



National Institutes of Health
Office of Extramural Research



NIH SBIR/STTR Presubmission Update Webinar

March 6, 2014

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SBIR/STTR Program Coordinator
Office of Extramural Research, NIH**





- **NIH SBIR and STTR Overview**
- Registration and Submission Requirements
- Common Submission Errors and Tips
- Finding SBIR and STTR Solicitations
- Budget Hard Cap Updates
- VC SBIR Participation
- Switching between SBIR and STTR
- SBIR Direct Phase II

*****This is NOT an SBIR 101 Webinar*****





Overview of NIH'S SBIR/STTR Programs:

<http://sbir.gov/content/sbir-webinars-posted-online>

This webinar **will be** posted online in the coming weeks. Check the NIH SBIR/STTR homepage:

<http://sbir.nih.gov>





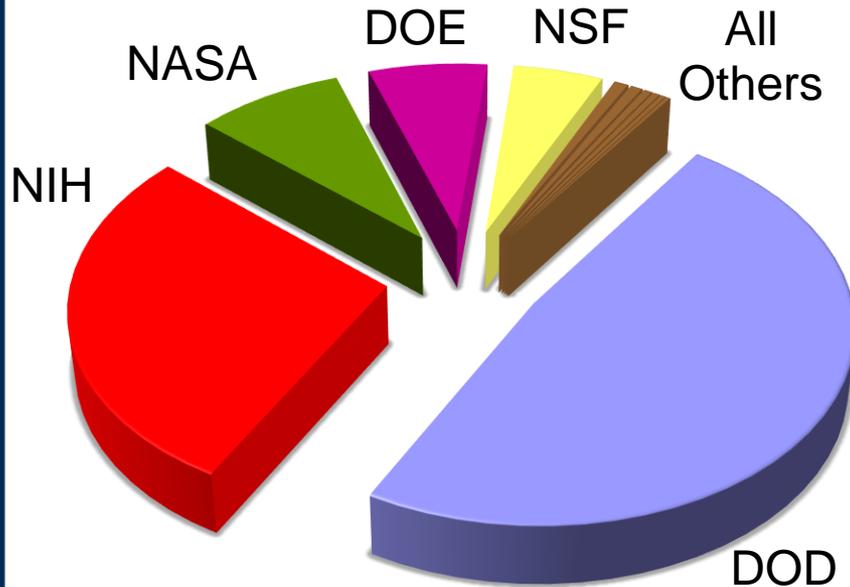
SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM 2.8%

Set-aside program for small business concerns to engage in Federal R&D – with potential for commercialization.

SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM 0.40%

Set-aside program to facilitate cooperative R&D between small business concerns and U.S. research institutions – with potential for commercialization.





**~ \$2.4B in FY12
across all agencies**

Agencies with SBIR and STTR Programs	
Department of Defense (DOD)	\$ 1.1 B
Department of Health and Human Services: National Institutes of Health (NIH)	\$717.0 M
National Aeronautics and Space Administration (NASA)	\$161.8 M
Department of Energy (DOE)	\$188.3 M
National Science Foundation (NSF)	\$ 150.6 M
Agencies with SBIR Programs	
U.S. Department of Agriculture (USDA)	\$19.3 M
Department of Homeland Security (DHS)	\$12.6 M
Department of Education (ED)	\$13.4 M
Department of Transportation (DOT)	\$8.6 M
Department of Commerce: National Oceanic and Atmospheric Administration (NOAA) and National Institute of Standards and Technology (NIST)	\$4.7 M
Environmental Protection Agency (EPA)	\$4.8 M

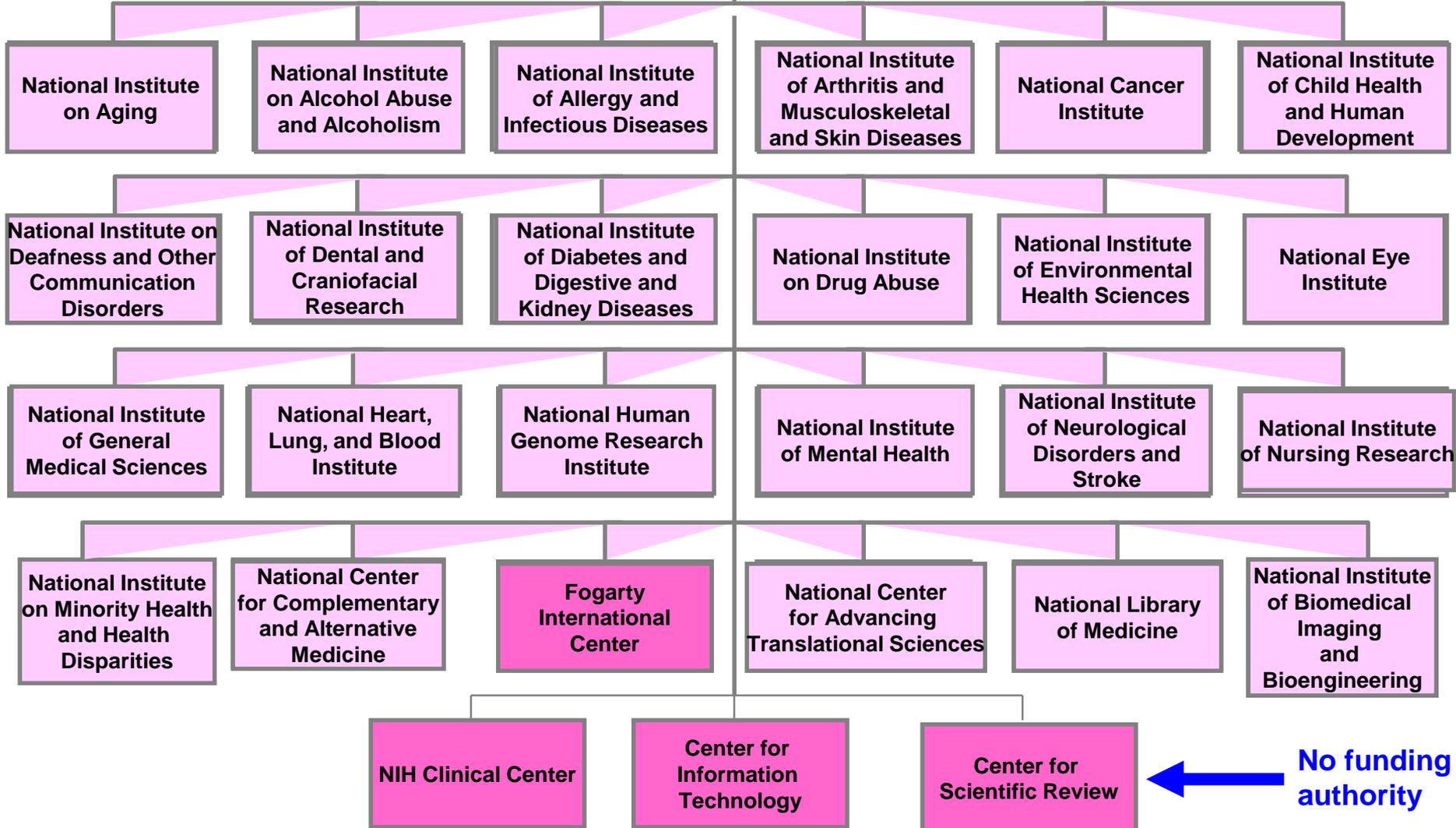




<http://www.nih.gov/icd>

Office of Research Infrastructure Programs

Office of the Director



← No funding authority



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.**



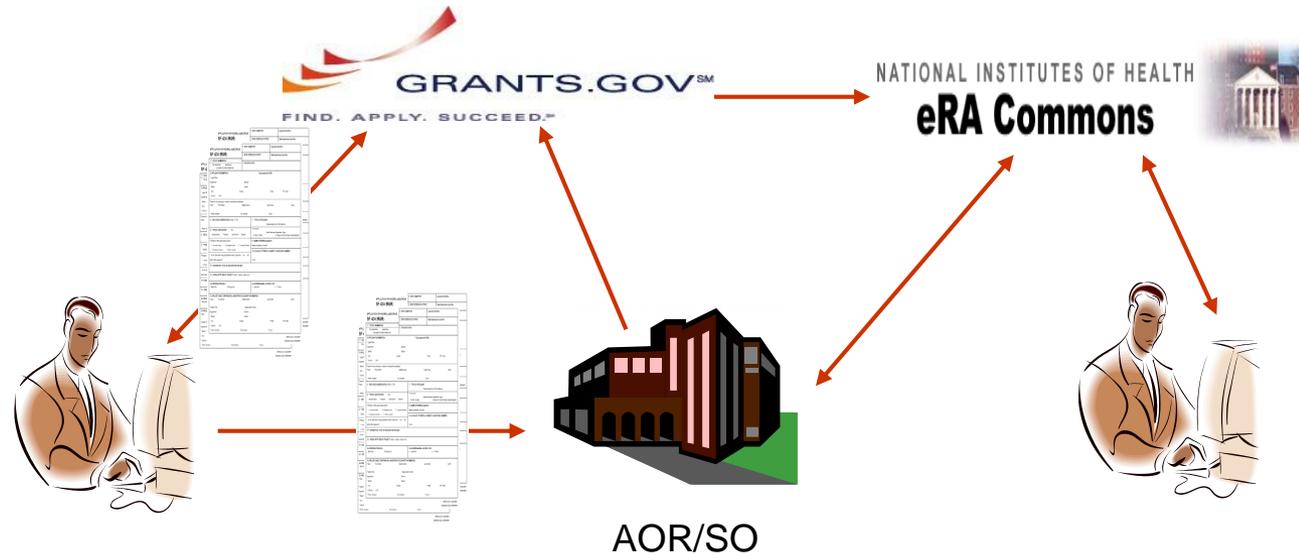


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High Level Process Overview



Find and download announcement, instructions and form package.

Prepare application per institution & agency guidelines.

AOR submits application to Grants.gov.

eRA downloads application and verifies compliance.

PI/SoC check submission status and view assembled application in eRA Commons.





Start Early – Registration can take 6 - 8 weeks!

1. **DUNS:** <http://bit.ly/12POPrL>
2. **SAM.gov:** <http://1.usa.gov/1ekYe4O>
3. **Grants.gov:** <http://1.usa.gov/1mHsAEa>
 - Federal-wide portal to find and apply for Federal grant funding
4. **eRA Commons:** <http://1.usa.gov/134CHb4>
 - NIH's system that allows applicants, grantees and Federal staff to share application/grant information
5. **SBA Registry:** <http://1.usa.gov/NxcSLK>
 - Must register and attach proof of registration to your application.





- All SBIR and STTR applicants are required to register with the SBA Company Registry Database
 - <http://www.sbir.gov/registration>
 - Applies to all HHS SBIR/STTR programs, including NIH, CDC, FDA, and ACF
- Attach proof of registration in the Other Project Information, Other Attachments section of the application
 - See section IV.2 of your FOA instructions for details





eRA Commons Help Desk

- Web:
<http://1.usa.gov/1eFqBGq>
- Phone: 1-866-504-9552
- TTY: 301-451-5939
- Hours : Mon-Fri, 7a.m. to 8 p.m. ET

Grants.gov Contact Center

- Toll-free: 1-800-518-4726
- Hours : 24x7 (Except Federal Holidays)
- Email :
support@grants.gov
- Resources:
<http://www.grants.gov/help/help.jsp>





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Corrective submissions must be made BEFORE the submission deadline and overwrite previous submissions.



- Errors stop application processing and must be corrected



- Warnings do not stop application processing and are corrected at the discretion of the applicant



The top five eRA Commons errors account for approximately 80% of the total errors.



- Each Senior/Key Person listed must include effort of **value > 0** in calendar months, or academic and summer months
 - It's okay to put 0 dollars (no salary), but NOT 0 effort.

Must be > 0 effort



A. Senior/Key Person

	Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary (\$)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary (\$)	* Fringe Benefits (\$)	* Funds Requested (\$)
1.						PD/PI							
2.													
3.													
4.													
5.													
6.													
7.													
8.													
9.	Total Funds requested for all Senior Key Persons in the attached file												
												Total Senior/Key Person	

Additional Senior Key Persons:

All application attachments must be in PDF format

- Use simple PDF-formatted files (**no Word files**)



- Do not use Portfolio or similar feature to bundle multiple files into a single PDF
- Disable security features such as password protection
- Keep file names to 50 characters or less and use only letters, numbers, underscore, hyphen, space and period
- Use meaningful filenames
- Do not include headers or footers
 - Section headings as part of the text (e.g., Specific Aims, Background & Significance) are encouraged
- Follow guidelines for fonts and margins

PDF Guidelines:

http://grants.nih.gov/grants/ElectronicReceipt/pdf_guidelines.htm



Close Form Print Page About

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix * First Name Middle Name * Last Name
Position/Title: Department:
Organization Name: Division:
* Street1: Street2:
* City: County: * State: Province:
* Country: USA: * Zip / Postal Code:
* Phone Number Fax Number * E-Mail
Credential, e.g., agency login: **Enter PI Commons Username**
* Project Role: PD/PI Other Project Role Category:
* Attach Biographical Sketch Add Attachment Delete Attachment
Attach Current & Pending Support Add Attachment Delete Attachment

PROFILE - Senior/Key Person 1

Prefix * First Name Middle Name * Last Name
Position/Title: Department:
Organization Name: Division:
* Street1: Street2:
* City: County: * State: Province:
* Country: USA: * Zip / Postal Code:
* Phone Number Fax Number * E-Mail
Credential, e.g., agency login: **Enter PI Commons Username**
* Project Role: **Select PD/PI role for each PI** Other Project Role Category:
* Attach Biographical Sketch Add Attachment Delete Attachment
Attach Current & Pending Support Add Attachment Delete Attachment

Reset Entry Select to attach additional Senior/Key Person Forms

eRA Commons username must be supplied in the *Credential* field of Sr/Key Person Page

For multiple PD/PI applications, select the PD/PI role for each PI and provide their eRA Commons username in the *Credential* field of Sr/Key Person Page





Close Form Print Page About

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: [] * First Name: [] Middle Name: [] * Last Name: [] Suffix: []

Position/Title: [] Department: []

Organization Name: [**Organization Name**] Division: []

* Street1: [] Street2: []

* City: [] County: [] * State: [] Province: []

* Country: [USA] * Zip / Postal Code: []

* Phone Number: [] Fax Number: []

Credential, e.g., agency login: []

* Project Role: [] PD/PI [] Other Project Role Category: []

* Attach Biographical Sketch [] Add Attachment [] Delete Attachment []

Attach Current & Pending Support [] Add Attachment [] Delete Attachment []

PROFILE - Senior/Key Person 1

Prefix: [] * First Name: [] Middle Name: [] * Last Name: []

Position/Title: [] Department: []

Organization Name: [**Enter Organization Name**] Division: []

* Street1: [] Street2: []

* City: [] County: [] * State: [] Province: []

* Country: [USA] * Zip / Postal Code: []

* Phone Number: [] Fax Number: [] * E-Mail: []

Credential, e.g., agency login: []

* Project Role: [] Other Project Role Category: []

* Attach Biographical Sketch [] Add Attachment [] Delete Attachment [] View Attachment []

Attach Current & Pending Support [] Add Attachment [] Delete Attachment [] View Attachment []

Reset Entry Select to attach additional Senior/Key Person Forms Next Person

NIH requires the Organization name for all Sr/Key listed.

Form pre-populates for PI, but NOT other key personnel.





APPLICATION FOR FEDERAL ASSISTANCE SF 424 (R&R)		3. DATE RECEIVED BY STATE	State Application Identifier
1. * TYPE OF SUBMISSION <input type="checkbox"/> Pre-application <input checked="" type="checkbox"/> Application <input type="checkbox"/> Changed/Corrected Application		4. a. Federal Identifier	
2. DATE SUBMITTED	Applicant Identifier	b. Agency Routing Identifier	
5. APPLICANT INFORMATION			
* Legal Name: <input type="text" value="Whatsamatta U"/>			
Department: <input type="text"/>		Division: <input type="text"/>	
* Street1: <input type="text" value="123 Easy Street"/>			
Street2: <input type="text"/>			
* City: <input type="text" value="My City"/>		County / F	
* State: <input type="text" value="MD: Maryland"/>			
* Country: <input type="text" value="USA: UNITED STATES"/>			
Person to be contacted on matters involving this application			
Prefix: <input type="text"/>		* First Name: <input type="text" value="Indy"/>	
* Last Name: <input type="text" value="Know"/>			
* Phone Number: <input type="text" value="301-555-1111"/>		Fax Number: <input type="text"/>	
Email: <input type="text" value="askera@mail.nih.gov"/>			
6. * EMPLOYER IDENTIFICATION (EIN) or (TIN):		<input type="text" value="44-4444444"/>	
7. * TYPE OF APPLICANT:		<input type="text" value="0: Private Institution of Higher Education"/>	
Other (Specify): <input type="text"/>			
Small Business Organization Type <input type="checkbox"/> Women Owned <input type="checkbox"/> Socially and Economically Disadvantaged			
8. * TYPE OF APPLICATION:		If Revision, mark appropriate by	
<input checked="" type="checkbox"/> New <input type="checkbox"/> Resubmission		<input type="checkbox"/> A. Increase Award <input type="checkbox"/> B. C.	
<input type="checkbox"/> Renewal <input type="checkbox"/> Continuation <input type="checkbox"/> Revision		<input type="checkbox"/> E. Other (specify): <input type="text"/>	

- If box 1=Application and box 8=New, then leave blank
- If box 1=Changed/Corrected and box 8=New, then enter previous Grants.gov tracking number
- Otherwise, use Institute and serial # of previous NIH grant/app (e.g., use CA987654 from 1R01CA987654-01)

- See Application Guide for definition of application types





- Talk to an NIH Program Officer about your application and **SUBMIT EARLY (days not hours and minutes)!**
 - Program Officer contact information found in the NIH SBIR/STTR Solicitation on <http://sbir.nih.gov>
 - Questions about who to contact? Email sbir@od.nih.gov





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Located on the NIH SBIR/STTR Homepage: <http://sbir.nih.gov>

Funding Opportunities for U.S. Small Businesses		
<p>2014 SBIR and STTR Omnibus Grant Solicitations of the NIH, CDC, FDA and ACF</p>	<p>SBIR Parent Funding Opportunity Announcement (PA-14-071) ←</p> <p>STTR Parent Funding Opportunity Announcement (PA-14-072) ←</p> <p>Program Descriptions and Research Topics and Appendix A (SBA approved topics for budget waivers) (PDF - 1 MB or MS Word - 350 KB)</p>	<p>Standard Receipt Dates: Apr 5, Aug 5, Dec 5</p> <p>AIDS and AIDS-Related Receipt Dates: May 7, 2014, September 7, 2014, January 7, 2015</p>
<p>NIH SBIR Direct to Phase II Pilot Solicitation/s</p>	<p>PAR-14-088 ←</p>	<p>Standard Receipt Dates: Apr 5, Aug 5, Dec 5</p> <p>AIDS and AIDS-Related Receipt Dates: May 7, Sept 7, Jan 7 expires Jan 8, 2017</p>
<p>Special Funding Opportunities and Announcements</p>	<p>See individual announcements ←</p>	<p>Targeted FOAs</p>
<p>SBIR Phase I Contract Solicitation PHS 2014-1 and Amendment #0001 (amended 10/24/2013, 11/20/2013)</p>	<p>PDF - 1.1 MB or MS Word - 530 KB and Contract Proposal Forms and Amendment #0001 and Amendment #0002 ←</p>	<p>Closing Date: December 2, 2013, 4 Solicitation informat</p> <p>NIH SBIR Contract Solicitation</p>

SBIR/STTR Omnibus Solicitation

NIH SBIR Direct Phase II

Targeted FOAs

NIH SBIR Contract Solicitation





http://grants.nih.gov/grants/funding/sbir_announcements.htm

Over 60 IC Specific Targeted FOAs

SBIR and STTR Funding Opportunities (62 Records - Sorted by Release Date)

Announcement Number	Issuing Organization	Other Participating Organizations	Release Date	Opening Date (SF424 Only) ?	Receipt Date(s)	Expiration Date	Activity Code(s)	Title
RFA-EB-14-001	NIBIB	NIMHD	02/18/2014	04/23/2014	May 23, 2014; September 23, 2014 : AIDS Dates: September 7, 2014; January 7, 2015	01/08/2015	R43, R44	Development and Translation of Medical Technologies to Reduce Health Disparities (SBIR) (R43/R44)
PA-14-102	NIAID	NIBIB, NIGMS	02/13/2014	04/07/2014	Standard Due Dates	01/08/2017	R41, R42	Innovative Technologies and Assays in Support of HIV Cure Research (ITAS-Cure) (R41/R42)
PA-14-101	NIAID	NIBIB, NIGMS	02/13/2014	04/07/2014	Standard Due Dates	01/08/2017	R43, R44	Innovative Technologies and Assays in Support of HIV Cure Research (ITAS-Cure) (R43/R44)
RFA-CA-14-002	NCI		02/12/2014	03/21/2014	04/21/2014	04/22/2014	R44,	SBIR Phase IIB Bridge Awards to Accelerate the Development of Cancer Therapeutics, Imaging Technologies,





- All NIH FOAs are cross posted on SBA's SBIR Website: <http://sbir.gov>
- NIH standard due dates: April 5, August 5, December 5
- Standard AIDS/AIDS-relates due dates: May 7, September 7, January 7
- ****Because April 5, 2014, falls on a Saturday, the next upcoming deadline will be Monday, April 7, 2014****





Which FOA is best for you?

SBIR vs STTR?

Phase I vs Fast-track vs Direct
Phase II?

****Contact your NIH SBIR/STTR
Program Officer!****





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- Reauthorization required that budgets over the hard cap (\$225,000 for Phase I and \$1,500,000 for Phase II) Agencies (**not applicants**) apply for waiver from SBA.
- SBA has recently approved a topics list, which allows budgets to exceed the hard caps as long as the project topics are on the list.
- Pre-approved topics list is Appendix A in regular topics document: <http://1.usa.gov/1iUa5Kh>.





- The approval is good for the 2014 SBIR/STTR Omnibus, and any FOA that falls on the topic list, including the Direct Phase II FOA.
- This pre-approved topics list will be updated annually.

****Contact your NIH SBIR/STTR Program Officer!****





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- Small business concerns that are majority-owned by multiple venture capital operating companies (VCOCs), hedge funds and/or private equity firms **ARE NOW ELIGIBLE** to apply (**NIH SBIR only**).
- See NOT-OD-13-071:
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-071.html>
- SBIR and STTR VCOC forms available at:
<http://grants.nih.gov/grants/forms.htm#sbir>

te: SBIR VCOC form also used for SBIR contracts





VC Case Study:

- A small business is 54% owned by a single VC and 12% owned by another VC. In the coming months, the small business expects to lower their 54% ownership to below 50%.

Are they eligible to apply for the upcoming deadline?





VC Case Study:

- Yes, as long as the small business meets the eligibility requirements of being less than 50% owned by a single VC firm **by the time of award (not submission)**
- Currently, the small business **IS NOT eligible** since the SBC is majority owned by a single VC firm
- Link to eligibility criteria for SBIR:
http://grants.nih.gov/grants/guide/pa-files/PA-14-071.html#_Section_II._Award_1

Would they need to fill out a VOCC form?





VC Case Study:

- No, not with the application since the company is **not** majority multiple VC-firm owned.
- Only fill out a VOCC form if the company is **majority owned by more than one** VC firm, hedge fund and/or private equity firm.
- However, if the SBC goes under 50% owned by the VC, the SBC would need to reevaluate after their equity distribution to see if they are now majority VC owned.





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NIH SBIR/STTR applicants may now **'switch'** programs at Phase II or Phase IIB to any active NIH SBIR or STTR solicitation.

Which means:

- Phase I STTR Awardees may apply for NIH SBIR or STTR Phase II
- Phase I SBIR Awardees may apply for NIH SBIR or STTR Phase II
- Phase II STTR Awardees may apply for NIH SBIR or STTR Phase IIB
- Phase II SBIR Awardees may apply for NIH SBIR or STTR Phase IIB

Note that not all NIH Institutes and Centers accept Phase IIB applications. Check the Omnibus Topics document for listing.

http://grants.nih.gov/grants/funding/sbirsttr1/2014-2_SBIR-STTR-topics.pdf





Helpful Tips:

- Must follow program rules (PI, % effort, sub-contracting, etc.)
- No special instructions or requirements from applicants
- NOT-OD-14-048: <http://1.usa.gov/1nWAsjg>
- Applicants are **strongly advised** to discuss this option with their program officer well in advance of any due date.





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- Allows small businesses that are ready for the Phase II stage of development to bypass applying for a Phase I grant.
- The SBC must already have a technology prototype, and must have tested its feasibility (i.e. completed Phase-I-type R&D) to move directly into a Phase-II-type R&D.
- Pilot SBIR Direct to Phase II Solicitation – it's own **SEPARATE FOA: [PAR-14-088](#)**.
- *Note: Not all ICs will accept Direct Phase IIs – only the ones listed on the solicitation. SBCs cannot apply for a Phase II and Direct Phase II for the same research project.*





- All ICs on the Direct Phase II FOA will accept technology on **anything** within their mission. *Note: NINDS has a few exceptions listed within the FOA.*
- Applicants are **strongly advised** to talk to their SBIR Program Officer before applying.
- Some ICs may issue their own separate Direct Phase II FOA/s in the future.





- A Direct Phase II is **not** a Phase IIB!
- No due dates past 12/5/2016 standard date.
- The Direct-to-Phase II authority is **not** available to the STTR program and **not** available for the CDC, FDA, and ACF SBIR programs.





How is a Direct Phase II different than a fast-track?

- A FT incorporates a submission and review process in which both Phase I and Phase II grant applications are submitted and reviewed together as one application
- Intended to reduce or eliminate the funding gap between phases

Which one is right for you?

- Talk to your SBIR Program Officer!





What is the review process?

- Application goes to NIH Center for Scientific Review.
- Application is assigned a small business study section (<http://1.usa.gov/1eL6koM>).
- Review staff have guidance on the new FOA,
- **It's too early to know the volume or the success rate!**





- NIH's SBIR and STTR Programs are getting more flexible (and complicated) as a result of the Reauthorization.
 - Increased set-aside percentages
 - See what changes have been made and are coming up:
<http://1.usa.gov/1eGSWxl>
- If you have questions – contact your SBIR/STTR Program Officer or email sbir@od.nih.gov.
- Work with your state SBDC (<http://1.usa.gov/1d0Z4TB>) or SBA District Office (<http://1.usa.gov/1a7dAd3>).



What is a Women-Owned Small Business?

- 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.
- <http://1.usa.gov/1d10b5q>

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](#).
- <http://1.usa.gov/1mKnU0a>



Get Connected!

- **Subscribe to the SBIR/STTR Listserv:**
 - Email LISTSERV@LIST.NIH.GOV with the following text in the message body: *subscribe SBIR-STTR your name*
- **NIH Guide for Grants and Contracts** (weekly notification)
<http://grants.nih.gov/grants/guide/listserv.htm>
-  **Follow us on Twitter: @NIHsbir**
- **Submit your SBIR/STTR Success Story at:**
<http://sbir.nih.gov>
- **Email: sbir@od.nih.gov**





2014 NIH SBIR/STTR Annual Conference

- **October 21 – 23, 2014**
- **Albuquerque, New Mexico**
- **Host: University of New Mexico Health Sciences Center**
- **Stay tuned – details to come!**





National Institutes of Health
Office of Extramural Research

For More Information

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Questions and Answers!

- Please enter your questions into the chat feature in your webinar console.
- We will do our best to answer all of your questions. If you still have a question after the webinar that we did not address, feel free to email sbir@od.nih.gov and we will respond to your promptly.

