NIH Small Business Applicant Assistance Programs (AAP)

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Select slides contain a “comment box” which has incorporated questions posed during the webinar. Look for this symbol:

![comment box icon]
on the slides.
There are 27 different Institutes and Centers (ICs), 24 of which award grants.

Each one has:

- Different missions
- Different funding priorities
- Different budgets
- Different types of grants they support
- Different procedures for making funding decisions
- Different funding strategies

ALWAYS CONTACT PROGRAM STAFF WELL IN ADVANCE OF APPLYING
The mission of NINDS is to seek fundamental knowledge about the brain and nervous system and to use that knowledge to reduce the burden of neurological disease.

Support research on hundreds of Neurological Disorders

https://www.ninds.nih.gov/
NIH Small Business Programs

SBIR · STTR
Small Business Innovation Research
Small Business Technology Transfer

• Congressionally mandated set-aside (3.65%)
  • FY 2017: $980M NIH and $55M NINDS
• For R&D with potential for commercialization
• Broad scope:
  • Therapeutics, diagnostics, tools for research
  • Bench research, translational research, early stage clinical trials
• A majority of our applications are investigator-initiated and come in through the omnibus solicitations

https://www.ninds.nih.gov/Funding/Small-Business-Grants
NINDS Small Business Priorities

NOT-NS-18-002

• NINDS gives priority to meritorious research proposals with the greatest potential to advance the NINDS mission
  • We are especially interested in:
    • Novel and innovative technologies that are new to the SBIR or STTR programs.
    • Technologies coming to the SBIR or STTR programs for their first indication or market opportunity.
    • Companies and applicants that are new to the SBIR and STTR programs.
    • NINDS Cooperative Agreement (U44) Translational Programs.

https://www.ninds.nih.gov/Funding/Small-Business-Grants
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 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 Time of Award
# SBIR and STTR Critical Differences

<table>
<thead>
<tr>
<th></th>
<th>SBIR (Small Business Innovation Research)</th>
<th>STTR (Small Business Technology Transfer)</th>
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<tbody>
<tr>
<td><strong>Set-Aside</strong></td>
<td>3.2%</td>
<td>0.45%</td>
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<tr>
<td><strong>Partnering Requirement</strong></td>
<td>Permits partnering</td>
<td>Requires a non-profit research institution partner (e.g. university)</td>
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<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>
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<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>
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**Award is always made to the small business**
Phases of SBIR/STTR

**Phase I:**
Guidelines: $150K/6 months
Hard Cap*: $225K/1-2 years
NINDS Waiver Guidelines: $700K (not more than $500K/yr)

**Phase II:**
Guidelines: $1M/1 year
Hard Cap*: $1.5M/1-3 years
NINDS Waiver Guidelines: $3M (not more than $1.5M/yr)

*NIH has a waiver from the Small Business Administration to exceed these Hard Caps for specific topics

SBIR/STTR budgets are in total cost (direct + indirect + fee)
Phases of SBIR/STTR: Fast-Track

**Fast-Track**

*Phase I ➔ Phase II*

- 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

*Across NIH all new application types (Phase I, Fast-Track) have roughly the same success rate*

**FAST-TRACK APPLICATIONS ARE NOT ELIGIBLE FOR THE NIH APPLICANT ASSISTANCE PROGRAM (NIH AAP)**
NIH Definition of Clinical Trial

Clinical Trials:
- Involve one or more human subjects
- Involve one or more interventions
- Prospectively assign human subject(s) to intervention(s)
- Have a health-related biomedical or behavioral outcome

Clinical Trials need to:
- Respond to a clinical trial-specific FOA
- Address additional review criteria specific for clinical trials
- Register and report clinical trial in ClinicalTrials.gov

For More Information:
https://grants.nih.gov/policy/clinical-trials/definition.htm
NINDS Support for Clinical Studies

- Clinical Research (e.g. diagnostics) are accepted through the general solicitations (clinical trials not allowed)
- NINDS does NOT participate in the Clinical Trials SBIR/STTR omnibus solicitations
- Clinical Trials are accepted through specific program announcements (clinical trials optional or required)
- **All these announcements utilize the Phase II or Fast Track mechanisms**

  *(no SBIR/STTR Phase I Clinical Trials for NINDS)*

<table>
<thead>
<tr>
<th>NINDS Exploratory Clinical Trials</th>
<th>PAR-18-618 (SBIR)</th>
<th>Stephanie Fertig <a href="mailto:fertigs@ninds.nih.gov">fertigs@ninds.nih.gov</a></th>
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<tbody>
<tr>
<td>NINDS Renewal Awards of SBIR Phase II Grants (Phase IIB) Clinical Trials and Clinical Research</td>
<td>PAR-18-617 (STTR)</td>
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<tr>
<td></td>
<td>PAR-18-665 (Phase IIB)</td>
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</table>

**NeuroNEXT**

| NINDS Exploratory Clinical Trials Program | PAR-18-628 | Codrin Lungu lunguci@ninds.nih.gov |

**NIH StrokeNet**

| StrokeNet Clinical Trials Network | PAR-18-628 | Claudia Moy moyc@ninds.nih.gov |

**NINDS Exploratory Clinical Trials**

- NINDS Renewal Awards of SBIR Phase II Grants (Phase IIB) Clinical Trials and Clinical Research

**NINDS does NOT participate in the Clinical Trials SBIR/STTR omnibus solicitations**

**Clinical Trials are accepted through specific program announcements (clinical trials optional or required)**

**All these announcements utilize the Phase II or Fast Track mechanisms**

*no SBIR/STTR Phase I Clinical Trials for NINDS*
SBIR and STTR Success Rates (FY17)

- Consider the same score range for SBIR and STTR
- SBIR program has more than 7x the budget but has roughly the same application success rate at NIH

Contact Us! We can help you determine what might be the best program for you
“SBIR is a tough route, and people should be aware of that. The reviewers are not concerned about feelings. But take the criticism seriously, correct the things that need correcting and be prepared to resubmit. Don’t give up because of a depressing review.”

“[SBIR] has been a long, trying, but worthwhile journey...from multiple submissions that were not discussed...to applications that scored below the funding levels...to concurrent applications (one Phase II and a Phase I) emerging from the rigorous peer review process with impact scores in the “Excellent" range.”
NIH reviews applications with panels made up of outside experts.

Most applications are reviewed at the Center for Scientific Review (CSR).

- Scientific Review Officer sets up the panel and runs review.
- Review panels look at grants from multiple Institutes/Centers.

Score can decide if you will be considered for funding (or not).

Budget is not “scorable”- a smaller project budget does not mean a better chance of being funded.

Academic Grant is NOT an SBIR/STTR Grant

ACADEMIC GRANT
- Expertise/Team (optional)
- Approach (Discovery Research)
- Environment
- Significance (Gain in Knowledge)
- Innovation (What is theoretically possible)

SBIR/STTR GRANT
- Expertise/Team
  - Phase I: Research and Development
  - Phase II: R&D Toward Commercial Development
- Approach (Product Development)
- Environment
- Science (MANDATORY)
- Innovation (Competitive Advantage)
- Significance (Changing a paradigm)
- Commercialization
Common Application Problems

• No Significance: Unimportant problem, unconvincing case for commercial potential or societal impact
• Inadequately defined test of feasibility (no milestones)
• Lack of innovation
• Diffuse, superficial or unfocused research plan
• Unrealistically large amount of work proposed
• Questionable reasoning in experimental approach
• Failure to consider potential pitfalls and alternatives
• Lack of experience with essential methodologies
• Unfamiliar with relevant published work
Commercialization Support

**Pre-SBIR/STTR:**
Entrepreneurial Assistance/Training
NIH I-Corps™ (pilot) and C3i Programs
- Open to current awardees of participating NIH Institutes/Centers
- Administrative Supplements: **PA-18-702** and **PA-18-517**

**NIH Applicant Assistance Program (AAP):**
- **PILOT:** NOT-CA-18-072;
  **www.dawnbreaker.com/aap**
- Companies who have not previously won an SBIR/STTR award from NIH
- NCI, NINDS or NHLBI mission
- Provide free services: application preparation, needs assessment, etc.

**Phase I:**
Market Analysis
Niche Assessment Program (NAP)
Entrepreneurial Assistance/Training
NIH I-Corps™ and C3i Programs

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

**Program Staff**
Contact Us BEFORE Submission for Advice/Feedback
NIH Applicant Assistance Program (AAP)

- Pilot Program
- **FREE!** Application preparation **ASSISTANCE**
- Three participating Institutes (NCI, NINDS, NHLBI)

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<thead>
<tr>
<th>NIH AAP PROGRAM</th>
<th>NOT PROVIDED</th>
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<tr>
<td><strong>Phase I Preparation Support and Review</strong></td>
<td>Grant Writer</td>
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<tr>
<td>Specific Aims Page Review and Advice</td>
<td>Development of Research Plan</td>
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<tr>
<td>Small Business Mentoring</td>
<td>Register small business for you, apply to NIH for you</td>
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<tr>
<td><strong>OPTION OF ADDITIONAL ASSISTANCE</strong></td>
<td></td>
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<tr>
<td>Preliminary Market Research</td>
<td>Comprehensive Market Report</td>
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<tr>
<td>IP Consultation</td>
<td>Comprehensive Patent Landscape Review</td>
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<tr>
<td>Team/Facilities Development</td>
<td>Actual staff or space</td>
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NIH AAP Timeline

Pilot Application Assistance Program

Early January
Round 1 AAP application date

Feb – April 5
Round 1 AAP Program

June 1st
Round 2 AAP applications due

Jun – Sept 5
Round 2 AAP Program

Next SBIR/STTR Receipt Date
September 5th, 2018 (Wednesday)

Calendar Year 2018
NIH AAP Eligibility

Application Deadline
• June 1st, 2018
• http://www.dawnbreaker.com/aap

Eligibility criteria
• Companies who have not previously won an SBIR/STTR award from NIH
• No current SBIR/STTR grants pending peer review
• Phase I applications only
• Project fits within the NCI, NINDS or NHLBI mission
  • Not sure if your project fits within our mission?

Contact Program Staff BEFORE Submission for Eligibility Questions
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
Encourage Inclusive Entrepreneurship

Encouraging Unrepresented Small Businesses (not a requirement for program eligibility)

- Women-owned and women-led businesses
- Socially and Economically Disadvantaged Businesses
- Minority-led businesses
- Small Businesses operating in an underrepresented (IDeA) state
• SIMPLE!
• CV of the Principle Investigator
• Abstract
• A description of how you believe the program will help you.
  • Some examples:
    • Entrepreneur with no previous experience applying to NIH
    • Academic research in an area lacking significant support for small businesses
• Apply at: http://www.dawnbreaker.com/aap
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 commercialization in the United States. These programs allow US-owned and operated small businesses to engage in federal research and development that has a high potential for commercialization.
Annual HHS SBIR/STTR Conference

- Register today! -

20th Annual HHS SBIR/STTR Conference

Dallas Regional Chamber

October 30-November 1, 2018
Dallas, TX
https://hhs20dallas.org/

Stay connected for updates!
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@NINDStranslate
http://www.ninds.nih.gov/dtr