Small Business Programs at NINDS

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

on the slides.
The National Institute of Neurological Disorders and Stroke (NINDS)

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/
SBIR/STTR Tip
Each Institute/Center (IC) has different policies

- Applications come to the NIH (not to a specific IC)
- Important to know which IC will take assignment
  - Each IC has a different mission/focus
  - Different policies, budget guidelines, and resources

- Contact NIH Program Staff well in advance of applying
  - We can help!
  - Contact Me: fertigs@ninds.nih.gov
  - Contacts for each IC: https://sbir.nih.gov/engage/ic-contacts

- 3.2% SBIR $861.4M
- 0.45% STTR $121.1M
- Total FY17 $982.5M
NINDS Is Investing Across the Research Spectrum

Basic
Fundamental Neuroscience
Disease-Focused Research

Translational
Assay Development
Pre-Clinical Research

Clinical
Phase I, II, III Trials
FDA Review
NINDS Translational and Clinical Programs

Preclinical and Early Clinical Trials

Grants

Clinical Trials/ Infrastructure Resources

Grants

NIH Programs

Resources

Contracts

ADME/Tox. Chemistry Manufacturing Clinical
NIH Small Business Programs

$980M (NIH)
$55M (NINDS)
Available for Small Businesses

• Congressionally mandated 3.65% set-aside
• For research with potential for commercialization
• Broad scope
  • Therapeutics, diagnostics, and tools for research
  • May include bench research, translational research, and early stage clinical trials
• Larger budgets for some topics (e.g. animal and clinical studies)
• A majority of our applications are investigator-initiated and come in through the omnibus solicitations

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 (For FOAs after 1/28/2013 NIH; 7/10/14 CDC)

Determined at Time of Award
# SBIR and STTR Critical Differences

<table>
<thead>
<tr>
<th>Requirement</th>
<th>SBIR (Small Business Innovation Research)</th>
<th>STTR (Small Business Technology Transfer)</th>
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</thead>
<tbody>
<tr>
<td>Required Set-Aside</td>
<td>3.2%</td>
<td>0.45%</td>
</tr>
<tr>
<td>Partnering Requirement</td>
<td>Permits partnering</td>
<td>Requires a non-profit research institution partner (e.g. university)</td>
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<tr>
<td>Work Requirement Guidelines</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>Principal Investigator</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

**Discovery Phase I**
- Feasibility

**Development Phase II**
- Full R/D

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

**Commercialization Phase III**

*Fast-Track Phase I + Phase II*

**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)
Fast-Track SBIR/STTR

**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

**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
**SBIR/STTR Tip**

**Pick the program that fits your project**

- 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

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

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**Contact Us! We can help you determine what might be the best program for you**

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<thead>
<tr>
<th></th>
<th>SBIR</th>
<th>STTR</th>
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<tbody>
<tr>
<td>Fast Track</td>
<td>19%</td>
<td>17%</td>
</tr>
<tr>
<td>Phase I</td>
<td>16%</td>
<td>16%</td>
</tr>
<tr>
<td>Phase II</td>
<td>37%</td>
<td>39%</td>
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NIH Provides a Wealth of Information Online: NIH Small Business Programs Website

https://sbir.nih.gov/
NINDS Small Business Programs: 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
NINDS Small Business Programs: Priorities
NOT-NS-18-002

Funding decisions are based on a combination of factors:

1. Potential for high impact on advancing the NINDS mission and the other programmatic priorities described in this Notice
2. Potential for commercialization
4. Previous performance of the applicant and/or company in the SBIR/STTR programs
5. For Phase II applicants: the results of the Phase I
6. Peer review scores and critiques
7. Availability of funds

https://www.ninds.nih.gov/Funding/Small-Business-Grants
SBIR/STTR Tip
Focus on Investigator Initiated Research

• NIH is generally not the final customer
  • Customers are clinicians, researchers, caregivers, patients, etc.
  • Many technologies need additional funds or resources from investors/partners after Phase II to get to market

• NINDS is focused on grants instead of contracts
  • “Parent” SBIR/STTR Grant Solicitations (PA-18-574/PA-18-575)
    • Where most of our funded applications are submitted
    • Company decides what market and product/service
  • Specific funding opportunities (http://sbir.nih.gov)
    • Not all of them have specific set-asides or separate reviews
    • Read funding opportunity carefully
Keys to reading a Funding Opportunity Announcement (FOA)

- Different FOAs:
  - Program Announcement (PA)
  - PAR: special receipt, referral and/or review
  - PAS: set-aside funds
  - RFA: special receipt date, review, etc.
- Cooperative Agreement (U versus R mechanisms)
- Read Funding Purpose and Opportunity Description
- Budget requirements and years allowed
- Type of Applications allowed (e.g. Phase I, Phase II, Fast Track)
- Eligibility: Is it a small business mechanism?
- Application and Submission Information
- Review Criteria
- Scientific/Research Contact(s) at the end
Many of these programs:
• Are milestone-drive
• Have SBIR Cooperative Agreement (U44)
• Have specific funding announcements

https://www.ninds.nih.gov/
NINDS Cooperative Translational Programs

Small Molecules (PAR-18-541):

- Cooperative agreement and SBIR Fast-Track award programs support small molecule drug discovery and development
- Access to consultants and contracts that provide discovery, preclinical development, and clinical trial support

Biologics (PAR-17-457/PAR-18-543):

- Cooperative agreement and SBIR Fast-Track award programs support the discovery and development of therapeutic Biotechnology Products and Biologics (e.g. peptides, proteins, oligonucleotides, gene therapies, and cell therapies)
- Access to consultants

Neural Devices (RFA-NS-18-012):

- Cooperative agreement and SBIR Fast-Track award programs support development, validation and verification, and early clinical studies of therapeutic and diagnostic devices to treat neurological disorders.
- Support for small clinical trial to collect safety and effectiveness data

Charles Cywin, Ph.D. (charles.cywin@nih.gov)

Chris Boshoff, Ph.D. (chris.boshoff@nih.gov)

Nick Langhals, Ph.D. (nick.Langhals@nih.gov)
NINDS Biomarkers Initiative
Facilitate the development of high quality biomarkers to improve the quality and efficiency of clinical research

Analytical Validation - Biomarker measurement performance characteristics

**PAR-18-549**

- To encourage rigorous analytical validation of candidate biomarker measures or endpoints consistent with FDA guidelines.
- Evaluation of the assay, its performance characteristics, and the optimal conditions

Clinical Validation - Biomarker for use in clinical trials and/or clinical practice

**PAR-18-548**

- To encourage rigorous clinical validation of a candidate biomarker using retrospective and/or prospective methods consistent with the purpose of the biomarker

Mary Ann Pellemounter, Ph.D. ([mary.pelleymounter@nih.gov](mailto:mary.pelleymounter@nih.gov))
NIH Definition of Clinical Trial

Does your study...
✓ 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?

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

Unsure how to answer the questions? We have a tool that can help! https://grants.nih.gov/ct-decision/
NIH Definition of Clinical Trial

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

Due Dates on or after January 25, 2018

All clinical trial applications **MUST** be submitted to an FOA that allows clinical trials

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)

<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>
</tr>
</thead>
<tbody>
<tr>
<td>NINDS Renewal Awards of SBIR</td>
<td>Par-18-617 (STTR)</td>
<td></td>
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<tr>
<td>Phase II Grants (Phase IIB) Clinical Trials and Clinical Research</td>
<td>Par-18-665 (Phase IIB)</td>
<td></td>
</tr>
<tr>
<td>Neurology Network of Excellence in Clinical Trials</td>
<td>Par-18-628</td>
<td>Codrin Lungu <a href="mailto:lunguci@ninds.nih.gov">lunguci@ninds.nih.gov</a></td>
</tr>
<tr>
<td>StrokeNet Clinical Trials Network</td>
<td>Par-18-628</td>
<td>Claudia Moy <a href="mailto:moyc@ninds.nih.gov">moyc@ninds.nih.gov</a></td>
</tr>
</tbody>
</table>
**Goal**: See the neural circuits in action to understand:

- How the brain moves, plans, executes
- How to monitor/modulate circuits for improved function
- That disordered brain circuits cause neuro/mental/substance use disorders

**Long-term goal**: Make circuit abnormalities the basis of diagnostics, and normalization of circuit function the target of intervention

*First Five Years*
- Emphasize technology development

*Second Five Years*
- Emphasize discovery driven science

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[https://braininitiative.nih.gov/](https://braininitiative.nih.gov/)
WHAT IS THE BRAIN INITIATIVE?

The Brain Research through Advancing Innovative Neurotechnologies® (BRAIN) Initiative is aimed at revolutionizing our understanding of the human brain. By accelerating the development and application of innovative technologies, researchers will be able to produce a revolutionary new dynamic picture of the brain that, for the first time, shows how individual cells and complex neural circuits interact in both time and space. Long desired by researchers seeking new ways to treat, cure, and even prevent brain disorders, this picture will fill major gaps in our current knowledge and provide unprecedented opportunities for exploring exactly how the brain enables the human body to record, process, utilize, store, and retrieve vast quantities of information, all at the speed of thought.

Highlights of The BRAIN Initiative®

- **News:** NIH BRAIN Initiative builds on early advances
- **2017 Funded Awards**
- **Discover the BRAIN Alliance new Website**
- **BRAIN Initiative Funding Opportunities**
- **Job Opportunities**

**BRAIN Initiative Partners**

- **Federal**
  - National Science Foundation (NSF)
  - Defense Advanced Research Projects Agency (DARPA)
  - U.S. Food and Drug Administration (FDA)
  - The Intelligence Advanced Research Projects Activity (IARPA)

- **Non-federal**
  - Foundations
  - Institutes
  - Universities
  - Industry

https://braininitiative.nih.gov/
Small Business Opportunities

Development, Optimization, and Validation of Novel Tools and Technologies for Neuroscience Research

- For large scale recording/manipulation of neural activity
- To facilitate the detailed analysis of complex circuits and provide insights into cellular interactions

Supports iterative refinement with the user community to increase incorporation into regular neuroscience practice

**PAR-18-501** (SBIR)

**PAR-18-515** (STTR)
Next-Generation Invasive Devices for Recording and Modulation in the Human Central Nervous System

- Supports translational and clinical studies for invasive recording and/or stimulating devices to treat nervous system disorders and better understand the human brain
- Direct-to-Clinical Research ([RFA-NS-18-023](https://nih.gov))
- Utilize the NIH BRAIN Public-Private Partnership Program *(not required)*

Nick Langhals, Ph.D. ([nick.Langhals@nih.gov](mailto:nick.Langhals@nih.gov))
BRAIN Public-Private Partnership Program

Program Goals: To facilitate partnerships between clinical investigators and manufacturers of the latest-generation *implantable stimulating and/or recording devices* for clinical neuroscience research in humans

- Device companies have signed Memoranda of Understanding (MOU) with the NIH to provide information on materials (devices, software, surgical tools, etc.) and support that each are willing to make available
- **Template Collaborative Research Agreements (CRAs)** have been developed to streamline agreements between academic institutions and commercial device manufacturers

[https://braininitiative.nih.gov/Resources/BRAIN_PPP](https://braininitiative.nih.gov/Resources/BRAIN_PPP)
Important Facts to Remember

• Duplicative projects may not be submitted to NIH using different grant programs

• Applications **may be** submitted to **different agencies** for similar work to support different aims/objectives

• Awards may not be accepted from different agencies **for duplicative projects**
SBIR/STTR Tip
Understanding Peer Review is Critical

• 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

https://www.csr.nih.gov has useful information about review for new applicants
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
SBIR/STTR Tip

Be Prepared to Resubmit

“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.”

Mary Potasek, Ph.D.
President and Co-founder
Simphotek

Talk to your Program Officer:

• **Before Submission** (there are NO stupid questions)
• After receiving the summary statement (regardless of how you did)
• **WE CAN HELP YOU!**
Beyond SBIR/STTR grants

**Pre-SBIR/STTR:**
Entrepreneurial Assistance/Training
NIH I-Corps™ (pilot) and C3i Programs

Applicant Assistance Program
For new/unsuccessful applicants

**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)

More information:
https://www.ninds.nih.gov/Funding/Small-Business-Grants/Entrepreneurial-Resources

Partnering Opportunities:
Sponsored/Discounted Attendance at Events/Conferences and Pitch Coaching
Applicant Assistance Program (AAP)  
NOT-CA-18-031

• Eligibility:
  – Companies who have not previously won an SBIR/STTR award from NIH
  – No current grants pending peer review
  – Phase I applications only
  – NCI, NINDS or NHLBI mission

• Free Services:
  – Needs Assessment/Small Business Mentoring
  – Phase I Application Preparation Support
  – Application Review
  – Team/Facilities Development
  – Market Research
  – Intellectual Property Consultation

• Encourage participation: women-owned businesses, socially/economically disadvantaged small businesses, small businesses in under-represented states

https://www.dawnbreaker.com/aap
- Save the Date -
20th Annual HHS SBIR/STTR Conference

October 30 - November 1, 2018
Dallas, Texas

Stay connected for updates!
@NIHsbir | https://sbir.nih.gov/
READ program announcements carefully
CONTACT a Program Officer before applying

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@NINDStranslate
http://www.ninds.nih.gov