



Overview of the NIH SBIR and STTR Programs

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AGENDA

- General Features of the SBIR & STTR programs
- Features & Nuances of NIH SBIR/STTR Program
 - Funding opportunities
 - Review process
 - Transitioning into the marketplace

Program Descriptions

Small Business Innovation Research (SBIR)

Set-aside program for small business concerns to engage in federal R&D --
2.5% with potential for commercialization.

Small Business Technology Transfer (STTR)

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

SBIR/STTR: 3-Phase Program



- PHASE I – R41, R43
- Feasibility Study
- \$100K and 6-month (SBIR)
- or 12-month (STTR) Award



- PHASE II – R42, R44
- Full Research/R&D
- \$750K and 2-year Award (SBIR & STTR)



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

SBIR Eligibility Checkpoints

- Organized for-profit U.S. business
- 500 employees or fewer, including affiliates
- PD/PI's primary employment must be with small business concern at time of award and for duration of project period

SBIR Eligibility Checkpoints

Small business concern must be:

- At least 51% U.S.- owned by individuals and independently operated
- or
- At least 51% owned and controlled by another (one) business concern that is at least 51% owned and controlled by one or more individuals

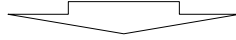
Agency Differences

Contracting Agencies

- Agency establishes plans, protocols, requirements
- Highly focused topics
- Procurement mechanism for DOD and NASA
- More fiscal requirements

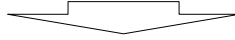
Granting Agencies

- Investigator initiates approach
- Less-specified topics
- Assistance mechanism
- More flexibility



DOD
NASA
EPA
DOC

HHS/NIH
ED
DOT
DHS



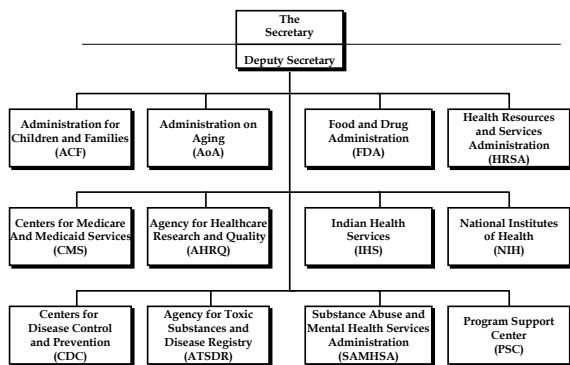
HHS/NIH
ED
DOE

NSF
USDA

NIH SBIR/STTR PROGRAM

Features and Nuances

U. S. Department of Health and Human Services



NIH Mission

Improve human health through biomedical and behavioral research, research training and communications.



Small Companies Can Help NIH meet its mission

Conduct innovative R/R&D that results in product, process, or service that will...

- Improve patient health
- Speed process of discovery
- Reduce cost of medical care/cost of research
- Improve research & communication tools

DHHS Budget and Award Amount

	SBIR	STTR
2006 Budget	\$571M	\$69M
NIH	\$640M	
****Propose a Realistic and Appropriate Budget for the Research****		
Phase I	\$100K* 6 months*	\$100K* 1 year*
Phase II	\$750K* 2 years*	\$750K* 2 years*

NIH SBIR/STTR Research Topics

*Examples from 200+ pages of topics!

Biodefense	Biosilicon devices
Biosensors	Biocompatible materials
Nanotechnologies	Acousto-optics / opto-electronics
Bioinformatics	Imaging devices
Diagnostic and Therapeutic Devices	Genetically engineered proteins
Telehealth	Proteomics / Genomics
	...

Our Ideas ...

1. SBIR/STTR Omnibus Solicitation (NIH, CDC, and FDA) SBIR PA-07-280; STTR PA-07-281

Release: January April 5, Aug 5, Dec 5 receipt dates

2. SBIR Contract Solicitation (NIH, CDC)

Release: August Early November receipt date

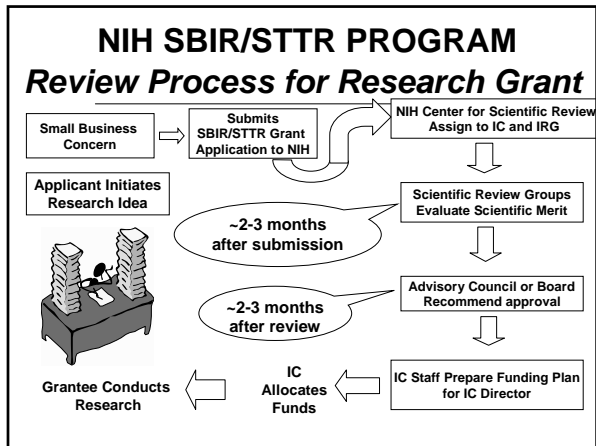
3. NIH Guide for Grants and Contracts

Release: Weekly Various receipt dates

Your Ideas ...

Investigator-initiated R&D

- Research projects related to the NIH mission
- "Other" areas of research within the mission of an awarding component



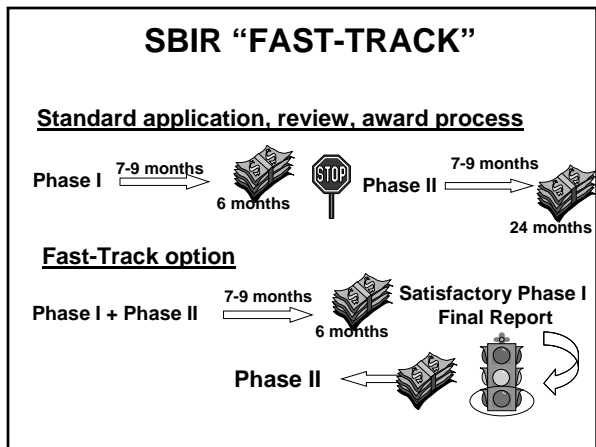
Review Criteria

1. Significance
2. Approach
3. Innovation
4. Investigators
5. Environment

Program staff do **NOT** participate in peer review process

... Protection of Human Subjects
 ... Animal Welfare
 ... Budget

STUDY SECTIONS DO NOT FUND!

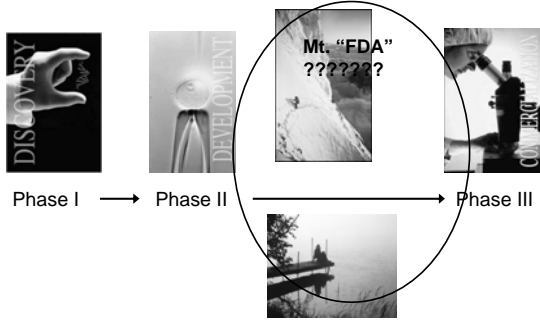


University Partnerships

- **Consultants on SBIR/STTR**
- **Subcontracts on SBIR/STTR**
(Provide analytical and other service support)
- **Senior Personnel on SBIR/STTR**
- **Own small firms**
(assign *someone else* PI)
- **Principal Investigator**
(with official permission from University)

*Applicant
must be the
small
business!*

Transitioning Innovative Ideas to the Marketplace



Phase II Competing Renewals

- **Goal:** Take existing, promising compound or devices developed under a Phase II award through the next step of discovery and development.
- **Stipulations:**
 - Available only to Phase II awardees
 - Focus -- Diagnostics, devices, tissue engineering, drug development
 - Funding level: \$750K to \$1M per year for maximum of 3 years
 - IC must have announced the opportunity

Contact Program Staff Prior to Submission

Technical Assistance Programs

Commercialization Assistance

(Phase II awardees)

Business & strategic planning

Builds alliances and investor partnerships

Niche Assessment

(Phase I awardees)

Identify other uses of technology

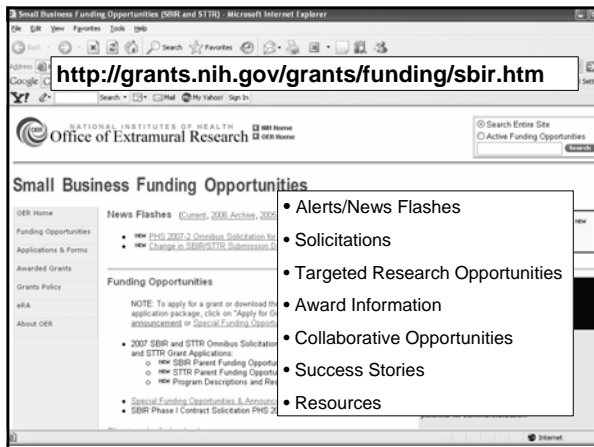
Determines competitive advantages

Develops market entry strategy

Pilot Manufacturing Assistance Program

Goal: Help make better manufacturing and operational decisions

- Decreasing development costs
- Decreasing cycle time to market
- Minimize operational expenses
- Increasing product quality



Stay Informed...

Listserves

➤ **NIH Guide for Grants and Contracts** (weekly notification)

<http://grants.nih.gov/grants/guide/listserv.htm>

➤ **NIH SBIR/STTR Notification**

<http://grants.nih.gov/grants/funding/listserv.htm>



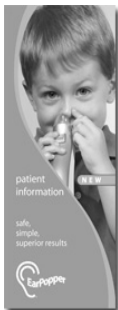
ARISIL (NY)
(1R44DC003613)

Product: Ear Popper

Technology: Development of a safe, simple, non-surgical device to drain the middle ear of fluid and restore hearing.

Uses of Device: Treating such common conditions as Otitis Media, Aerotitis/Barotitis (caused by rapid elevation changes), and Eustachian Tube Dysfunction in children and adults.

Importance of SBIR: Critical in establishing the feasibility of developing a device that may replace surgery and drugs for draining middle ear fluid.



***I'm from the Government, and
I'm here to help you....***

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