SBIR-STTR Program
General Overview

Presented by
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USC Webinar Part 1
My Background

- 25+ years in the Federal Government
  - NIH:
    - SBIR/STTR Program Manager: Office of the Director
    - Researcher: National Cancer Institute
  - FDA
  - USDA
  - Interagency policies/initiatives (DOD, NSF, DOE, NASA, DHS, etc.)
- 10+ years in non-profit and for-profit environments
  - The Jackson Laboratory, Director of Sponsored Research
  - Small TX biotech company, VP Research
  - Small FL-based consulting company, Program Manager
- Scientific Background
  - Microbiology
  - Immunology
  - Cancer genetics
Topics to Discuss

- SBIR/STTR Overview
- Program eligibility
- Principal Investigator eligibility
- Relationship between a faculty member, university, and company

Dates for Upcoming Webinars!

- **Sept 21**: SBIR/STTR Application Structure and the NIH Peer Review Process
- **Sept 28**: How to Write your NIH SBIR/STTR Specific Aims Page and Commercialization Plan
SBIR/STTR Overview
SBIR/STTR History Review

• SBIR - created by Federal legislation in 1982.

• SBIR - created to provide funding for **early-stage** innovative ideas that are **too high risk** for private investment.

• Envisioned as an “Economic Stimulus”
  • Strong signal to Federal Agencies to make more effective use of innovative scientists and engineers employed by small companies that have the potential to convert R&D funds into new products and create new jobs – to optimize return on taxpayers’ dollars.

*Largest and most important source of early-stage technology R&D financing for America’s Entrepreneurs!*

SBIR/STTR Program Descriptions

• **Small Business Innovation Research (SBIR)**
  - Set-aside program for small businesses to engage in Federal R&D – with potential for commercialization
  - 3.2% of the extramural research budget for agencies with a budget greater than $100M per year
    ~$3.2 billion to spend each year

• **Small Business Technology Transfer (STTR)**
  - Sister set-aside program to facilitate *cooperative* R&D between small businesses and U.S. research institutions – with potential for commercialization.
  - 0.45% of the extramural research budget for agencies with a budget greater than $1B per year
    ~$450 million to spend each year

Over 5,000 new awards every year
SBIR/STTR Program Objectives

- Goal is to commercialize new innovations from U.S. small businesses:
  - 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
  - Foster technology transfer through cooperative R&D between small businesses and research institutions (STTR)

- Significant risk reduction:
  - Funds projects too early to attract investment capital
**SBIR/STTR Program Structure**

**PHASE I** *(Feasibility Study)*
- Award: Generally, up to $250,000 TC*
- Project Period: Generally, 6 mos (SBIR); 1 yr (STTR)

**PHASE II** *(Full Research/R&D)*
- Award: Generally, up to $750,000*
- Project Period: Generally, 2 years (SBIR/STTR)

**PHASE II B** *(Competing Renewal/R&D)*
- Clinical R&D; Complex Instrumentation/Tools
- Award/Project Period: Generally, $3M/3 years (NIH)

**PHASE III** *(Commercialization Stage)*
- Does not use of SBIR or STTR funds

*As of July 2023, agencies may issue a Phase I award up to $295,924 and a Phase II award up to $1,972,828 without seeking SBA approval. Any award above those levels requires a waiver.
Program Eligibility
SBIR Program Eligibility Criteria

- Applicant is organized as a for-profit business - based in the U.S.
- 500 employees or less, including affiliates*
- PI’s primary employment must be with the small business
- Eligibility is determined at the time of award

*If company is a joint venture, additional requirements must be met:
https://www.sbir.gov/faqs/eligibility-requirements
STTR Program Eligibility Criteria

- Applicant is organized as a for-profit small business - based in the U.S.

- Formal cooperative R&D effort
  - Minimum 40% by small business
  - Minimum 30% by U.S. research institution

- U.S. research institution
  - College or university
  - Other non-profit research organization
  - Federal R&D center

- Intellectual Property Agreement
  - Allocation of rights in intellectual property and rights to carry out Follow-on R&D and commercialization effort
Principal Investigator (PI) Eligibility
Principal Investigator (PI) Eligibility

SBIR:

- Primary employment of PI **MUST** be with the Small Business
- **More than 51%** time must be spent with the Small Business
- Not required to Spend 51% on Project -- Just in Company
- **No minimum time required to be spent on project** (10% - 20% is typical)

- **Note:** 51% does not mean working 20+ hours per week at Small Business while still employed F/T by University.

STTR:

- The PI may be from either the small business or the partnering institution
More on PI Rules

● For both SBIR and STTR awards, the Small Business PI and the University PI for the subcontract must be different individuals.

● If a University employee (or his/her spouse or dependent child) has a financial interest, leadership position in, or is employed by the Small Business, the faculty employee may not serve as the PI on the University subcontract from that Small Business.

● Establishing a separation of entities and roles is important.
  ○ Having the same person on both sides of the collaboration blurs the respective parties’ project roles, responsibilities and effort/time commitments.
  ○ Some agencies may be more restrictive (e.g., NSF).
Still More on PI Rules

SBIR:

● Primary employment with Small Business precludes full-time employment at another organization.

● Therefore, a full-time employee of the University may not serve as the PI of the SBIR grant.

● **Options:** PI takes a leave of absence from the University or assigns someone else as PI

● **Multiple PI project:** At least one must meet the primary employment requirement.

● *Occasionally,* funding agency allows deviations from the primary employment requirement - rare.
Even More Still on PI Rules

STTR:

- The PI may be employed with the Small Business or the participating non-profit research institution as long as s/he has a formal appointment with or commitment to the applicant small business
  - Characterized by an official relationship between the small business and that individual.
  - May or may not involve salary or other remuneration.
- The PD/PI must commit at least 10% effort to the project.
- Combined with University activities, effort may not exceed 100%.
Subcontractor Eligibility - SBIR

- Small Business *may* subcontract with a nonprofit research institute (and is encouraged!)

- Small Business should typically perform 2/3 of the work based on budget in Phase I. (50% of the work in Phase II)
  - *Deviations must be justified and approved by NIH.*

- Subcontracts may be with another company, university or other nonprofit organization.
Subcontractor Eligibility - STTR

- Small Business **must** partner with a nonprofit research institution
- Small Business **must** perform at least 40% of the effort (both Phases)
- Research Institution **must** perform at least 30% of the effort (both Phases)
- Balance of effort can go to either or additional parties (e.g., large company)
- IP agreement must be negotiated between parties
Research Space, Faculty, and COI
Use of University Space

- The Small Business must have space that it owns or controls to perform its R&D.
  - If use of University facilities by the Small Business is anticipated, use must be approved and covered by an agreement (Lease or License).

- Small Business certifies that their portion of R&D will occur in small business facilities using company employees unless otherwise indicated in the application and approved in the funding agreement.

- Performing the Small Business portion of R&D in University space using University resources – *unless specifically approved by the funding agency and allowed by the University* – subjects the company to potential criminal, civil, or administrative sanctions.
Things to Consider for Faculty

- Planning Phase: 1-4 months
- RI PI should disclose invention to its appropriate research institution office
- RI PI should discuss collaboration with Small Business and identify a FOA
- If Human Subjects are involved in the research - determine who will perform what activities? University? Company?
- Discuss potential Conflict of Interest (COI) issues with your institution
More on COI

- NIH exempts Phase I SBIR/STTR programs from federal COI regulations.

- Therefore, the University is not required to disclose to NIH any relationship or COI that the SBIR/STTR may create with a faculty member.

- However, University policy may be stricter and require that faculty disclose all financial relationships with the private sector in their annual COI disclosure, including information about participation in SBIR or STTR grants.
Even More on COI....

- Some University policies state that for funded Phase I SBIR and STTR programs, full disclosure is considered to be a sufficient management plan for the conflicts in most cases.

- During Phase II, however, PIs must comply with federal regulations for disclosure and manage any apparent/actual COI.
Scenario A: University employee (or family member) with NO significant financial interest

- Typically, the University employee may participate in or serve as a PI of a subcontract on SBIR/STTR projects if s/he has no ownership interests, is not employed by or has a position with the Small Business or has no other significant financial interests.

- In some cases (determined by COI office), the University employee may serve as a PI of a STTR project.
Scenario B: Ownership Interest, Employment, or Financial Interest Related to IP

- University employee cannot be PI for the Small Business and PI of a subcontract on the same SBIR or STTR project.
- University employee cannot work at both the company and the University on research related to SBIR or STTR projects.
- University employee who has an ownership interest in a Small Business cannot conduct or supervise research activities in his/her University laboratory through subcontracts on SBIR or STTR projects awarded to the Small Business.
- University employee paid directly from a Small Business with whom they have an ownership interest cannot conduct research for that entity in their University laboratory space.
SBIR/STTR Participating Agencies
SBIR and STTR Participating Agencies

Department of Agriculture (USDA)

Department of Commerce (DoC)
NIST, NOAA

Department of Defense (DoD)

Department of Education (ED)

Department of Energy (DOE)

Dept of Health and Human Services (HHS)
NIH, FDA, CDC, ACL

Department of Homeland Security (DHS)

Department of Transportation (DOT)

Environmental Protection Agency (EPA)

National Aeronautics and Space Administration (NASA)

National Science Foundation (NSF)
Federal R&D Agencies Are All Different...Mission And Culture
Program Differences Between Agencies

• **Solicitations**
  - Number of Solicitations single vs. multiple annually
  - Topic Areas – broad vs. focused

• **Proposals**
  - Proposal Preparation Instructions – no unified process
  - Proposal Review Process – external peer review or internal review
  - Proposal Success Rates – vary between agencies

• **Awards**
  - Type of Award – Contract, Grant, Cooperative Agreement
  - Financial Details – indirect cost rates
  - Dollar Amount of Award
  - Gap funding
## Federal Agency Differences

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<thead>
<tr>
<th>Federal Agency Comparison</th>
<th>DOD</th>
<th>NIH</th>
<th>DOE</th>
<th>NASA</th>
<th>NSF</th>
<th>USDA</th>
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<td><strong>Research Topics</strong></td>
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<td><strong>Investigator-Initiated Ideas</strong></td>
<td>N</td>
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Standard SBIR/STTR Phase I Process

- Agencies describe R&D topics in solicitations at fixed time periods over the year – generally not rolling.
- Small Business prepares/submits proposal.
- Agencies evaluate based on technical merit, company’s qualifications, and commercial potential / societal benefit.
- Agencies make Phase I awards.
## Differences Between SBIR and STTR Programs

<table>
<thead>
<tr>
<th></th>
<th>SBIR</th>
<th>STTR</th>
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<tbody>
<tr>
<td><strong>Partnering Requirement</strong></td>
<td>Permits partnering</td>
<td>Requires a non-profit 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 or small business (check solicitation)</td>
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<td><strong>Work Requirement</strong></td>
<td>May subcontract up to: 33% (Phase I) 50% (Phase II)</td>
<td>Minimum: 40% Small Business 30% Research Institution Partner</td>
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<tr>
<td><strong>Program Size</strong></td>
<td>3.2% set-aside</td>
<td>0.45% set-aside</td>
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<tr>
<td><strong>Majority VC ownership</strong></td>
<td>Allowed by some agencies</td>
<td>Not allowed</td>
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<tr>
<td><strong>Participating Agencies</strong></td>
<td>11 agencies (extramural R&amp;D budget &gt; $100M)</td>
<td>5 agencies (extramural R&amp;D budget &gt; $1B)</td>
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</tbody>
</table>

The small business is ALWAYS the applicant and awardee!
Required Registrations

- Dun and Bradstreet DUNS #
- System for Award Management (SAM)
- SBA Company Registration
- NSF: Fast Lane - Company and PI Registration
- NIH: eRA Commons – Signing Official and PD/PI
- DOD: Defense SBIR/STTR Innovation Portal
Mission:
To seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

National Institutes of Health
National Institutes of Health

The largest public funder of biomedical research in the world, investing more than $50 billion in FY22 to enhance life, and reduce illness and disability.
ONE NIH, 27 Cultures

Each Institute/Center has its own

- mission
- budget (and success rates)
- activities
- way of doing business

You are in the right place to learn the myriad nuances!
NIH SBIR/STTR Budget Allocations FY2023

- **3.2% SBIR** $1.1 billion
- **0.45% STTR** $146 million
- **Total FY23** $1.2 billion

### Pie Chart
- **Cancer**
- **Allergy and Infectious Diseases**
- **Aging**
- **Heart, Lung, and Blood**
- **General Medical Sciences**
- **Neurological Disorders and Stroke**
- **Diabetes, Digestive, and Kidney Disorders**
- **Mental Health**
- **Drug Abuse**
- **Child Health**
- **Eye**
- **Translational Sciences**
- **Environmental Health**

### Institutes
- NIAAA
- NIDCD
- NIBIB
- ORIP
- NINR
- NCCIH
- NLM
- NIAMS
- NHGRI
- NIDCR
- NIMHD
- NIAMS
- NLM
National Institutes of Health

- Posts broad topics and targeted initiatives
  - Omnibus Solicitations
  - RFAs, PAs
  - Encourages “investigator-initiated” research ideas

- Open communication
  - Contact with Program Director is encouraged throughout the process
    - Share draft Specific Aims and discuss
    - Discuss Budget, Team, etc.
    - Understand IC priorities
    - PHS Assignment Request Form: Use to impact study section makeup and IC assignment

- Reviewer roster is shared with applicant

- Reporting: Not onerous (relatively speaking)
NIH SBIR/STTR Phases

**Discovery**
- **Phase I**
- Feasibility
- **Development**
- **Phase II**
- Full R & D

**Phase I** → **Phase II**

**Fast-Track**

**Commercial Market**
- **Phase III**
- **Competing Renewal Award**
  - **Phase IIB**
- **Commercialization Readiness Pilot (CRP)**

**Commercialization Readiness Pilot (CRP)**
- Up to $300K (see **FOA**)
- Only Some NIH Institutes/Centers participate

**Phase I: $295,924***
- 1-2 years

**Phase II: $1,972,828***
- 1-3 years

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

<table>
<thead>
<tr>
<th>Small Business Program Phases</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td><strong>Phase I</strong></td>
<td>A Phase I award helps you focus on the feasibility, technical merit, and commercial potential of your research project.</td>
</tr>
<tr>
<td><strong>Phase II</strong></td>
<td>A Phase II award lets you continue the research and development efforts initiated in Phase I. Once you’ve reached your Phase I milestones, you can apply for a Phase II award, even before the end of the Phase II award. You may submit your application for a Phase II award up to six receipt dates after your Phase I budget period expires.</td>
</tr>
<tr>
<td><strong>Fast-Track</strong></td>
<td>The fast-track process allows you to submit both Phase I and Phase II in one application for review. The Fast-Track mechanism can minimize the funding gap between phases but requires a fully developed Phase II application/plan at the time of submission.</td>
</tr>
<tr>
<td><strong>Direct to Phase II (SBIR Only)</strong></td>
<td>If your project has already demonstrated feasibility but you have not received a Phase I SBIR or STTR, you can apply for a Direct to Phase II award and bypass Phase I.</td>
</tr>
<tr>
<td><strong>Phase IIB</strong></td>
<td>Some NIH Institutes and Centers offer Phase IIB awards for Phase II projects that require extraordinary time and effort beyond the standard Phase II period of 2 years. See the <a href="https://example.com">Phase IIB FAQs</a> for more information.</td>
</tr>
<tr>
<td><strong>Commercialization Readiness Pilot (CRP) Program</strong></td>
<td>The Commercialization Readiness Pilot (CRP) Program provides awarded Phase II and Phase IIB small businesses technical assistance and funding for late-stage development. Read more about the <a href="https://example.com">CRP program</a>.</td>
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More info here |
Technical Assistance and Entrepreneurial Training

**Discovery Phase I**
- TABA Funding: Requested in the Application
  - Phase I: $6,500/year
  - Phase II: $50K
- Needs Assessment
  - Click here for details

**Development Phase II/IIB**
- Consulting Services
  - Click here for details

**Technical and Business Assistance (TABA) Programs**

**Additional Entrepreneurial Training and Assistance**
- NIH I-Corps™
  - Click here for details
- NIH Concept to Clinic Commercializing Innovation (C3i): Medical Devices
  - Click here for details
- Diversity Supplement (PA-21-345)

https://sbir.nih.gov/tap
NIH Key Priority Areas

- **NIH Strategic Plan 2021-2025**
- **Advancing Biomedical and Behavioral Sciences**
  - Driving foundational science
    - Inventing tools and technologies to catalyze discovery
  - Preventing disease and promoting health
    - Developing new/improved vaccines
  - Developing and Optimizing Treatments, Interventions and Cures
    - Catalyzing Cell Engineering, Bioengineering, Regenerative Medicine
- **Developing, Maintaining and Renewing Scientific Research Capacity**
  - Enhancing biomedical Workforce
  - Some SBIR FOAs focus on workforce development
- **Exemplifying and Promoting the Highest Level of Scientific Integrity, Public Accountability and Social Responsibility in the Conduct of Science**
  - Promoting good stewardship
  - Leveraging partnerships (Federal, PPP, etc.)
NIH Funding Opportunities Abound!

- Omnibus Solicitations - SBIR

  - SBIR Program: PA-23-230 (Clinical trial not allowed)
    - PHS 2023-2 Omnibus Solicitation of the NIH, CDC and FDA for Small Business Innovation Research Grant Applications (Parent SBIR [R43/R44] Clinical Trial **Not Allowed**)
    - Receipt Dates: September 5, 2023; January 5, 2024; April 5, 2024

  - SBIR Program: PA-23-231 (Clinical trial required)
    - PHS 2023-2 Omnibus Solicitation of the NIH, CDC, and FDA for Small Business Innovation Research Grant Applications (Parent SBIR [R43/R44] Clinical Trial **Required**)
    - Receipt Dates: September 5, 2023; January 5, 2024; April 5, 2024

Focus is on Investigator-initiated research
NIH Funding Opportunities (cont.)

- Omnibus Solicitation - STTR
  - STTR Program: PA-23-232 (Clinical trial not allowed)
    - PHS 2023-2 Omnibus Solicitation of the NIH for Small Business Technology Transfer Grant Applications (Parent STTR [R41/R42] Clinical Trial Not Allowed)
    - Receipt Dates: September 5, 2023; January 5, 2024; April 5, 2024
  - STTR Program: PA-23-233 (Clinical trial required)
    - PHS 2023-2 Omnibus Solicitation of the NIH for Small Business Technology Transfer Grant Applications (Parent STTR [R41/R42] Clinical Trial Required)
    - Receipt Dates: September 5, 2023; January 5, 2024; April 5, 2024

Focus is on Investigator-initiated research
## NIH Funding Opportunities (cont.)

### Examples of Targeted Opportunities ([NIH Guide](https://pubs.niaid.nih.gov/NIHGuide/))

| Notice of Special Interest (NOSI): Advancing Biomedical Research in Pulmonary Non-Tuberculous Mycobacterial (NTM) Infections | NOT-AI-23-050 | NIAID | Jun 27, 2023 | Jul 17, 2026 |
| Notice of Special Interest (NOSI): Using Targeted Degradation of Protein and non-Protein Targets for the Development of Novel Anti-Infectives | NOT-AI-23-049 | NIAID | Jun 23, 2023 | Jul 17, 2026 |
| Limited Competition: Human Pangenome Coordinating Center (U41) Clinical Trial Not Allowed | RFA-HG-23-025 | NHGRI | Jun 20, 2023 | Aug 16, 2023 |
| Notice of Special Interest (NOSI): Promoting Research and Development of Vaccines Against Enteric Viruses | NOT-AI-23-048 | NIAID | Jun 15, 2023 | Jul 17, 2026 |
| Interactive Digital Media (IDM) Biomedical Science Resources for Pre-College Students and Teachers (SBIR) (R43/R44 Clinical Trial Not Allowed) | PAR-23-213 | NIGMS | Jun 15, 2023 | Sep 06, 2025 |
| **Field-Deployable, Low-Cost Point-of-Need Approaches and Technologies to Lower the Barriers to Substance Use Disorders (SUD) Diagnosis and Treatment (R43/R44 Clinical Trial Optional)** | RFA-DA-24-018 | NIDA | May 23, 2023 | Nov 11, 2023 |
| Field-Deployable, Low-Cost Point-of-Need Approaches and Technologies to Lower the Barriers to Substance Use Disorders (SUD) Diagnosis and Treatment (R41/R42 Clinical Trial Optional) | RFA-DA-24-017 | NIDA | May 23, 2023 | Nov 10, 2023 |
| Notice of Special Interest (NOSI): Developmentally Tailored HIV Prevention and Care Research for Adolescents and Young Adults | NOT-MH-23-250 | NIMH | May 19, 2023 | Sep 08, 2026 |
## National Institutes of Health

### Examples of Targeted Opportunities (cont.)

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<th>Description</th>
<th>Code</th>
<th>Agency</th>
<th>Start Date</th>
<th>End Date</th>
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<tr>
<td>Small Business Transition Grant For Early Career Scientists (R42 Clinical Trial Not Allowed)</td>
<td>RFA-CA-23-035</td>
<td>NCI</td>
<td>Apr 21, 2023</td>
<td>Aug 22, 2023</td>
</tr>
<tr>
<td>SBIR Phase IIB Bridge Awards to Accelerate the Development of Cancer-Relevant Technologies Toward Commercialization (R44 Clinical Trial Optional)</td>
<td>RFA-CA-23-034</td>
<td>NCI</td>
<td>Apr 21, 2023</td>
<td>Aug 22, 2023</td>
</tr>
<tr>
<td>Industrialization and Translation of Extracellular Vesicles for use in Regenerative Medicine (U43/U44 Clinical Trials Not Allowed)</td>
<td>PAR-23-267</td>
<td>NCATS</td>
<td>Apr 18, 2023</td>
<td>Jun 07, 2025</td>
</tr>
<tr>
<td>Developing Regulated Therapeutic and Diagnostic Solutions for Patients Affected by Opioid and/or Stimulants use Disorders (OUD/StUD) (R41/R42 Clinical Trial Optional)</td>
<td>RFA-DA-24-038</td>
<td>NIDA</td>
<td>Apr 18, 2023</td>
<td>Feb 15, 2025</td>
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<tr>
<td>Notice of Special Interest (NOSI): Synthetic Biology for Biomedical Applications.</td>
<td>NOT-EB-23-002</td>
<td>NIBIB</td>
<td>Apr 14, 2023</td>
<td>May 17, 2026</td>
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<tr>
<td>Notice of Special Interest (NOSI): Development of Innovative Informatics and Data Science Technologies, Tools, and Methods for Vision Research</td>
<td>NOT-EY-23-005</td>
<td>NEI</td>
<td>Apr 3, 2023</td>
<td>Feb 16, 2026</td>
</tr>
<tr>
<td>Notice of Special Interest (NOSI): Promoting Language and Communication in Minimally Verbal/Non-Speaking Individuals with Autism</td>
<td>NOT-DC-23-009</td>
<td>NIDCD</td>
<td>Apr 3, 2023</td>
<td>Jun 06, 2026</td>
</tr>
<tr>
<td>NHLBI Notice of Clarification and Availability of Frequently Asked Questions (FAQs) for RFA-HL-23-008 and RFA-HL-23-009 &quot;NHLBI SBIR Phase IIB Small Market Awards&quot;</td>
<td>NOT-HL-23-082</td>
<td>NHLBI</td>
<td>Mar 16, 2023</td>
<td>N/A</td>
</tr>
</tbody>
</table>

NIH Phase I Success Rate Data

SBIR Grants, Phase I: Competing Applications, Awards, and Success Rates

FY2022:
Appns: 3080
Awards: 457
Success Rate: 15%

Data for this report are available at NIH Data Book - https://report.nih.gov/nihdatabook/report/115
NIH Phase II Success Rate Data

SBIR Grants, Phase II: Competing Applications, Awards, and Success Rates

- **FY2022:**
  - Appns: 1161
  - Awards: 307
  - Success Rate: 26%

Data for this report are available at NIH Data Book - https://report.nih.gov/nih databook/report/116
NIH Fast-Track Success Rate Data

Fast Track SBIR Grants: Competing Applications, Awards, and Success Rates

- Applications
- Awards
- Success Rate (%)

FY2022:
Appns: 532
Awards: 95
Success Rate: 18%

Data for this report are available at NIH Data Book - https://report.nih.gov/nih databook/report272
Common Application Problems

Problems with Significance

• Scientific premise is weak or not even stated
• Neither significant nor exciting new research (i.e., won’t advance science)
• Lack of compelling rationale
• Incremental science; low impact research

Problems with Innovation

• Not clearly addressed in application
• Not a new technology or improvement over existing technology

Problems with Specific Aims

• Dependent upon one another
• Too ambitious, too much work proposed
• Unfocused aims, unclear goals
• Limited aims and uncertain future directions
Common Application Problems (cont.)

Problems with Experimental Approach
- Insufficient detail on approaches
- Too much unnecessary experimental detail
- Insufficient preliminary data (or literature research) to show likelihood of establishing feasibility
- Lack of specific, quantifiable, and testable feasibility milestones
- Little or no expertise with approach
- Lack of appropriate controls
- Lack of biostatistician
- Missing potential pitfalls/alternative strategies
- Ph II: Failure to demonstrate Ph I feasibility
- Ph II/FT: Weak Commercialization Plan
Common Application Problems (cont.)

Problems with Investigator/Team
• No demonstration of expertise or lack of publications regarding approaches
• Low productivity, few recent papers
• No collaborators recruited or no letters from collaborators
• Team has not worked together in the past

Problems with Environment:
• Facilities/Other resources not well described
• Necessary equipment is not available
Trans-Agency Research Topics (1)

- Advanced Communications Technologies
  - DOD; NIH; NASA; NSF; DOE; DOC
  - SBIR.gov Award Data

- Artificial Intelligence
  - All Agencies except ED
  - SBIR.gov Award Data

- Biotechnology
  - DOD; NIH; NSF; EPA; USDA
  - SBIR.gov Award Data

- High-Performance Computing
  - DOD; NIH; NASA; NSF; DOC
  - SBIR.gov Award Data

- Microelectronics
  - DOD; NIH; NSF; NASA; DOE; USDA; DOC
  - SBIR.gov Award Data

- Quantum Information Science
  - DOD; DOE; NSF
  - SBIR.gov Award Data

- Robotics
  - All Agencies except ED
  - SBIR.gov Award Data

- Space Technologies
  - DOD; NASA; NSF; DOE; DOC
  - SBIR.gov Award Data
Trans-Agency Research Topics (2)

- Advanced Materials
  - DOD; NIH; NSF; NASA; DOE; DOT
  - [SBIR.gov Award Data](#)

- Medical Devices
  - DOD; NIH; NSF; DOE
  - [SBIR.gov Award Data](#)

- Infectious Diseases
  - DOD, NIH; NSF; USDA; DOC; DHS
  - [SBIR.gov Award Data](#)

- Sensor Technologies
  - DOD; NIH; NASA; NSF; DOE; EPA; NIST; NOAA; USDA; EPA
  - [SBIR.gov Award Data](#)
It is proposed that this SBIR-funded technology, which is based on a new class of inexpensive, chemically treated filter paper that has been invented with DARPA support, will revolutionize the use of sophisticated RNA testing in epidemiology and public health screening, where the samples of interest must be collected in low resource environment.

Military and civilian surgeons have a significant need for a biodegradable implant that can deliver antibiotics to the site of a bone fracture and replace craniofacial bone defects. Hospitalizations due to injuries and injury-related bone replacement and reconstruction were the leading cause of hospitalization for the Army, Navy and Marine Corps, and the second leading cause of hospitalization for the Air Force.

A therapy that can be deployed rapidly, and safely en route to the hospital for civilians and also for soldiers on the battlefield could greatly reduce the trauma mortality rates due to both hemorrhage and traumatic brain injury. Sonication of pre-filled syringes of dodecafluoropentane emulsion (DDFPe), an oxygen therapeutic, can be employed to produce in spec nanoemulsion suitable for IV administration.
SBIR/STTR Advantages

- Provides very early stage high-risk (high payoff) R&D product development funding
- Validation of your R&D efforts
- Provides leverage for follow on funding
- Non-dilutable source of capital
- Attractive to Investors
- Not a loan – no repayment required
- No loss of equity ownership
- No royalty payback
- Intellectual property rights remain with the small business
- Preferences, including sole source contracts, for follow-on Phase III government funding or procurement possible
SBIR/STTR Disadvantages

• Many processes, policies, rules to follow
• Slow process (3-5 years through Phase II)
• Requires R&D capability and writing skills
• Must propose mission relevant projects
  o Very specific for contracting agencies
  o Much more leeway for granting agencies
• Government contracts and accounting can be onerous
Take Aways

- Understand the various agency cultures and your reviewer audience
- Be strategic about the grants you pursue
- Identify programs and potential partners/SMEs for initiatives that align with your project.
- Be proactive and meet with agency staff so you are well-positioned to apply
  - Develop value proposition – Aims / White papers
- Be persistent!
Thank You!

Jo Anne Goodnight

joanne.goodnight@gmail.com