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

May 29, 2019

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SBIR/STTR Program Coordinator
Office of Extramural Research, NIH
NIH SBIR/STTR Website

https://sbir.nih.gov
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.
New to SBIR/STTR?

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.

http://sbir.nih.gov/infographic
Congressionally Mandated Programs

**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
SBIR Purpose and Goals

- 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
STTR Purpose and Goals

• 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**

<table>
<thead>
<tr>
<th>Agency</th>
<th>Approx Budget</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department of Defense (DOD)</td>
<td>$1.750 B</td>
</tr>
<tr>
<td>Department of Health and Human Services (DHHS), including the National Institutes of Health (NIH)*</td>
<td>$1.088 B</td>
</tr>
<tr>
<td>Department of Energy (DOE), including Advanced Research Projects Agency – Energy (ARPA-E)</td>
<td>$291.7M</td>
</tr>
<tr>
<td>National Science Foundation (NSF)</td>
<td>$202.4 M</td>
</tr>
<tr>
<td>National Aeronautics and Space Administration (NASA)</td>
<td>$198.0 M</td>
</tr>
</tbody>
</table>

**6 AGENCIES WITH ONLY SBIR PROGRAMS**

<table>
<thead>
<tr>
<th>Agency</th>
<th>Approx Budget</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department of Agriculture (USDA)</td>
<td>$27.0M</td>
</tr>
<tr>
<td>Department of Homeland Security (DHS): Science and Technology Directorate (S&amp;T) &amp; Countering Weapons of Mass Destruction Office (CWMD)</td>
<td>$20.8 M</td>
</tr>
<tr>
<td>Department of Commerce: National Oceanic and Atmospheric Administration (NOAA) &amp; National Institute of Standards and Technology (NIST)</td>
<td>$14.2M</td>
</tr>
<tr>
<td>Department of Transportation (DOT)</td>
<td>$8.5 M</td>
</tr>
<tr>
<td>Department of Education (ED)</td>
<td>$7.5 M</td>
</tr>
<tr>
<td>Environmental Protection Agency (EPA)</td>
<td>$4.2 M</td>
</tr>
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</table>

*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
Technical & Business Assistance

• 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:
  o making better technical decisions concerning such projects;
  o solving technical problems which arise during the conduct of such projects;
  o minimizing technical risks associated with such projects; and
  o developing and commercializing new commercial products and processes resulting from such projects, including intellectual property protections.
SBIR/STTR Legislative Update

- 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 Table]

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

<table>
<thead>
<tr>
<th>2019 Budget</th>
<th>SBIR</th>
<th>STTR</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIH</td>
<td>$1B</td>
<td>$141M</td>
</tr>
<tr>
<td>CDC</td>
<td>~$12M</td>
<td>N/A</td>
</tr>
<tr>
<td>ACL (NIDILRR)</td>
<td>~$3M</td>
<td>N/A</td>
</tr>
<tr>
<td>FDA</td>
<td>~$1M</td>
<td>N/A</td>
</tr>
</tbody>
</table>
Program Eligibility Criteria

- 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
STTR Eligibility Criteria

• Applicant is a Small Business Concern

• Formal Cooperative R&D Effort
  o Minimum 40% by small business
  o Minimum 30% by US research institution

• US Research Institution
  o College or university; other non-profit research organization; Federal R&D center

• Intellectual Property Agreement
  o Allocation of rights in IP and rights to carry out follow-on R&D and commercialization
NIH SBIR/STTR 3-Phase Program

**Discovery**

**Phase I** Feasibility Study
- **Budget Guide:** $150K for SBIR and STTR
- **Project Period:** 6 months (SBIR); 1 year (STTR)

**Development**

**Phase II** Full Research/R&D
- $1M for SBIR and STTR, over two years

**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** Commercialization
- NIH, generally, not the “customer”
- Consider partnering and exit strategy early
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](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

<table>
<thead>
<tr>
<th></th>
<th>SBIR</th>
<th>STTR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Partnering Requirement</strong></td>
<td>Permits partnering</td>
<td>Requires a non-profit research institution partner (e.g. university)</td>
</tr>
<tr>
<td><strong>Work Requirement</strong></td>
<td>Guidelines: May outsource 33% (Phase I) 50% (Phase II)</td>
<td>Minimum Work Requirements: 40% small business 30% research institution partner</td>
</tr>
<tr>
<td><strong>Principal Investigator</strong></td>
<td>Primary employment (&gt;50%) must be with the small business</td>
<td>PI may be employed by either the research institution partner or small business</td>
</tr>
</tbody>
</table>

**Award is always made to the small business**
No SBIR/STTR funding authority
NIH SBIR/STTR Budget Allocations FY2019

- 3.2% SBIR $1B
- 0.45% STTR $141M
- Total FY19 $1.145B
NIH SBIR/STTR  
3-Phase Program

**Feasibility**  
**Phase I**

**Development**  
**Phase II**

**Competing Renewal Award**  
**Phase IIB**

$3M for up to 3 years

**Commercialization**  
**Phase III**

**Commercialization Readiness Pilot (CRP)**
Congressional authority back!
Re-implemented fall/winter
$3M for up to 3 years

**Direct to Phase II**
Congressional authority back!
Re-implemented.

**Fast-Track**
NIH SBIR/STTR
Fast-Track

Discovery
Phase I

Feasibility

Development
Phase II

Full R/D

Competing Renewal Award
Phase IIB

$3M for up to 3 years

Commercialization
Phase III

Additional R/D

• Simultaneous submission and review of Phase I and II
• Phase I is awarded
• Milestones/aims of Phase I are assessed by program staff BEFORE Phase II is awarded

Fast-Track

Direct to Phase II

Phase I → Phase II
NIH SBIR/STTR
Direct to Phase II

Discovery Phase I
- Feasibility

Development Phase II
- Full R/D
- Fast-Track

Competing Renewal Award Phase IIB
- $3M for up to 3 years
- Additional R/D

Commercialization Phase III

Direct to Phase II
- SBIR only
- Bypass Phase I grant
- SBIR FOAs allow Direct Phase II
Phase IIB Competing Renewal Award

- 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.

https://sbir.nih.gov/funding
<table>
<thead>
<tr>
<th></th>
<th>Omnibus</th>
<th>Targeted</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Due Dates</strong></td>
<td>Standard Due Dates</td>
<td>Standard or Customized Due Dates</td>
</tr>
<tr>
<td><strong>Review</strong></td>
<td>SBIR/STTR panels at CSR</td>
<td>SBIR/STTR panels at CSR &lt;OR&gt; SBIR/STTR panel at IC</td>
</tr>
<tr>
<td><strong>Application Instructions</strong></td>
<td>Follow SF424 R&amp;R SBIR/STTR Application Guide &amp; Annotated Form Set</td>
<td>Follow SF424 R&amp;R SBIR/STTR Application Guide &amp; Annotated Form Set &lt;AND&gt; any additional instructions in FOA</td>
</tr>
</tbody>
</table>

Read FOA very carefully!
NIH, CDC, & FDA SBIR/STTR Grant Solicitation “Parent” FOAs:
https://sbir.nih.gov/funding#omni-sbir

Clinical Trial Required

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

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.

Learn more at [https://grants.nih.gov/policy/clinical-trials/definition.htm](https://grants.nih.gov/policy/clinical-trials/definition.htm)
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.


### 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)
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.

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

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

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.

<table>
<thead>
<tr>
<th>Does IC/Office/Agency Fund/Support Clinical Trials under SBIR/STTR Awards?</th>
<th>No*</th>
<th>Yes**</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Does IC/Office/Agency accept clinical trials applications under this mechanism?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Clinical Trials SBIR/STTR Omnibus/Parent Funding Opportunity Announcement/s</th>
<th>X</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Clinical Trials SBIR/STTR IC/Office/Agency - Specific Funding Opportunity Announcement/s</th>
<th>X</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Clinical Trials NON-SBIR/STTR Funding Opportunity Announcement/s where Small Businesses are eligible to apply</th>
<th>X</th>
<th></th>
</tr>
</thead>
</table>

Other Information:
If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.

2019 Program Descriptions and Research Topics Document

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)
Clinical Trials Updates

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

Frequently Asked Questions

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

General Questions

Application Preparation & Submission

Clinical Trials

- 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

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

Percentage of New Applicant Companies and New Awardee Companies

- %New Applicant Companies
- % New Awardee Companies

Dollars of NIH Funded SBIR/STTR Awards in FYs 2012-2016 in Millions
Dollars Per Person of NIH Funded SBIR/STTR Awards in FYs 2012-2016

[Map showing the distribution of dollars per person of NIH Funded SBIR/STTR Awards across the United States, with different shades indicating various dollar ranges.]
Some of our Home Runs

Electronic Submission

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
Submit via ASSIST or Workspace

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)*

**SBIR/STTR Information**

- **Agency to which you are applying (select only one):**
  - [ ] DOE
  - [ ] HHS
  - [ ] USDA
  - [ ] Other: [ ] Required
  - (This 9-digit code is obtained from the Small Business Administration)

- **Program Type (select only one):**
  - [ ] 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 I
  - [ ] Phase IIA
  - [ ] Phase IIB
  - [ ] Commercialization Readiness Program (See agency-specific instructions to determine applicable type participation)

- **Phase I Letter of Intent Number:** [ ] Optional

- **Questions 1-7 must be completed by all SBIR and STTR Applicants:**
  - **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? [ ] Yes [ ] No
    - 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. [ ] Required.

  - **1c.** Is your small business majority owned by venture capital operating companies, hedge funds, or private equity firms? [ ] Yes [ ] No
    - Selection required.

  - **1d.** Is your small business a Faculty or Student-Owned entity? [ ] Yes [ ] No
    - Selection required.

  - **2.** Does this application include subcontracts with Federal laboratories or any other Federal Government agencies? [ ] Yes [ ] No
    - If yes, insert the names of the Federal laboratories/agencies:
    - Required if Yes, Up to 250 characters.
<table>
<thead>
<tr>
<th>Due Date</th>
<th>Scientific Review</th>
<th>Council Review</th>
<th>Award Date (earliest)</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 5th</td>
<td>May/June</td>
<td>Aug/Sept</td>
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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

Scientific Review Group evaluates scientific merit

3 Months

IC allocates funds

Grantee conducts research

2-4 Months
Review Criteria

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
Most Important Piece of Advice

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

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](https://samar.gov)
I-Corps™ at NIH
An intensive *Entrepreneurial Immersion* course for scientists

Facilitating Partnerships

12 Participating ICs + CDC
**Niche Assessment Program-Foresight S&T**  
(Phase I Awardees)

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

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**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
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.

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  - Email LISTSERV@LIST.NIH.GOV with the following text in the message body: subscribe SBIR-STTR your name

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