The Department of Health and Human Services (HHS) utilizes grants, cooperative agreements and contracts to support research and development in the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. The largest percentage of HHS SBIR and STTR awards are made as grants, primarily through the National Institutes of Health, or the NIH. The NIH is the largest granting organization participating in the SBIR and STTR programs. The NIH budget for Fiscal Year 2020 was $1.1B for the SBIR program and $150M for the STTR program.

FUNDING TOPICS DOCUMENT
To understand the NIH grant application process, the recommended starting point is the NIH Application Process Infographic. The Center for Disease Control (CDC) and the Food and Drug Administration (FDA) utilize the NIH application process, while Administration for Community Living (ACL) has a separate process not covered below but can be found here. Only NIH participates in the STTR program.

BEFORE YOU APPLY
HHS funds health, life science, and biomedical discoveries that could improve the lives of patients and their families. Applicants are encouraged to review the NIH portfolio and read the Success Stories to see the wide breath of technologies and health related topic areas supported by SBIR and STTR funds.

You are encouraged to reach out to small business program staff to discuss your research interests throughout the entire application, review, and award process. There is nothing more important to your success with HHS than to reach out to small business program staff, particularly during the planning stages of your application. Applicants should consider writing a succinct (1-page or less) concept or specific aims to provide in advance of a phone consultation with staff. As components of the NIH, CDC, and FDA may have different budgetary guidance or targeted programs, it is important to identify the Institutes or Centers that may be applicable to your research. The Program Descriptions and Research Topics document (Word – 614 KB, PDF – 2.31 MB) describes the awarding components, their topics of interest, and staff contacts. This document is updated annually. A list of the HHS SBIR/STTR Agency Contacts is always readily available on the website. Contacts can readily direct you to the appropriate Institute if your research idea does not fit with their mission. If you are unsure who to contact the Small Business Education and Entrepreneurial Development (SEED) can direct you to the appropriate Institute or Center.
FUNDING OPPORTUNITIES

The NIH advertises funding opportunities through the posting of grant solicitations or Funding Opportunity Announcements (FOAs). Current FOAs are posted on the SEED website and the NIH Guide for Grants and Contracts regularly. Applicants can choose to submit to an omnibus or targeted solicitation.

OMNIBUS SOLICITATIONS

Researcher-initiated ideas are proposed via the SBIR and STTR Omnibus grant solicitations which have three standard application cycles per year. These FOAs do not target a specific topic. 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 (ICs) identified in 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. The Program Descriptions and Research Topics document identifies topics of interest for each participating Institute or Center (IC). Each Institute or Center also includes comments regarding unique SBIR/STTR guidelines that may pertain to their organization, including budget limits, adjustments to duration of awards, or related solicitations. Most small business applications to the NIH are submitted to Omnibus solicitations. 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.

TARGETED SOLICITATIONS

Targeted SBIR/STTR grant solicitations are focused on specific research areas identified by the participating Institutes or Centers. Some targeted FOAs, identified as RFAs (Requests for Applications) or PASs (Program Announcements with Set-aside funds), have funding set-aside in the Institute or Center’s budget for that targeted program. Targeted solicitations may have different receipt dates than the standard receipt dates used by the Omnibus solicitations.

ALLOWABLE BUDGETS

The SBIR/STTR Statute (15 U.S.C. §638) establishes cap for the maximum dollar amount of SBIR and STTR awards, above which an agency must request a SBA-approved waiver. Generally, HHS allows for SBIR and STTR budgets up to the SBA budget guidelines, but individual NIH Institutes and Centers can set their own budget limits. The NIH recognizes that some biomedical innovations require additional funding to reach the marketplace. For those topics, the NIH has a waiver from the SBA to allow larger awards. The list of SBA approved waiver eligible topics is updated on a yearly basis. Applicants are strongly encouraged to contact program officials prior to submitting any application in excess of the total award amounts listed above and early in the application planning process.
APPLICATION PREPARATION AND SUBMISSION

Once you’ve identified an opportunity of interest, you can access the application forms and begin preparing your application using ASSIST, NIH’s online application preparation and submission system, or Grants.gov Workspace. Regardless of the system you will use, you need to complete a one-time registration with eRA Commons to submit to the NIH. It is recommended that you register with eRA Commons at least 6 weeks prior to the submittal date of a submission.

Prepare your application following guidance on the How to Apply – Application Guide page (including SBIR and STTR Instructions), instructions in the funding opportunity, and any related notices in the NIH Guide for Grants & Contracts. The proposal that you will submit to the NIH is a collection of forms and documents that you will upload into 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 the 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 the funding opportunities and application process necessary to submit to the NIH, CDC or 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 program staff 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.

<table>
<thead>
<tr>
<th>*SBIR/STTR, CRP Only</th>
<th>Cycle I</th>
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<td>Application Due Dates</td>
<td>September 5</td>
<td>January 5</td>
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<td>Scientific Merit Review</td>
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<td>Advisory Council Round</td>
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<td>Earliest Project Start Date</td>
<td>April</td>
<td>July</td>
<td>September or December*</td>
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NIH INSTITUTES

- National Cancer Institute (NCI)
- National Eye Institute (NEI)
- National Heart, Lung and Blood Institute (NHLBI)
- National Human Genome Research Institute (NHGRI)
- National Institute of Aging (NIA)
- National Institute of Allergy and Infectious Disease (NIAID)
- National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
- National Institute of Biomedical Imaging and Bioengineering (NIBIB)
- Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
- National Institute of Deafness and Other Communication Disorders (NIDCD)
- National Institute of Dental and Craniofacial Research (NIDCR)
- National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
- National Institute on Drug Abuse (NIDA)
- National Institute of Environmental Health Sciences (NIEHS)
- National Institute of General Medical Sciences (NIGMS)
- National Institute of Mental Health (NIMH)
- National Institute on Minority Health and Health Disparities (NIMHD)
- National Institute of Neurological Disorders and Stroke (NINDS)
- National Institute of Nursing Research (NINR)

NIH CENTERS

- NIH Clinical Center (CC)
- Center for Information Technology (CIT)
- Center for Scientific Review (CSR)
- Fogarty International Center (FIC)
- National Center for Advancing Translational Sciences (NCATS)
- National Center for Complementary and Integrative Health (NCCIH)