ENCOURAGING INCLUSIVE ENTREPRENEURSHIP

NCI SMALL BUSINESS INNOVATION RESEARCH (SBIR) FUNDING

Kory Hallett, PhD
Christie A. Canaria, PhD
Program Director
NCI SBIR Development Center
SPEAKERS

Kory Hallett
Program Director

Christie Canaria
Program Director
NCI SBIR APPLICANT POOL

SUCCESS RATES CHANGE

- **Not Underrepresented**: 85%
  - WOSB: 11%
  - SDB: 3%
  - WOSB+SDB: 1%

- **Underrepresented**

<table>
<thead>
<tr>
<th>Category</th>
<th>Original Submission</th>
<th>Resubmission</th>
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<tbody>
<tr>
<td>Success Rate</td>
<td>13.8%</td>
<td>24.4%</td>
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</table>


data from [NCI SBIR APPLICANT POOL](#)
Be Prepared to Resubmit!

Competitive Program:

- FY16 NIH SBIR Phase I Success Rate: 14%

“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
Development Center: 4 CORE ACTIVITIES

FUNDING/OVERSIGHT
- Seed emerging technology areas by developing targeted funding opportunities either as grants or contracts
- Administer all 400+ SBIR/STTR awards at the NCI

OUTREACH
- Attend conferences and workshops & visit state-based organizations and universities to raise awareness of the program

GUIDANCE / MENTORSHIP
- Help applicants prepare for application, resubmission, and discuss funding options
- Other initiatives to assist our awardees – i-Corps, Translational Resources Workshops, Webinars

NETWORKING / PARTNERSHIPS
- Collaborations with pharma, med-tech, and investor community
- Maintain a network of investors, and facilitate connections between NCI SBIR portfolio companies and potential investors/strategic partners
ENTREPRENEURIAL ECOSYSTEM

- SBIR/STTR Congressionally mandated programs
- Phase IIB Bridge program
- Investor Initiatives
- Highlighting success stories
- Social media

Policy

Finance

Culture

Markets

Human Capital

Supports

at NCI SBIR DEVELOPMENT CENTER

- I-Corps™ at NIH
- Customer discovery
- Outreach to institutions and incubators
- Commercialization assistance programs
- FRAC Workshop

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Small Business Innovation Research (SBIR)
Set-aside program for small business concerns to engage in Federal R&D with the potential for commercialization
*Federal agencies with an extramural R&D budget > $100M*

Small Business Technology Transfer (STTR)
Set-aside program to facilitate cooperative R&D between small business concerns and U.S. research institutions with the potential for commercialization
*Federal agencies with an extramural R&D budget > $1B*

<table>
<thead>
<tr>
<th></th>
<th>FY11</th>
<th>FY18</th>
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<tbody>
<tr>
<td><strong>Set Aside</strong></td>
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<tr>
<td><strong>NIH:</strong></td>
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<td><strong>NCI:</strong></td>
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<tr>
<td><strong>SBIR</strong></td>
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<tr>
<td><strong>STTR</strong></td>
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<tr>
<td><strong>FY11</strong></td>
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<td><strong>FY18</strong></td>
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<tr>
<td><strong>2.5%</strong></td>
<td>3.2%</td>
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<tr>
<td><strong>0.3%</strong></td>
<td>0.45%</td>
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NIH: $1.073B
NCI: $167M
NIH has 27 Institutes and Centers

23 “separate” SBIR/STTR Programs

NIH: $1.073B
NCI: $167M
THREE-PHASE PROGRAM

FAST-TRACK (PH I & II)

DIRECT TO PH II

- Proof-of-Concept
- Up to $400,000 over 6 to 12 months

- Research & Development
- Commercialization plan required
- Up to $2M over 2 years

- Technology validation & clinical translation
- Follow-on funding for SBIR Phase II awardees from any federal agencies
- Expectation that applicants will secure substantial 3rd party investor funds
- $4M over 2-3 years

Standard Award | Hard Cap | Waiver Cap (IC Specific)
--- | --- | ---
Phase I | $150K | $252K | NCI: $400K
Phase II | $1.0M | $1.68M | NCI: $2.0M

Waiver topics:

@NCISBIR
NIH and NCI Assistance: More than just $$$

Non-Federal Funds

SBIR Ph I  SBIR Ph II  NCISBIR Ph IIIB Bridge  SBIR Ph III

CROSSING THE VALLEY OF DEATH

Applicant Assistance Program

NCI Resources for Commercialization Workshops

NCI Peer Learning and Networking Webinar

NCI Investor Initiatives

Targeted NCI Workshops
(e.g. the 2016 NCI SBIR Workshop to facilitate the Development of Molecularly Targeted Radiotherapy)

I-Corps at NIH

Niche Assessment Program

NIH-Managed

Commercialization Assistance Program
ELIGIBILITY

✓ Applicant must be a Small Business Concern (SBC)

✓ Organized for-profit U.S. business

✓ 500 or fewer employees, including affiliates

✓ > 50% U.S.- owned by individuals and independently operated

OR

> 50% owned and controlled by another (one) business concern that is > 50% owned and controlled by one or more individuals

OR (SBIR ONLY)

> 50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these
## SBIR – STTR: Critical Differences

<table>
<thead>
<tr>
<th>SBIR</th>
<th>STTR</th>
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<tbody>
<tr>
<td><strong>Permits</strong> research institution partners (e.g., universities)</td>
<td><strong>Requires</strong> research institution partners (e.g., universities)</td>
</tr>
<tr>
<td>Small business concern may outsource ~33% of Phase I activities and 50% of Phase II activities</td>
<td>Minimum 40% of the work should be conducted by the small business concern (for profit), and minimum of 30% by a U.S. research institution (non-profit)</td>
</tr>
<tr>
<td><strong>ELIGIBILITY:</strong> The PD/PI’s primary employment (i.e., &gt;50%) MUST be with the SBC for the duration of the project period</td>
<td><strong>ELIGIBILITY:</strong> IP Agreement providing necessary IP rights to the SBC in order to carry out follow-on R&amp;D and commercialization</td>
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<tr>
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<td>PI primary employment not stipulated (min. 10% effort to project)</td>
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SCORED REVIEW CRITERIA

Significance
Does the product address an important problem, and have commercial potential? Is there a market pull for the proposed product?

Approach
Are design and methods well-developed and appropriate? Are problem areas addressed? Are potential pitfalls and alternative approaches provided?

Innovation
How novel is the technology/product and the approaches proposed to test its feasibility?

Investigator
Are the investigators, collaborators and consultants appropriately trained and capable of completing all project tasks?

Environment
Does the scientific environment contribute to the probability of success? Facilities? Independence?

Commercialization
Is the company’s business strategy one that has a high potential for success?

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# FOAs & Receipt Dates

<table>
<thead>
<tr>
<th>TITLE</th>
<th>SBIR</th>
<th>STTR</th>
<th>RECEIPT DATES</th>
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<tbody>
<tr>
<td>Omnibus Solicitation (expires April 7, 2020)</td>
<td>PA-19-272 (General)</td>
<td>PA-19-270 (General)</td>
<td></td>
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<tr>
<td></td>
<td>PA-19-273 (Clinical Trial)</td>
<td>PA-19-271 (Clinical Trial)</td>
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<tr>
<td>SBIR Technology Transfer (technology transfer out of NIH intramural labs)</td>
<td>PA-18-705</td>
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<tr>
<td>SBIR IMAT (Innovative Molecular Analysis Technology) Development</td>
<td>PAR-18-303 (SBIR only)</td>
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<tr>
<td>Development of Highly Innovative Tools and Technology for Analysis of Single Cells</td>
<td>PA-17-147 (SBIR)</td>
<td>PA-17-148 (STTR)</td>
<td>September 5; January 5; April 5</td>
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<tr>
<td>Tools for Cell Line Identification</td>
<td>PA-16-186 (SBIR only)</td>
<td></td>
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<tr>
<td>Cancer Prevention, Diagnosis, and Treatment Technologies for Low-Resource Settings</td>
<td>PAR-18-801 (SBIR)/PAR-18-802 (STTR)</td>
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<tr>
<td>Phase IIIB Bridge Award Open to federally-funded Phase II awardees</td>
<td>RFA-CA-19-047 (SBIR only)</td>
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<td>August 9, 2019</td>
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<tr>
<td>Contract Solicitation</td>
<td>Program Solicitation</td>
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<td>Historically October</td>
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<tr>
<td></td>
<td>PHS 2020 TBD</td>
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<tr>
<td>Administrative Supplement to Support Ongoing Awards</td>
<td>PA-18-591</td>
<td></td>
<td>Throughout the project period</td>
</tr>
<tr>
<td>Administrative Supplement to Support Diversity</td>
<td>PA-18-837</td>
<td></td>
<td>Throughout the project period</td>
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GET READY FOR SBIR/STTR
When is SBIR/STTR appropriate?

“My laboratory was working in drug development and it takes a long time to license a technology. It was hard to push forward with only R01 funding and we had neat technology, worth pursuing.”

Lori Hazlehurst, Ph.D.
Professor, Pharmaceutical Sciences
West Virginia University
President and Co-founder, Modulation Therapeutics

“Aruna Gambhir, MS, MBA
CEO and Co-Founder, CellSight Technologies

“Investors want to see that a technology works. SBIR funding has been critical to our company to show that our technology works.”
NIH and NCI Assistance: More than just $$$

NIH-Managed

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I-Corps at NIH

NIH-Managed

Niche Assessment Program

Commercialization Assistance Program

NCI-Managed

NCISBIR Ph IIB Bridge

Non-Federal Funds

CROSSING THE VALLEY OF DEATH
NIH/NCI Applicant Assistance Program (AAP)

- FREE! Application preparation **ASSISTANCE**
- 2019: CANCER TECHNOLOGIES ONLY

<table>
<thead>
<tr>
<th>NIH AAP PROGRAM</th>
<th>NOT PROVIDED</th>
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<tbody>
<tr>
<td>Phase I Preparation Support and Review</td>
<td>Grant Writer</td>
</tr>
<tr>
<td>Specific Aims Page Review and Advice</td>
<td>Development of Research Plan</td>
</tr>
<tr>
<td>Submission Process Coaching</td>
<td>Register small business for you, apply to NIH for you</td>
</tr>
</tbody>
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**AAP GOAL:**
Provide a mentor for applicants with great technology, but little NIH experience and limited NIH experience in their network.
Application

**ACADEMIC GRANT**

- **Expertise/Team**
  - Discovery Research

- **Approach**
  - Discovery Research

- **SCIENCE**
  - Innovation
    - What is theoretically possible
  - Significance
    - Gain in Knowledge

- **Environment**

**SBIR/STTR GRANT**

- **Expertise/Team**
  - Phase I: Research and Development
  - Phase II: Commercial Development

- **PRODUCT**
  - Innovation
    - Competitive Advantage
  - Significance
    - Changing a paradigm

- **Environment**

- **Commercialization**

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AAP Eligibility

• Simple eligibility criteria:
  • Not previously funded through NIH SBIR/STTR*

• Particularly interested in applicants by individuals currently underrepresented in the biosciences *(not a requirement for program)*
  • Women-owned / Run businesses
  • Minority-owned / Run businesses
  • Small Businesses operating in an underrepresented (IDeA) state

* Applicants who received NIH SBIR/STTR funding prior to 2009 may still be eligible
Recognizing IDeA States

Institutional Development Award (IDeA)
AAP Application

• Simple
• Designated AAP application portal
  1. Answer a series of structured questions
  2. Upload supporting documents, e.g. abstract
  3. Submit
AAP Timeline

1 Cohort in 2019
For applicants applying to the September 5th 2019 NCI SBIR/STTR receipt date

- **April 18th**: Application Portal Opens
- **May 30th**: 2019 AAP applications due by 5pm EST
- **May 9th**: Info webinar
- **May 21st**: Online Q&A
- **Jun – Sept 5**: 2019 AAP Program
NCI SBIR Program Staff

Michael Weingarten, MA
Director
NCI SBIR Development Center

Greg Evans, PhD
Lead Program Director
Cancer Biology, E-Health, Epidemiology, Research Tools

Patricia Weber, DrPH
Program Director
Digital Health, Therapeutics, Biologics, FRAC Workshop

Deepa Narayanan, MS
Program Director
Imaging, Clinical Trials, Radiation Therapy, Investigator Initiatives, FRAC Workshop

Ming Zhao, PhD
Program Director
Cancer Diagnostics & Therapeutics, Cancer Control & Prevention, Molecular Imaging, Bioinformatics, Stem Cells

Christie Canaria, PhD
Program Director
Cancer/Biological Imaging, Research Tools, Devices, I-Corps at NIH, Scientific Communications

Kory Hallett, PhD
Program Director
Monoclonal Antibodies, Immunotherapy, Biologics, and Program Analysis

Let’s discuss your project!
Send Specific Aims to ncisbir@mail.nih.gov

Andrew J. Kurtz, PhD
Lead Program Director
Biologics, Small Molecules, Nanotherapeutics, Molecular Diagnostics, Bridge Award

Jian Lou, PhD
Program Director
In-Vitro Diagnostics, Theranostics, early-stage drug development, Bioinformatics, Investigator Initiatives

Amir Rahbar, PhD, MBA
Program Director
In-Vitro Diagnostics, Biologics, Therapeutics, Proteomics

Jonathan Franca-Koh, PhD, MBA
Program Director
Cancer Biology, Biologics, Small Molecules, Cell Based Therapies

Ashim Subedee, PhD
Program Director
Cancer Therapeutics and Diagnostics, Imaging, Cancer Prevention and Control, Digital Health, Investigator Initiatives
THANK YOU

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