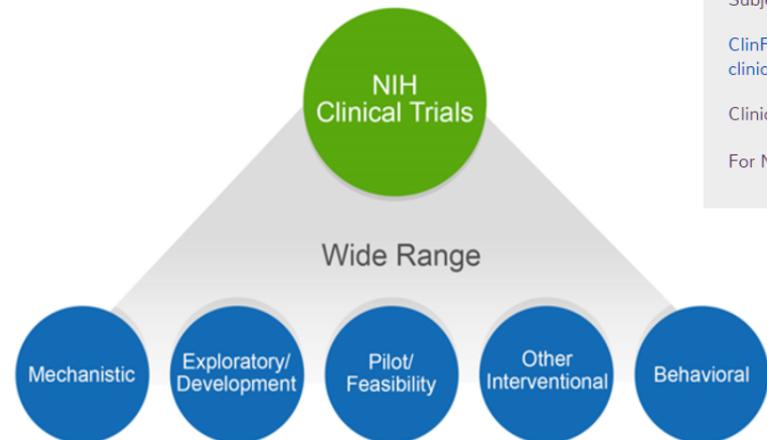
A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. [Learn more](#)

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

FIND OUT HERE

Related

- FAQs
- Training
- Research Subjects
- ClinRegs: clinical tri
- Clinicaltri
- For NIH S



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





The specific set of topics that are funded by a particular IC/Office/Agency depends on whether the IC/Office/Agency funds/supports Clinical Trials under SBIR/STTR Awards. Use the following table and explanations to determine which list of topics is applicable.

	No*	Yes**
Does IC/Office/Agency Fund/Support Clinical Trials under SBIR/STTR Awards?		X

2019 Program Descriptions and Research Topics Document

Does IC/Office/Agency accept clinical trials applications under this mechanism?	Yes	No	Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.
Clinical Trials SBIR/STTR Omnibus/Parent Funding Opportunity Announcement/s	X		
Clinical Trials SBIR/STTR IC/Office/Agency - Specific Funding Opportunity Announcement/s	X		https://grants.nih.gov/grants/guide/pa-files/PAS-18-188.html https://grants.nih.gov/grants/guide/pa-files/PAS-18-187.html https://grants.nih.gov/grants/guide/pa-files/PAR-18-186.html https://grants.nih.gov/grants/guide/pa-files/PAR-18-185.html https://grants.nih.gov/grants/guide/pa-files/PAR-18-184.html https://grants.nih.gov/grants/guide/pa-files/PAR-18-183.html
Clinical Trials NON-SBIR/STTR Funding Opportunity Announcement/s where Small Businesses are eligible to apply		X	





New Human Subjects and Clinical Trials Information Form



- Required for all applications with due dates on or after January 25, 2018
- Consolidates human subjects and clinical trial information into one place
- Expands information required for studies meeting definition of NIH clinical trial
- Collects information at the study level
- Aligns with ClinicalTrials.gov

[NOT-OD-17-062](#) New NIH "FORMS-E" Grant Application Forms and Instructions

[NOT-OD-17-119](#) New "FORMS-E" Grant Application Instructions Available





Institutes allowing Clinical Trials under Omnibus

National Cancer Institute ([NCI](#))

National Eye Institute ([NEI](#))

National Heart, Lung, and Blood Institute ([NHLBI](#))

National Human Genome Research Institute ([NHGRI](#))

National Institute on Aging ([NIA](#))

National Institute on Alcohol Abuse and Alcoholism ([NIAAA](#))

Eunice Kennedy Shriver National Institute of Child Health and Human Development ([NICHD](#))

National Institute on Deafness and Other Communication Disorders ([NIDCD](#))

National Institute on Drug Abuse ([NIDA](#))

National Institute of General Medical Sciences ([NIGMS](#))

National Institute of Mental Health ([NIMH](#))

National Institute of Nursing Research ([NINR](#))

National Institute on Minority Health and Health Disparities ([NIMHD](#))

National Center for Complementary and Integrative Health ([NCCIH](#))

Centers for Disease Control and Prevention ([CDC](#)) (SBIR only)

SBIR Omnibus/Parent Clinical Trial Required Funding Opportunity Announcement ([PA-19-273](#))

STTR Omnibus/Parent Clinical Trial Required Funding Opportunity Announcement ([PA-19-271](#))





<https://sbir.nih.gov/faqs#ct>

→ C <https://sbir.nih.gov/faqs#ct> ☆

ABOUT

FUNDING

APPLY

REVIEW

POLICY

TECHNICAL ASSISTANCE

RESOURCES

STATISTICS AND SUCCESSES

ENGAGE AND CONNECT

New to SBIR/STTR

Frequently Asked Questions

Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

PUBLIC FAQs

NIH STAFF FAQs

RELATED NIH STAFF FAQs

Show All FAQs Print All FAQs

General Questions

Application Preparation & Submission

Clinical Trials

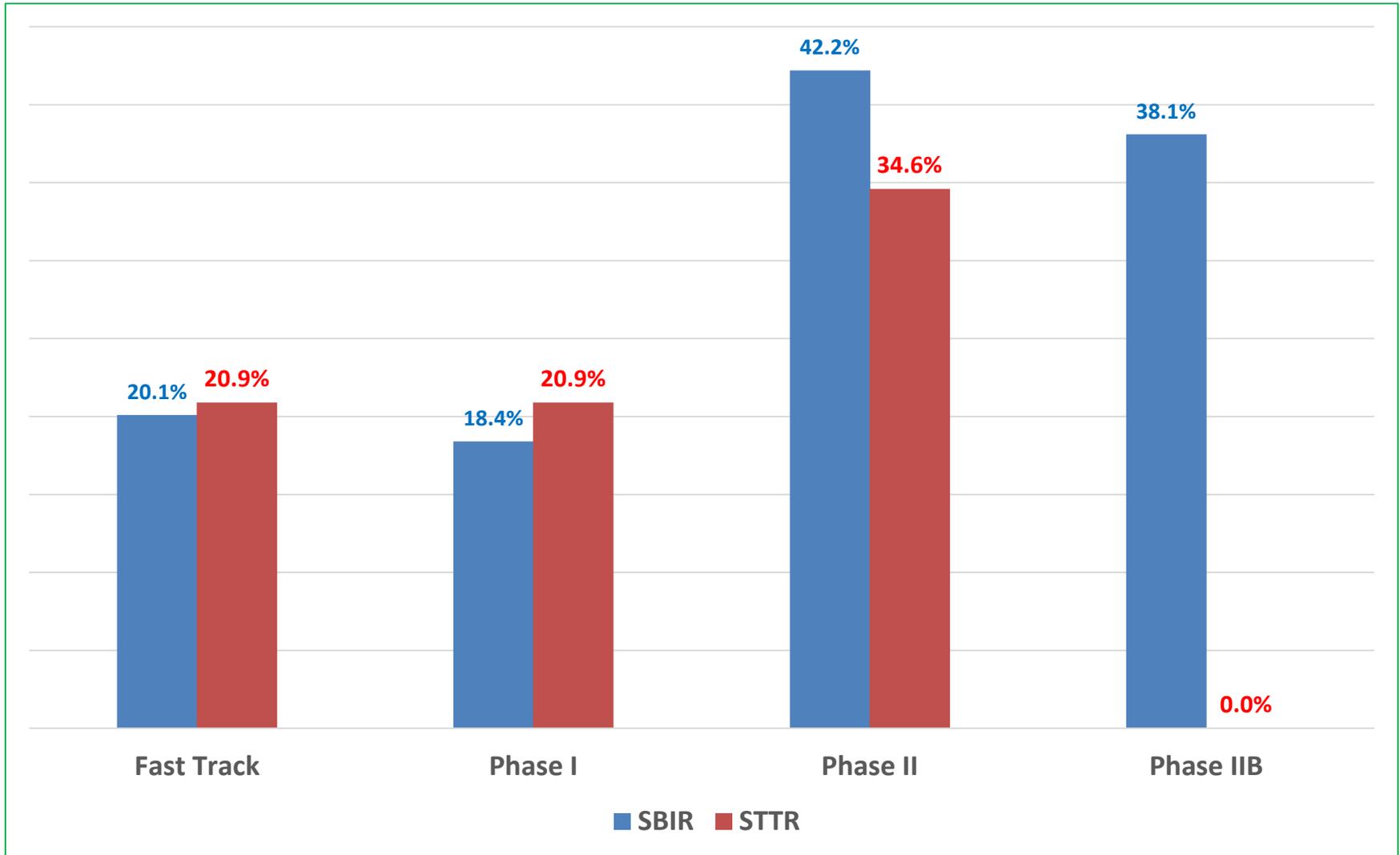
Print This Section

- › What are clinical trials?
- › What are the clinical trial requirements for grants and contracts?
- › Under which funding opportunity should a small business apply if the research project includes a clinical trial?
- › Is Good Clinical Practice (GCP) training required?
- › Are there additional review criteria for research projects including a clinical trial?
- › What are the requirements for registering and reporting NIH-funded clinical trials in ClinicalTrials.gov?





NIH SBIR/STTR 2018 Success Rate by Phase



Note: STTR Ph2B 1 application, no award.





NIH-wide SBIR/STTR Grant Success Rates 2018

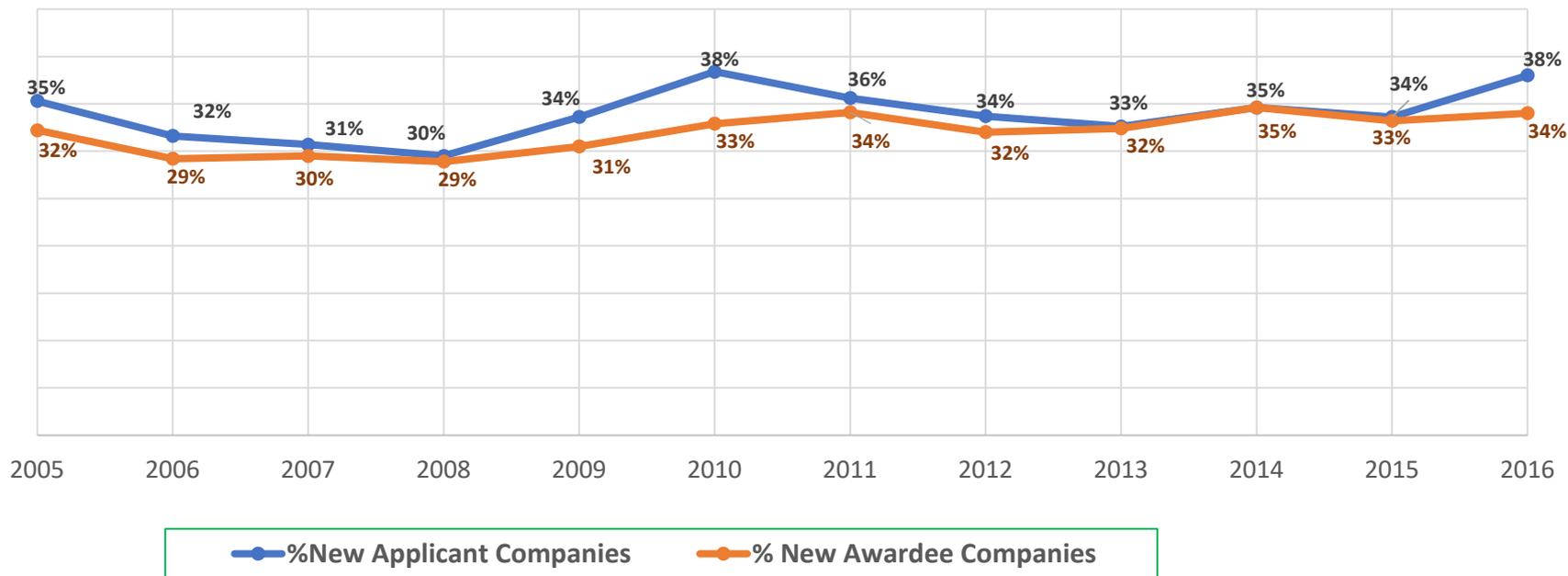
Fiscal Year	SBIR/STTR	Phase	Number of Applications Reviewed	Number of Applications Awarded	Success Rate	Total Funding
2018	SBIR	Phase I	3,607	665	18.4%	\$164,092,776
2018	SBIR	Fast Track	730	147	20.1%	\$41,420,240
2018	SBIR	Total Phase II	619	258	41.7%	\$214,967,591
2018	SBIR	Regular Phase II	531	224	42.2%	\$176,948,384
2018	SBIR	Phase IIB	84	32	38.1%	\$36,023,223
2018	STTR	Phase I	1,011	211	20.9%	\$52,320,567
2018	STTR	Fast Track	129	27	20.9%	\$8,767,497
2018	STTR	Total Phase II	79	27	34.2%	\$20,972,412
2018	STTR	Regular Phase II	78	27	34.6%	\$20,972,412
2018	STTR	Phase IIB	1	0	0.0%	\$0
2018	FY TOTAL		6,177	1,337	21.6%	\$504,146,584

Success Rates Posted Online: <https://sbir.nih.gov/statistics/award-data>





Percentage of New Applicant Companies and New Awardee Companies



Some of our Home Runs



www.sbir.gov/news/success-stories



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

Registrations are required!!!

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



ASSIST

NIH's web-based service for the preparation, submission and tracking of grant applications.

Learn more about preparing your application using ASSIST

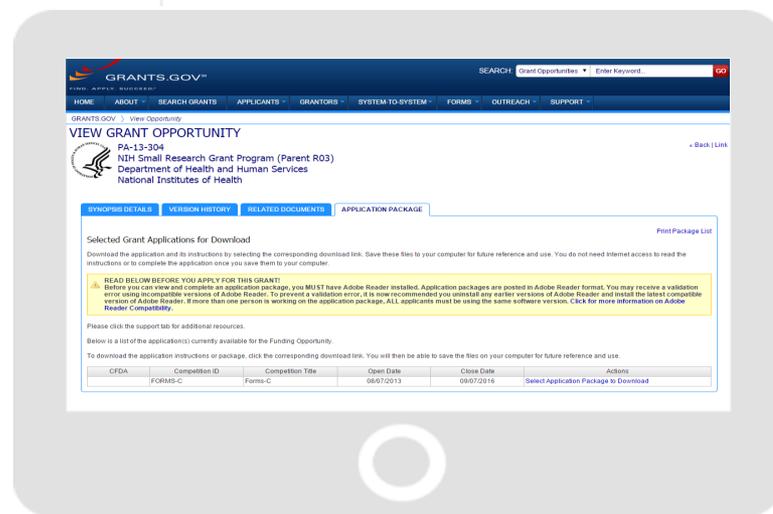
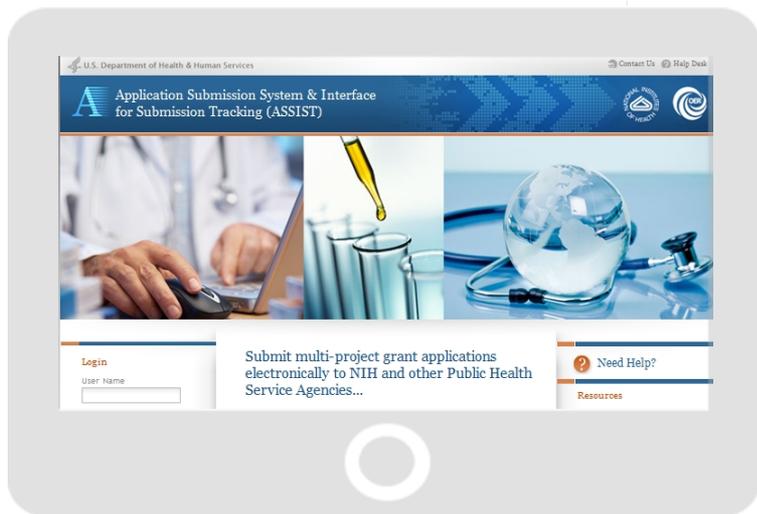
Grants.gov Workspace

A shared, online environment managed by Grants.gov where multiple users may simultaneously work on different forms within an application package.

Learn more about preparing your application using Grants.gov Workspace

Institutional Solutions (System-to-System, S2S)

Institution's own system to prepare and submit application data to Grants.gov complying with all application requirements.





Annotated Form Set for NIH Grant Applications

FORMS-E Series

(Application due dates on/after January 25, 2018)

Form only included in small business funding opportunity announcements.

SBIR/STTR Information

OMB Number: 4040-0001
Expiration Date: 10/31/2019

*** Agency to which you are applying (select only one)**

DOE HHS USDA Other:

Check HHS for all NIH, CDC, and FDA submissions.

*** SBC Control ID:** **Required.** (This 9 digit code is obtained from the Small Business Administration)

*** Program Type (select only one)** Must select SBIR or STTR (not Both).

SBIR STTR

Both (See agency-specific instructions to determine whether a particular agency allows a single submission for both SBIR and STTR)

*** Application Type (select only one)**

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

Not valid for STTR.

Not valid for HHS (NIH, CDC, FDA).

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

Check opportunity for allowable Application Types.

Phase I Letter of Intent Number:

Leave blank. N/A for HHS (NIH, CDC, FDA) submissions.

*** Agency Topic/Subtopic:** **Optional.**

Questions 1-7 must be completed by all SBIR and STTR Applicants:

<input type="checkbox"/> Yes <input type="checkbox"/> No	* 1a. Do you certify that at the time of award your organization will meet the eligibility criteria for a small business as defined in the funding opportunity announcement? Selection required. Must meet SBIR/STTR eligibility requirements at time of award (not submission).
	* 1b. Anticipated Number of personnel to be employed at your organization at the time of award. <input style="width: 50px;" type="text"/> Required.
<input type="checkbox"/> Yes <input type="checkbox"/> No	* 1c. Is your small business majority owned by venture capital operating companies, hedge funds, or private equity firms? Selection required.
<input type="checkbox"/> Yes <input type="checkbox"/> No	* 1d. Is your small business a Faculty or Student-Owned entity? Selection required.
<input type="checkbox"/> Yes <input type="checkbox"/> No	* 2. Does this application include subcontracts with Federal laboratories or any other Federal Government agencies? * If yes, insert the names of the Federal laboratories/agencies: <input style="width: 100%; height: 20px;" type="text"/> Selection required.
	Required if Yes. Up to 250 characters.





Timeline: New Applications



Due Date	Scientific Review	Council Review	Award Date (earliest)
April 5 th	May/June	Aug/Sept	October
Sept 5 th	Oct/Nov	Jan/Feb	March
Jan 5 th	Feb/Mar	May/June	July





Applicant initiates research idea



Small Business Concern confirms Eligibility



Submits SBIR/STTR grant application to NIH electronically



NIH Center for Scientific Review assigns to IC and IRG

1-2 Months



IC staff prepare funding plan for IC Director



Advisory Council or Board recommend Approval

3 Months



Scientific Review Group evaluates scientific merit

2-4 Months



IC allocates funds



Grantee conducts research



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





Talk to a HHS Program Officer at least a month before a deadline for application specific advice.

The screenshot shows the SBIR/STTR website interface. A navigation menu on the left includes: REVIEW, POLICY, TECHNICAL ASSISTANCE, RESOURCES, STATISTICS AND SUCCESS, and ENGAGE AND CONNECT. A yellow button labeled 'New to SBIR/STTR' is visible. A 'Contact' dropdown menu is open, listing: Contact SBIR/STTR, IC Program Contacts, eRA Service (IC Program Contacts submission Qs), and Connect. An 'Engage' dropdown menu lists: Twitter, Listserv, News, Webinar, and Events. A 'Financial/Grants Mgmt Contact' section lists: Ms. Linda Whipp (Phone: 301-496-1472, Fax: 301-402-3672, Email: Linda.Whipp@nih.gov), Ms. Judy Fox (Phone: 301-443-4704, Fax: 301-443-3891, Email: Judy.Fox@nih.gov), Ms. Vandhana Khurana, MBA (Phone: 240-669-2966, Fax: 301-493-0597, Email: khuranav@niaid.nih.gov), and Jason Lundgren (Phone: 240-669-2973, Fax: 301-493-0597, Email: Jason.Lundgren@nih.gov). A table below lists program contacts for the National Institute on Alcohol Abuse and Alcoholism (Megan Ryan, M.B.A., Phone: 301-443-4225, Email: mryan1@mail.nih.gov) and the National Institute of Allergy and Infectious Diseases (Dr. Natalia Kruchinin, Phone: 240-669-2919, Fax: 240-627-3162, Email: kruchinn@niaid.nih.gov).

[Click here for the list of HHS SBIR Program Managers](#)

Not sure who to contact? Email sbir@od.nih.gov





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 (who must be US citizens)
- 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](#)



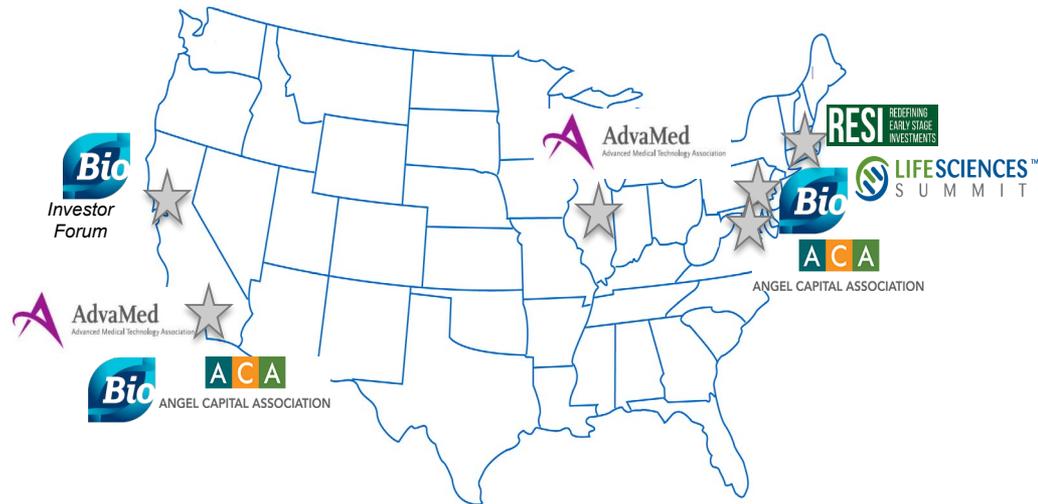
I-Corps™ at NIH

An intensive *Entrepreneurial Immersion* course for scientists



12 Participating ICs + CDC

Facilitating Partnerships





Niche Assessment Program-Foresight S&T

(Phase I Awardees)

- Helps jump start commercialization efforts
- Determines competitive advantages
- Develops market entry strategy



Commercialization Accelerator Program - Larta, Inc.

(Phase II Awardees)

- Technical Assistance/Training in:
 - Strategic/business planning
 - FDA requirements
 - Technology evaluation
 - Manufacturing issues
 - Patent and licensing issues
- Helps build strategic alliances
- Facilitates investor partnerships
- Individualized mentoring/consulting





Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

NIH Entrepreneurs in Residence

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

NIH Entrepreneurs in Residence (EIRs)

Experienced life science executives to help take your technology to the market

NIH EIRs are a FREE business resource for small business awardees seeking assistance with **commercializing their technology** and **ensuring success in the market**. There are no fixed time commitments or funding required - support is on an "as needed" basis to assist you with your commercialization objectives.





Get Connected!

- Subscribe to the SBIR/STTR Listserv:
 - Email LISTSERV@LIST.NIH.GOV with the following text in the message body: **subscribe SBIR-STTR your name**
- [NIH Guide for Grants and Contracts](#) (weekly notification)
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QUESTIONS?

Submit using the “Questions”
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Control Panel.

