Leveraging NCI
SBIR/STTR Opportunities with
Direct to Phase II Pilot and Phase IIB Bridge Awards

March 6, 2014  12:30 – 1:45 pm EST

For audio, dial in: 855-244-8681
Meeting ID: 736 159 274
For Technical Support, call 866-229-3239 and choose option 1

Patti Weber        Andy Kurtz
Submit Your Questions

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Submit Your Questions

- Please submit questions of a general nature via the Q&A Box with no proprietary information.

- Please be advised we will not answer questions specific to your project in this webinar.

- You can also send your questions to NClsbir@mail.nih.gov

- The webinar slides, audio recording, and Q&A will be published to the website, http://sbir.cancer.gov

- All webinar registrants will be emailed links to access webinar slides, audio recording, and Q&A

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Patti Weber              Andy Kurtz
Today’s Presentation

Patti Weber
- Overview & Recent Updates in Eligibility
- The NIH SBIR/STTR Programs
- New Direct to Phase II Pilot Program
- The NCI SBIR Development Center

Andrew Kurtz
- Finding Funding Opportunities
- NCI Bridge Phase IIB Award
- Practical Strategies for Applying

Q&A
Congressionally-Mandated Programs

- **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*
  - Set Aside (FY14): 2.8%
  - Set Aside (FY15): 2.9%

- **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*
  - Set Aside: 0.4%

~$700M annually at NIH
~$115M annually at NCI
## Set-aside is Increasing

<table>
<thead>
<tr>
<th>FY</th>
<th>SBIR Set-aside</th>
<th>STTR Set-aside</th>
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<tbody>
<tr>
<td>2011</td>
<td>2.5%</td>
<td>0.30%</td>
</tr>
<tr>
<td>2012</td>
<td>2.6%</td>
<td>0.35%</td>
</tr>
<tr>
<td>2013</td>
<td>2.7%</td>
<td>0.35%</td>
</tr>
<tr>
<td>2014 (current)</td>
<td>2.8%</td>
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<tr>
<td>2015</td>
<td>2.9%</td>
<td>0.40%</td>
</tr>
<tr>
<td>2016</td>
<td>3.0%</td>
<td>0.45%</td>
</tr>
<tr>
<td>2017</td>
<td>3.2%</td>
<td>0.45%</td>
</tr>
</tbody>
</table>
Reasons to Seek SBIR/STTR Funding

- Provides seed funding for innovative technology development

- **Not a Loan**
  - No repayment is required
  - Doesn’t impact stock or shares in any way (i.e., non-dilutive)

- Intellectual property rights retained by the small business

- Provides recognition, verification, and visibility

- Helps provide leverage in attracting additional funding or support (e.g., venture capital, strategic partner)

Ask questions any time using the Q&A box
SBIR/STTR Reauthorization Act Of 2011: NIH Implementation Of Key Changes (What to Expect and When)

The SBIR/STTR Reauthorization Act of 2011 and the recently released SBIR and STTR Policy Directives have brought about numerous changes to the programs many of which are quite complex. NIH is diligently working to implement these changes some of which are easily handled so implemented immediately. Others are more complex and will take time.

The following key change areas have been provided by the Small Business Administration (SBA). Each links to a description of each change and the implementation steps NIH is taking. The information will be regularly updated as NIH progresses so check back regularly. NIH is working with SBA on its implementation plan.

1. Funding
2. Eligibility
3. Streamlining the Award Process
4. Data & Reporting
5. New Measures to Guard Against Fraud, Waste, Abuse
6. Increased Support for Commercialization

For more information regarding SBA's implementation plan, read Sean Greene's (Associate Administrator for Investment and the Special Advisor for Innovation at SBA) blog which includes links to the recently released Policy Directives, a synopsis of key changes, and FAQs.

Matthew E. Portnoy, Ph.D.
NIH SBIR/STTR Program Coordinator
Office of Extramural Programs, NIH
sbir@od.nih.gov
• SBIR/STTR applicants must register at the SBA Company registry at SBIR.gov.

• VC-backed companies (VCOC, hedge fund, private equity firms) **CAN NOW** apply (**NIH SBIR only**).

• Applicants can request $5000 in Technical Assistance, beyond award cap. If requested, cannot participate in NIH Technical Assistance Programs
  • Example: regulatory consultant
Increased caps for pre-approved waiver topics (see FOA) – Ph I $300K, Ph II $2M

• Otherwise: Ph I $225K, Ph II $1.5M

Switching between SBIR and STTR mechanisms

• Applicants can apply for Phase II SBIR funding based on Phase I STTR award or vice versa.
• Applicants can apply for Phase IIB SBIR funding based on Phase II STTR award or vice versa.

• Direct to Phase II Pilot Program now active
The NIH
SBIR/STTR Programs

http://sbir.nih.gov

Ask questions any time using the Q&A box
SBIR & STTR: Three-Phase Program

Phase I
- Proof-of-Concept study
- $150,000 over 6 months (SBIR) or 1 year (STTR)

Phase II
- Fast Track Application
- Combined Phase I & II
  - Research & Development
  - Commercialization plan required
  - $1 million over 2 years

Phase III
- Commercialization stage
- Use of non-SBIR/STTR funds

- Direct to Phase II
  - Skip Phase I

- Hard caps on award sizes: $225,000 for Phase I; $1.5 million for Phase II
- Certain awards may exceed these caps if covered by topic-specific waivers
- Actual funding may vary by topic
# NIH Timeline for New Applications

![Image](image.png)

**6 - 9 months**

<table>
<thead>
<tr>
<th>Due Date</th>
<th>Scientific Review</th>
<th>Council Review</th>
<th>Award Date (earliest)</th>
</tr>
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<tbody>
<tr>
<td>April 5</td>
<td>July</td>
<td>October</td>
<td>December</td>
</tr>
<tr>
<td>August 5</td>
<td>October</td>
<td>January</td>
<td>April</td>
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<tr>
<td>December 5</td>
<td>March</td>
<td>May</td>
<td>July</td>
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SBIR Eligibility Requirements
New Rules starting 1/28/13

- Applicant is a Small Business Concern (SBC)
- Organized for-profit U.S. business
- 500 or fewer employees, including affiliates
- PI’s primary employment (>50%) must be with the SBC at time of award & for duration of project
- > 50% U.S.- owned by individuals and independently operated*
  OR
- > 50% owned and controlled by other business concern/s that is/are
  > 50% owned and controlled by one or more individuals*
  OR
- > 50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these *

*Formerly >= 51%; *New rule starting 1/28/13, NIH SBIR only

Ask questions any time using the Q&A box
STTR Eligibility Requirements

- Applicant is a Small Business Concern (SBC)
- Organized for-profit U.S. business
- Formal cooperative R&D effort
  - Minimum 40% by small business
  - Minimum 30% by US research institution
- US Research Institution: college or university; non-profit research organization; Federally-Funded R&D Center (FFRDC)
- Principal Investigator’s primary employment may be with either the SBC or the research institution
- SBC must have right to IP to carry out follow-on R&D and commercialization
## SBIR vs. STTR: Which Program is Best for You?

<table>
<thead>
<tr>
<th>SBIR</th>
<th>STTR</th>
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<tbody>
<tr>
<td><strong>Principal Investigator</strong></td>
<td><strong>Research Partner</strong></td>
</tr>
<tr>
<td>Primary employment <strong>must</strong> be with small business</td>
<td>PI may be employed by either small business or research institution, and must commit minimum of 10% effort to project</td>
</tr>
<tr>
<td>Permits partnering</td>
<td>Requires partnering with US research institution</td>
</tr>
<tr>
<td><em>Small business must do</em> 67% Phase I, 50% Phase II</td>
<td><em>Small business min. 40%, Research institution min. 30%</em></td>
</tr>
</tbody>
</table>

- Small Business Concern is ALWAYS the Applicant/Awardee Organization
- Funding rates vary annually based primarily on application numbers
- The best choice is the fit for your budget and leadership structure
Fast Track

- Promising preliminary data but still potential to propose aims that could be considered reasonable for a Ph I study, and/or good milestones to attempt to hit to make go/no go decision

- If there are reasonable/logical aims to include & fit timeline/budget as Ph I, Fast Track is likely a better option (over Direct to Phase II) because there would be more total money available
Fast Track or Direct to Phase II: Which Program is Best for You?

Direct to Phase II

- Have preliminary data that is equivalent to what we expect from the end of an NIH Ph I award
  - (e.g. in vivo proof of concept data for a therapeutic)
- Where it wouldn’t make sense to do additional preclinical proof-of-concept
- Already in humans, doing clinical trials – probably best candidates
Direct to Phase II Pilot Program

- 2014 SBIR Direct to Phase II Solicitation: **PAR-14-088**
- Check the funding announcement: Only NCI and NIH ICs listed are participating in Direct to Phase II Pilot
- Applies to SBIR programs only, **NOT STTR**
- Designed for SBCs that have completed Phase I-type milestones with non-SBIR funds

Ask questions any time using the Q&A box
Direct to Phase II Pilot Program

- Standard receipt dates apply:
  - April 5 (Monday April 7, 2014), August 5, December 5
- Effective until 2017

- Standard SBC eligibility rules apply
- Transition Rate Benchmark for SBCs awarded >20 Ph I last 5 years

\[
\frac{\# \text{ Ph II awards}}{\# \text{ Ph I awards}} \geq 0.25
\]

- Verify your SBC Transition Rate on the Company Registry at SBIR.gov

Ask questions any time using the Q&A box
Therapeutics: 33%

Devices for Cancer Therapy: 7%

Imaging: 20%

In Vitro Diagnostics: 21%

Tools for Basic Research: 7%

Health IT & Software Tools: 12%

Pipeline of 400+ vetted projects

Ask questions any time using the Q&A box
NCI SBIR Development Center
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, SBIR Investor Forum, FRAC Workshop

Deepa Narayanan, MS
Program Director
Cancer Imaging, Clinical Trials, Radiation Therapy, SBIR Investor Forum, FRAC Workshop

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

Christie Canaria, PhD
AAAS Science & Technology Policy Fellow
Policy, Outreach, Success Stories, Scientific Communications, SBIR Investor Forum, FRAC Workshop

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, FRAC Workshop

Todd Haim, PhD
Program Director
Small Molecules, Biologics, Immunotherapeutics, Theranostics, SBIR Investor Forum, FRAC Workshop

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

Jennifer Shieh, PhD
Program Director
Digital Health, Bioinformatics, Research Tools, Evaluation, SBIR Investor Forum, FRAC Workshop
Development Center staff are responsible for:

- Conducting regular outreach events to help recruit more focused, commercially-minded SBIR applicants
- Coaching applicants on developing stronger applications
- Providing oversight and active management of projects
- Mentoring and guiding companies throughout the award period
- Facilitating matchmaking with potential third-party investors and strategic partners
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Andrew Kurtz
• Finding Funding Opportunities
• NCI Bridge Phase IIB Award
• Practical Strategies for Applying

Q&A
SBIR/STTR
Funding Opportunities

http://sbir.cancer.gov/funding/
Multiple Funding Solicitations
Know the Application Deadlines

- **SBIR & STTR Omnibus Solicitations for Grant Applications**
  
  *Release:* January
  
  *Receipt Dates:* April 5 *(April 7, 2014)*, August 5, and December 5

- **See the NIH Guide for other Program Announcements (PA’s) and Requests for Application (RFA’s), i.e. grants**

  *Release:* Weekly
  
  *Receipt Dates:* Various

- **NCI SBIR Bridge Phase IIB Award (RFA-CA-14-002)**

  *Release:* February
  
  *Receipt Date:* April 21

http://grants.nih.gov/grants/guide
Welcome to the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs at the National Institutes of Health

News Flashes

- HHS Reissues PHS 2013-02 SBIR and STTR Omnibus Grant Solicitations Implementing Venture Capital Provision and SBA Company Registry Requirement of the SBIR/STTR Reauthorization Act of 2011
- NIH Fiscal Policy for Grant Awards - FY 2013
- NAP Program CLOSED
- NIH Office of Technology Transfer offers new exclusive license agreements for start-up companies

(Current, Archived News Flashes)

Funding Opportunities for U.S. Small Businesses

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<td>Report Fraud</td>
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</table>
http://grants.nih.gov/grants/guide
NCI SBIR
Phase IIB Bridge Award
(RFA-CA-14-002)

http://sbir.cancer.gov/funding/phase2bridgeaward.asp
SBIR & STTR: Three-Phases

**PHASE I – R41, R43**
- Feasibility Study
- $150K and 6-month (SBIR) *
- or 12-month (STTR) Award

**PHASE II – R42, R44**
- Full Research/R&D
- $1M and 2-year Award (SBIR & STTR) *
- Commercialization plan required

**Phase II Bridge Award**

**PHASE III**
- Commercialization Stage
- Use of non-SBIR/STTR Funds

* Note: Actual funding levels may differ by topic.
Competing Renewal Program for SBIR Phase II Awards

- Provides additional NIH funding to extend selected projects
- Involves another peer-review cycle to evaluate progress & future plans
- Accelerates commercialization by incentivizing partnerships with third-party investors & strategic partners \textit{earlier in the development process}

\textbf{How does NCI accomplish this goal?}

- NCI gives competitive preference and funding priority to applicants that can raise substantial third-party funds (i.e., $\geq 1:1$ match)
  
  “…Applicants are expected to leverage their previous NIH SBIR support, as well as the opportunity to compete for additional NCI funding under this [funding announcement], to negotiate and attract third-party financing needed to advance a product or technology toward commercialization…”
Partnership Benefits

Benefits to the NCI

• Opportunity to leverage millions of dollars in external resources
• Valuable input from third-party investors:
  1. Rigorous commercialization due diligence prior to award
  2. Commercialization guidance during the award
  3. Additional financing beyond the Bridge Award project period

Benefits to third-party investors

• Opportunity to partner with small businesses to develop & commercialize:
  1. Technologies that have been vetted by NIH peer-review, **AND**
  2. Projects for which substantial proof-of-concept data already exists

➢ **Opportunity to share in the early-stage investment risk with the NCI**
16 Bridge Awards To Date

NCI Total $35,262,319
Third-Party Investments $94,300,756
Leverage > 2 to 1

Venture Capital: ~1/3
Strategic Partners: ~1/3
Individuals & Other: ~1/3
Section III.3 (Eligibility Information)

General Requirements

The Phase IIB Bridge Award application must represent a continuation of the R&D efforts performed under a previous Federally-funded SBIR or STTR Phase II award. Phase IIB Bridge Award applications may be predicated on the following categories of prior Phase II awards:

- SBIR Phase II grant or contract awards funded by any Federal agency
- STTR Phase II grant or contract awards funded by any Federal agency

NOTE: Applicants who intend to submit a Phase IIB Bridge Award application that is predicated on a Phase II award funded by a Federal agency other than the NIH or a previous Phase II contract award MUST contact the SBIR Development Center prior to submission, so that the NCI can properly arrange for such applications to be accepted.

The proposed R&D must fall within the technical scope of this FOA as described under Section I (Specific Objectives for SBIR Phase IIB Bridge Award Applications)
Cancer Therapeutics

- Small molecule anticancer agents
- Anticancer biologics, including therapeutic vaccines
- Multifunctional cancer therapeutics based on nanotechnology
- Anticancer drug delivery systems

Cancer Imaging Technologies, Interventional Devices & In Vivo Diagnostics

- Medical devices for in vivo cancer imaging and image-guided interventions
- Radiation therapy devices and other ablative techniques
- Cancer imaging agents, including imaging radiopharmaceuticals and nanotechnology-based contrast agents
- Devices and technologies for in vivo cancer diagnostics
- Devices and technologies that directly enable the delivery of cancer therapies

In Vitro and Ex Vivo Cancer Diagnostics and Prognostics

- Molecular diagnostics and prognostics, including in vitro diagnostic multivariate index assays (IVDMIA)
- Image analysis tools for diagnosis
- Spectroscopic techniques for in vivo and ex vivo tissue analysis
To be responsive to this FOA, the development activities completed under the previous SBIR or STTR Phase II award MUST provide the appropriate technical foundation to justify continued development of the technology for a cancer-relevant indication/use.

Platform technologies that were initially developed for a non-cancer indication/use (e.g., SBIR or STTR Phase II projects funded by an NIH Institute/Center other than the NCI, or SBIR or STTR Phase II projects funded by a Federal agency other than the NIH) may be responsive only if the earlier data demonstrates technical proof-of-concept that is scientifically relevant to the cancer indication/use.

To be responsive under this FOA, the aims of the project must focus on a cancer-relevant indication/use as the primary product or service.
Award Budget
Budgets up to $1,000,000 total costs per year may be requested

Award Project Period
Project periods up to 3 years may be requested

Applicants may not exceed these limits!!
Supplemental Information Requested for all Bridge Applications
**Statement of Need** (included within the 12-page Commercialization Plan)

Applicants **MUST** provide a concise Statement of Need. This statement is **EXPECTED** to provide answers to the questions listed below:

- What is the perceived “Valley of Death” for the product/technology under development?

- Why is additional government funding critically needed to accelerate the development of the product or technology toward commercialization? Specifically, what activities are being proposed under this FOA that would not otherwise be possible through independent third-party investments OR would be significantly delayed without additional NIH support?

- To what extent would a possible award under this FOA advance the product or technology far enough to attract sufficient, independent third-party financing and/or strategic partnerships to carry out full commercialization?
**Fundraising Plan** (included within the 12-page Commercialization Plan)

Consistent with achieving the goals of this program, applicants are expected to provide a Fundraising Plan. This plan is expected to include the following information:

- A detailed and specific plan for securing substantial, independent third-party investor funds
  - Any third-party investment support received up to one (1) year prior to the application receipt date may be counted toward the total
- The type(s) of independent third-party investor funds (i.e., cash, convertible debt, etc.) that will be secured during the project period
- The source(s) of independent third-party investor funds (e.g., venture capital, state funds) that will be secured during the project period
- The total amount of independent third-party investor funds that will be secured during the project period
- The anticipated schedule for receiving independent third-party investor funds, including any relevant terms and conditions stipulated by the investors and/or strategic partners
Use of Third-Party Investment Funds (included within the 12-page Commercialization Plan)

- The Federal funds provided by a Phase IIB Bridge Award can only be used for advancing the research-related elements of the project

➢ The use of any third-party investor funds will be at the discretion of the small business

Applicants should provide sufficient information to demonstrate a substantial, value-added contribution toward the commercialization of the product or service, including answers to the following questions:

- What are the specific activities that the third-party investor funds will support?
- Have the investors attached any restrictions/triggers/milestones to future payments (i.e., tranches)? If so, what are they?
SBIR/STTR Information (Section IV.2)

SBIR/STTR Commercialization History (included within the 12-page Commercialization Plan)

The following questions should be addressed for all SBIR/STTR awards received from ANY Federal agency:

• Has the company gone through any name changes within the past 5 years? If so, then all previous company names should be listed in the application.

• Is the company a subsidiary or a spin-off? If so, then the name of the parent company should be provided.

• What percentage of the company’s revenue was derived from SBIR/STTR funding during each of the past 5 years, including both Phase I and Phase II awards? Applicants should report a percentage value for each year individually.

• What is the total number of SBIR/STTR Phase II awards that the company has received from the Federal government? For each award, companies should provide the award number, the award amount, project duration, and the name of the awarding agency.

• What are the total revenues that have been generated to date as a result of the commercialization of the SBIR/STTR projects funded within the past 5 years?
Letters of Support

• In addition to standard letters of support documenting collaborations, access to expertise, or to unique research resources, etc, include letters of support documenting commitments from third-party investors

• Letters of support from these institutional partners should indicate any actual or planned/conditional financial commitment as a specific dollar figure or range, consistent with the instructions provided under Section IV.2, Other Attachments, “Fundraising Plan”

• Appropriate documentation of third-party investor commitment(s) may include a conditional letter of support stating that the third-party funding is contingent upon NIH selecting the application for an award

• **Documentation of support from third-party investors should corroborate the Fundraising Plan**
Supplemental Information: [other] documents related to third-party investors and their commitment

- Include documentation of support from third-party investors, such as term sheets or redacted bank statements or other appropriate documents (other than letters of support)

- Collate all such documents in one file (with a list of the attached documents at the beginning)

- Use the filename "Third-Party Investors"; (Note that this filename will become a bookmark in the application)
Ability to raise matching funds is a component of the Phase II Bridge Award

Milestone-Based Awards

Phase II Award

Year 1+

Milestones reached?
Matching funds secured for year 1?

YES

SBIR Bridge Award

1st Year
Portion of funds

Milestones reached?
Matching funds secured for year 2?

YES

2nd Year
Portion of funds

Milestones reached?
Matching funds secured for year 3?

YES

3rd Year
Portion of funds

NO

STOP

STOP

Private investor / strategic partner continues to support commercialization
Standard NIH Review Criteria

- Significance *
- Investigators
- Innovation
- Approach *
- Environment

PLUS some additional review considerations
Submit Your Questions

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- Please submit questions of a general nature via the Q&A Box with no proprietary information.
- Please be advised we will not answer questions specific to your project in this webinar.
- You can also send your questions to NCIsbir@mail.nih.gov
- The webinar slides, audio recording, and Q&A will be published to the website, http://sbir.cancer.gov
- All webinar registrants will be emailed links to access webinar slides, audio recording, and Q&A

PLEASE SHARE YOUR FEEDBACK WITH US