

COURSE 3, TUTORIAL 4

AN OVERVIEW OF THE HHS SBIR/ STTR SOLICITATION PROCESS



The Department of Health and Human Services provides both grants and contracts. However, almost 95% of all HHS SBIR and STTR awards are made as grants primarily through the National Institutes of Health, or NIH. NIH is the largest granting organization participating in the SBIR and STTR programs. Its budget for Fiscal Year 2017 is \$861M for SBIR and \$121M for STTR. These programs are both large and unique.

FUNDING AND TOPICS DOCUMENTS

To understand the funding mechanisms used by HHS, the recommended starting point is the [NIH SBIR/STTR funding page](#). In the preliminary text, you will find a link to the SF424 (R&R) SBIR/STTR Application Guide, as well as a companion document called the Annotated SBIR/STTR Form Set. I suggest that you download these to your desktop right away and put them in a folder. Navigating further down the page, you come to a collection of five icons, each containing the name of a solicitation group or type. In this orientation, we will focus uniquely on the first - the 2018 SBIR and STTR Omnibus/Parent Grant Solicitations of the NIH, CDC and FDA.

Let's closely examine each item associated with the Omnibus Solicitation before we delve into the Topics Document and the Funding Opportunity Announcements. The abbreviation PA stands for **Parent Announcements**. These are broad Funding Opportunity Announcements for specific activities or types of research. There are two PAs for the SBIR program – one that specifies Clinical Trials Not Allowed and another, which specifies that Clinical Trials [are] Required. There is another parallel set of two funding opportunities for the STTR program. All of

these Funding Opportunity Announcements, or FOAs, are for investigator-initiated applications. There is also a Topics Document and another entitled “2018 SBA approved topics list for budget waivers.” These documents are updated and reissued annually. We'll discuss each of these in a moment. There is also a hyperlink to the [NIH SBIR/STTR Grant Forms](#). It's easy to navigate to everything that you may need from this one page. There is also a reminder on the right-hand side of the grey box indicating that there are THREE standard receipt dates for proposals in response to the program announcements. The option to submit an application on one of these three receipt dates is a unique feature of the HHS SBIR and STTR programs.

Let's download the Topics Document now to your desktop. Although the hyperlink refers to this as the [2018 Program Descriptions and Research Topics Document](#) – it is actually the Omnibus Solicitation, as noted on the cover page. You will also notice that the cover page indicates that this document is for both the SBIR and STTR programs. In the Program Descriptions section, it clarifies that NIH will accept and consider SBIR and STTR grant applications in any area within the mission of the awarding Components - that is the Institutes and Centers, or ICs, identified in

Solicitation Gantt Chart

(Approximate Time Periods)

Month	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEPT	OCT	NOV	DEC	JAN	FEB
DOE														
1st SBIR/STTR Solicitation														
2nd SBIR/STTR Solicitation														
DoD														
1st SBIR Solicitation														
1st STTR Solicitation														
2nd SBIR Solicitation														
2nd STTR Solicitation														
3rd SBIR Solicitation														
3rd STTR Solicitation														
HHS														
Omnibus	X		X					X						
Targeted SBIR/STTR Solicitations														
R&D Contracts														
NASA														
SBIR Solicitation														
STTR Solicitation														
NSF														
1st SBIR Solicitation														
1st STTR Solicitation														
2nd SBIR Solicitation														
2nd STTR Solicitation														

See solicitation for exact release and due dates

the Omnibus Solicitation. Unlike other agencies that often designate unique topics for the SBIR or STTR program – all NIH topics can be addressed using either the SBIR or STTR program.

REACH OUT TO INSTITUTE CONTACTS

Let's look at the first Institute in the solicitation - the National Institute of Aging, or NIA. In the Table of Contents, under NIA, you will find a section entitled NIA Non-Clinical Trials Topics, with the four divisions of NIA listed underneath. This is followed by NIA Clinical Trial Topics, with the four divisions listed. This format is new and with each Institute you should look to see if the topics of interest to you fall under Non-Clinical Trial OR Clinical Trial topics. As in the past, the cognizant contact person's name, phone number, and e-mail are listed at the end of each Institute's section. You are encouraged to reach out to the contact to discuss your research interests throughout the entire application, review, and award process. A list of the [HHS SBIR/STTR Agency Contacts](#) is always readily available, as well as the contact information for the NIH SBIR/STTR program office. You are reminded that there is nothing more important to your success with NIH than to reach out to the NIH contacts early and often. This is especially important during the planning stages when you should discuss your research interests to determine if they are well-aligned with the needs of the Institute or Center. Con-

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tacts can readily direct you to the appropriate Institute, if your research idea does not fit with their mission.

BUDGET CAPS

The 2018 Program Descriptions and Research Topics Document is about 280 pages in length and is rich with descriptions of the IC's research interests. Each Institute or Center also includes comments regarding unique SBIR/STTR guidelines that may pertain to their organization. For example, budget limits, adjustments to duration of awards, or related solicitations may be mentioned. One item that you may often see referenced is SBA budget caps. There is a document entitled "SBA Approved Topics List for Budget Waivers" on the Funding page, which is revised and updated annually. The SBIR and STTR programs do have statutory budget limits. However, given the costs associated with maturing medical technologies, the Small Business Administration has made exceptions for a number of NIH SBIR and STTR topics. The topic areas that have a waiver are identified on the NIH SBIR/STTR Funding page and in the document we just referenced. Companies that wish to propose budgets in excess of the statutory limits are strongly encouraged to contact NIH program officials prior to submitting any award budget in excess of the statutory amounts.



Let's go back to the NIH SBIR/STTR Funding page and look at the SBIR Omnibus Funding Opportunity Announcement link. When you navigate to the "SBIR Omnibus Funding Opportunity Announcement" you are presented with a considerable amount of information. If this is the first time that you have visited this page, you may be overwhelmed by the number of hyperlinks. Much of the information provided are links to related organizations, and documents. For example, the first two sections entitled "Participating Organizations" and "Components of Participating Organizations" contain compilations of the links to the Agencies participating in this Funding Opportunity Announcement, or FOA. Navigate further down the page until you come to "Part 2. Full Text of Announcement." This is the section that you need to explore in detail. An important companion document is one that was recommended to download at the outset entitled SF424 (R&R) SBIR/STTR Application Guide. You will need this when you start to develop your application.

There are a number of unique characteristics of the HHS program. Let's look at a number of them – starting with eligibility.

VENTURE CAPITAL OPERATING COMPANIES

Small Business Concerns, or SBCs, that are majority-owned by multiple venture capital operating companies (or VCOCs), hedge funds, or private equity firms are NOW eligible to apply to the NIH SBIR program for any NIH SBIR Funding Opportunity Announcement issued after January 28, 2013. This is unique to NIH, CDC and the Department of Energy's Advanced Research Projects Agency. The other Agencies participating in the SBIR program have not opted to participate in the Majority VC ownership authority. Please note that within HHS, both the FDA and ACF SBIR program, as well as the NIH STTR program do not participate in this authority.

ASSIST, GRANTS.GOV AND ERA COMMONS

Another unique feature of HHS is that it allows a small business to choose between two methods of submitting an application. An applicant may submit the proposal using either ASSIST or Grants.gov. Use of either method requires that one must complete a one-time registration with the eRA Commons. It is recommended that you register with eRA Commons at least 6 weeks prior to the submittal date of a submission. The proposal that you will submit to NIH is actually a collection of forms and documents that you will upload into either ASSIST or Grants.gov as an application. In order to understand the structure of your application, you should download the appropriate grants package as early as possible. For the first-time applicant, anticipate that it will take considerable time to understand the structure and how to prepare a compelling application.

Another unique feature of working with NIH is the resubmission of applications. To learn more about the resubmission option, review the section called "Resubmission Applications" in the SF424 (R&R) SBIR/STTR Application Guide for NIH and other PHS Agencies [PHS stands for Public Health Service].

In this tutorial, we have touched briefly on only one of the HHS solicitations - the SBIR Omnibus Solicitation for NIH, CDC and FDA. It will take you time to learn how to write winning proposals in response to the many HHS opportunities. The best way to increase the likelihood of success is to reach out to the HHS SBIR/STTR program office, as well as to the numerous Points of Contact within each of the Institutes and Centers. Be sure to take advantage of the opportunity to communicate frequently with agency personnel who are positioned to assist in paving a straighter road to success.

HHS SBIR/STTR RESOURCES

HHS SBIR/STTR Agency Contact Information

<https://sbir.nih.gov/engage/ic-contacts>

Life Science Contacts by State

<https://sbir.nih.gov/resources/lifescience-state-contacts>

NIH SBIR/STTR Funding

<https://sbir.nih.gov/funding>

NIH SBIR/STTR Application Process Infographic

<https://sbir.nih.gov/infographic>

SBIR/STTR Instructions for NIH and Other PHS Agencies SF424 (R&R) Application Packages

<https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/sbir-sttr-forms-e.pdf>

Small Business Grant Applications: Annotated SF424 (R&R) Form Set

<https://grants.nih.gov/grants/ElectronicReceipt/files/AnnotatedFormsSmallBusFORMS-E.pdf>

eRA SERVICE DESK

<https://grants.nih.gov/support/index.html>

Phone: 1-866-504-9552, Hours: Mon–Fri, 7 a.m. to 8 p.m. Eastern Time (closed on federal holidays)