



## Small Pharmaceutical Business Educational Forum Public Workshop

# SMALL BUSINESS FUNDING OPPORTUNITIES

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Office of Extramural Research  
Office of the Director  
National Institutes of Health

4/28/2006



# Topics to Discuss Today

Extramural Programs Reserved for Small Business

**SMALL BUSINESS INNOVATION  
RESEARCH (SBIR) PROGRAM**

**SMALL BUSINESS TECHNOLOGY  
TRANSFER (STTR) PROGRAM**

***“The best way to predict the future...  
is to create it.”***

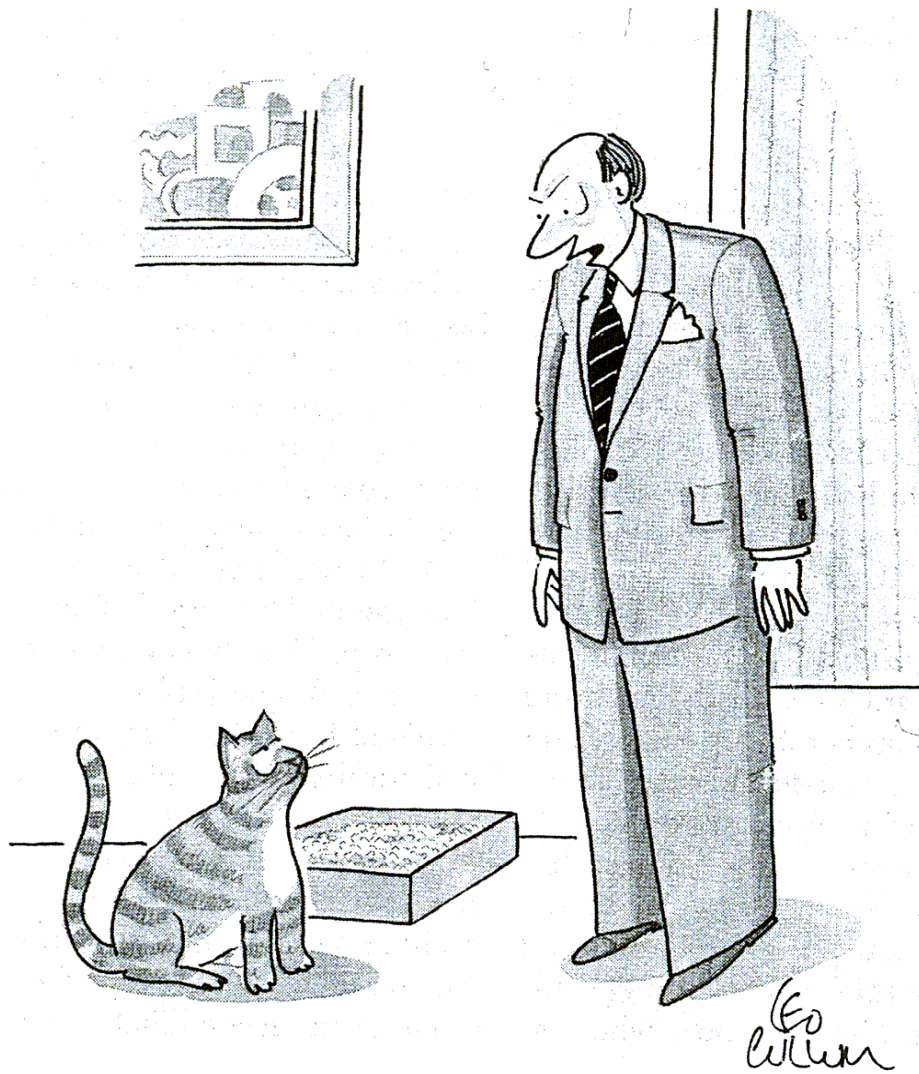
# Program Descriptions

- SBIR: Set-aside Program for Small Business Concerns to **engage in Federal R&D** - with potential for commercialization.

2.5%

- STTR: Set-aside Program to facilitate **cooperative R&D** between Small Business Concerns **and** U.S. Research Institutions-- with potential for commercialization.

0.3%

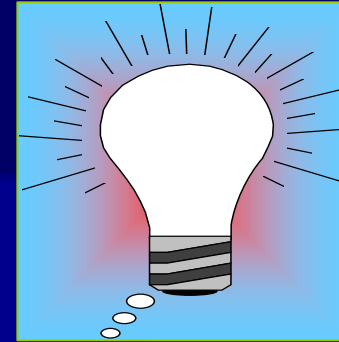


*"Never, ever, think outside the box."*

# SBIR/STTR: 3-Phase Program

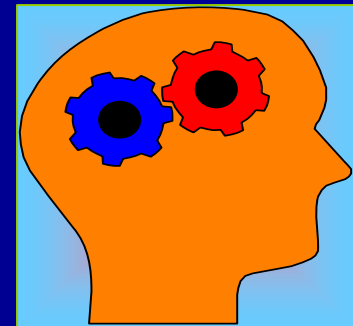
## PHASE I

- ➔ Feasibility Study
- ➔ \$100K and 6-month (SBIR) or 12-month (STTR) Award



## PHASE II

- ➔ Full Research/R&D
- ➔ \$750K and 2-year Award (SBIR/STTR)



## PHASE III

- ➔ Commercialization Stage
- ➔ Use of non-SBIR/STTR Funds



# SBIR PROGRAM ELIGIBILITY CHECKPOINTS

- Organized **for-profit** U.S. business
- At least **51% U.S.- owned** and independently operated
- Small Business **located in the U.S.**
- 500 or fewer employees**
- P.I.'s **primary employment with small business during project**

# STTR PROGRAM

## ELIGIBILITY CHECKPOINTS



**Applicant** is Small Business Concern



Formal **Cooperative R&D** Effort

- ⇒ Minimum 40% by small business
- ⇒ Minimum 30% by U.S. research institution



U.S. **Research Institution**

- ⇒ College or University; other non-profit research organization; Federal R&D center



**Intellectual Property** Agreement

- ⇒ Allocation of Rights in IP and Rights to Carry out Follow-on R&D and Commercialization

# SBIR / STTR ELIGIBILITY OWNERSHIP AND CONTROL



- Contact the **SBA** Size Specialists
- Request an eligibility determination

<http://www.sba.gov/size/indexcontacts.html>



# Important Facts to Remember

- Eligibility is determined at time of award
- The PI is not required to have a Ph.D./M.D
- The PI is required to have expertise to oversee project scientifically / technically
- Applications may be submitted to different agencies for similar work
- Awards may not be accepted from different agencies for duplicative projects

# SBIR AND STTR PROGRAMS

## ***CRITICAL DIFFERENCES***

- **Research Partner**

**SBIR: Permits** partnering

[Outsource ~ 33% Phase I and  
50% Phase II R&D]

**Award is  
always made to  
Small Business**

**STTR: Requires** partnering  
(Research Institution)

[Small business concern performs 40% and  
U.S. research institution performs 30% work]

# SBIR AND STTR PROGRAMS

## *CRITICAL DIFFERENCES*

- **Principal Investigator**

**SBIR: Primary (>50%) employment must be with small business concern**

**STTR: Primary employment not stipulated**

~~[PI can be from research institution and/or from small business concern\*]~~

# SBIR / STTR Participating Agencies



- DOD SBIR/STTR
- HHS SBIR/STTR
- NASA SBIR/STTR
- DOE SBIR/STTR
- NSF SBIR/STTR
- DHS SBIR
- USDA SBIR
- DOC SBIR
- ED SBIR
- EPA SBIR
- DOT SBIR

TOTAL ~ \$2.0 + B

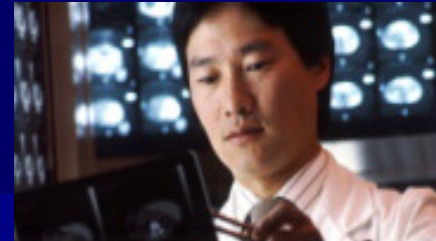
4/2/2006  
FY 2005

# NIH SBIR/STTR PROGRAM

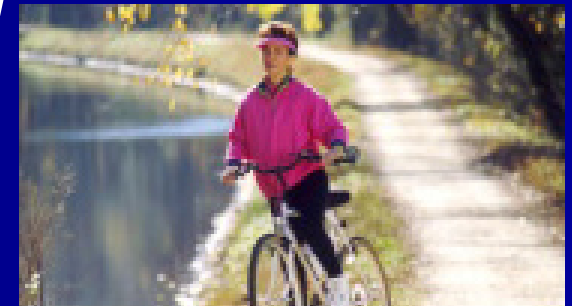
***FEATURES and NUANCES***



# NIH Mission



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



4/28/2006



# SBCs can use SBIR/STTR help NIH meet its mission

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

- Improve patient health  
(prevention, detection, diagnosis and treatment of disease or disability)
- Speed process of discovery
- Reduce cost of medical care
- Improve research tools/ reduce cost of research
- Help in training of research investigators
- Increase health knowledge base

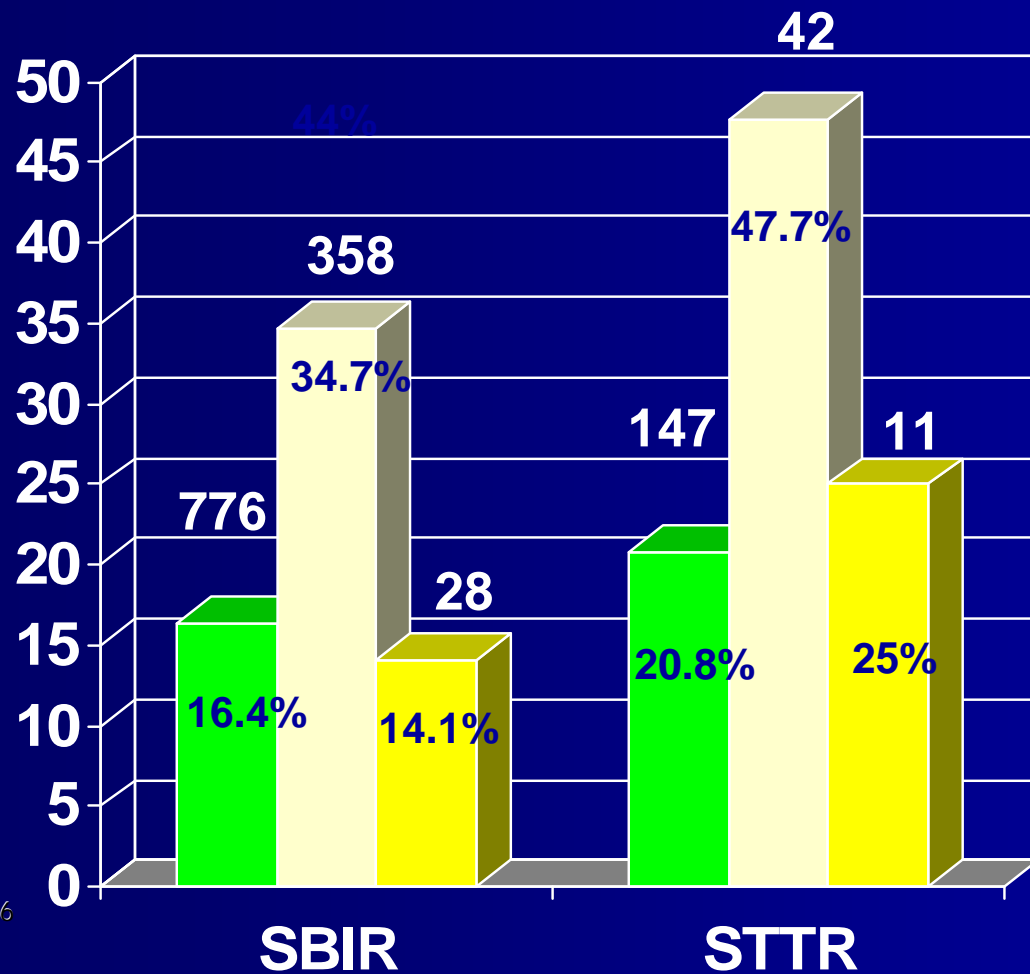
# DHHS Budget and Award Amount

2006 Budget	SBIR	STTR
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# NIH SBIR/STTR FUNDING RATES FISCAL YEAR 2005

Success Rate (%)



\$640 M  
SBIR/STTR



# Types of SBIR / STTR Awards

~95%

- **GRANTS:** you decide the research and product to be designed or developed (SBIR / STTR)

~4-5%

- **CONTRACTS:** The government decides the research and general product to fill their perceived need (SBIR only)

<1%

- **COOPERATIVE AGREEMENTS:** Similar to grants, but awarding IC has substantial involvement in carrying out the project's activities.

# SOLICITATION DATES

**SBIR/STTR Omnibus / Grant  
Solicitation (NIH, CDC and FDA)  
“Parent Announcement”**

*Release: January*  
*Submission: Apr 1*  
*Aug 1*  
*Dec 1*

**SBIR Contract Solicitation  
(NIH and CDC)**

*Release: August*  
*Receipt: November*  
*(~2nd Friday)*

**NIH Guide for Grants and  
Contracts**

*Release: Weekly*  
*Receipt : Dates as noted*

# SBIR/STTR Omnibus Solicitation

- Mission statement
  - General areas of research
  - Research Topics
  - "Other" Research Within the Mission of the IC (a.k.a. "Your Ideas")
- <http://grants1.nih.gov/grants/funding/sbir.htm>

# SBIR/STTR RESEARCH GRANT TOPICS

Our Ideas.... examples

**Biodefense**

**Biosensors**

**Nanotechnologies**

**Bioinformatics**

**Behavioral research**

**Computational  
Biology**

**Drug Delivery/Drug  
Discovery**

**Biosilicon** devices

**Biocompatible materials**

**Acousto-optics / opto-  
electronics**

**Imaging** technologies

**Genetically engineered  
proteins**

**Proteomics / Genomics**

**Complementary & Alt. Med  
(CAM)**

...

# SBIR/STTR RESEARCH GRANT TOPICS

## Drug Delivery Systems for Orofacial Disease

### **NIDCR and NIBIB**

- Design and development of novel delivery systems for rapid and/or sustained, on-demand release of therapeutic agents in the oral cavity

Dr. Rosemarie Hunziker, Center for Biotechnology and Innovation  
**National Institute of Dental and Craniofacial Research**  
Email: [hunzikerr@nidcr.nih.gov](mailto:hunzikerr@nidcr.nih.gov)

- Development of fundamentally new or portable delivery systems that may also have application to other disease conditions that share clinical requirements with orofacial diseases

Dr. Peter Moy, Division of Discovery Science & Technology  
**National Institute of Biomedical Imaging and Bioengineering**  
Email: [moype@mail.nih.gov](mailto:moype@mail.nih.gov)

# **SBIR/STTR RESEARCH GRANT TOPICS**

## **Pharmacologic Agents and Drugs for Mental Disorders**

### **National Institute of Mental Health (NIMH)**

- **Development of pharmacologic compounds for probing and treating psychiatric brain disorders**
- **Research aimed at identifying new drug development targets**
- **Budgets up to \$250,000 total costs per year and time periods up to 2 years for Phase I may be requested.**
- **Budgets up to \$450,000 total costs per year and up to 3 years may be requested for Phase II.**

**<http://grants.nih.gov/grants/guide/pa-files/PA-06-028.html>**

# SBIR RESEARCH GRANT TOPICS

Competing Renewal Awards for Pharmacologic Agents and Drugs for Mental Disorders (SBIR only)

## National Institute for Mental Health

- Preclinical studies, including pharmacology and toxicology, beyond those conducted under the Phase I (R43) and initial Phase II (R44)
- Completion of studies as required by the Food and Drug Administration (FDA) for Investigational New Drug (IND) or Radioactive Drug Research Committee (RDRC) application
- Studies in normal healthy volunteers to determine a drug's safety profile, metabolism, etc.
- Clinical studies in patient/disease population to assess the drug's effectiveness
- <http://grants.nih.gov/grants/guide/pa-files/PA-06-079.html>



# SBIR/STTR RESEARCH GRANT TOPICS

## Your ideas...

- *Investigator-initiated R&D*
- *Research topics related to the NIH mission*
- *“Other” areas of research within the mission of an awarding component*
- ... **Take-home Message #2**

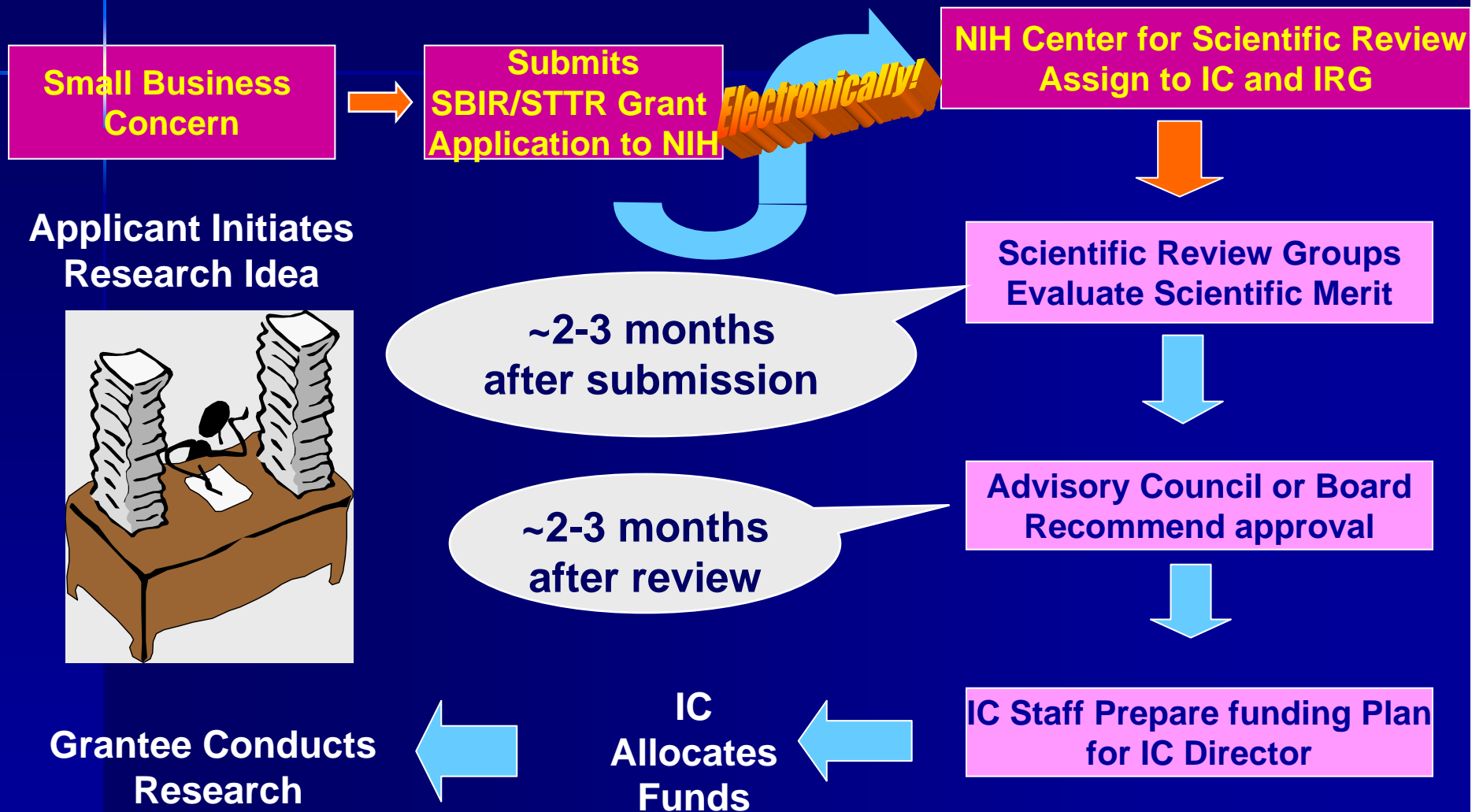
# NIH SBIR/STTR RESEARCH AREAS

**Angioscopes  
to Zebrafish**

# Grant Application Process

# NIH SBIR/STTR PROGRAM

## *Review Process for Research Grant*



# Cover Letter: A Valuable Tool



- Suggest potential awarding component(s)
- Suggest key areas of expertise required
- Indicate individual(s) or organization(s) in conflict
- For resubmissions, indicate review history
- Request same or different study section
- Justify your request

# APPLICATION TO AWARD TIMELINE

2-tiered review process  
→

## SBIR/STTR Receipt Dates

Apr 1  
Aug 1  
Dec 1

## Scientific/Technical Peer Review

June/July  
Oct/Nov  
Feb/March

## Adv Council Board Review

Sept/Oct  
Jan/Feb  
May/June

## Est. Award Date

Nov  
Mar  
July

**90-Day pre-award costs are allowable:  
*At applicant's own risk.....***

# NIH SBIR/STTR FAST-TRACK

## Bridging the Funding Gap

### Phase I + Phase II

(Simultaneous submission and Concurrent review)

7-9 months



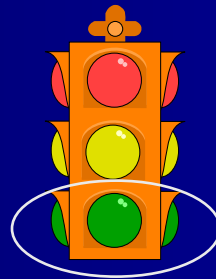
Phase I

6 month award (SBIR)  
12 month award (STTR)



Phase II  
2-year award

Funding Gap  
Reduced/Eliminated



Once Phase I Completed:  
Submit satisfactory  
Phase I Final Report



Discuss Fast-Track option with Program Director

# REVIEW CRITERIA

## (Phase I)

- **Significance (Real Problem/Real People)**
- **Approach (Research Design, Feasible)**
- **Innovation (New or Improved?)**
- **Investigators (PI and team)**
- **Environment (Facilities/Resources)**
  - ... **Protection of Human Subjects**
  - ... **Animal Welfare**
  - ... **Budget**



# Submitting an Application Electronically

Are you **R**  **ady?**

- Find out at <http://era.nih.gov/ElectronicReceipt/>
- New electronic Grants.gov application SF424 (R&R)
  - Check the Timeline
  - Register EARLY... <http://grants.gov/>

# Electronic Submission Information:

<http://era.nih.gov/ElectronicReceipt/>



## NIH Electronic Research Administration Electronic Submission of Grant Applications

- Home
- [Drivers for Change](#)
- [Electronic Submission Timeline](#)
- [Preparing for Electronic Submission](#)
- [Applying through Grants.gov](#)
- [Electronic Submission FAQ](#)
- [Related NIH Guide Notices](#)
- [Service Providers](#)
- [Communication Resources/Outreach](#)
- [Support](#)
- [Links](#)
- [History of Electronic](#)

### Electronic Submission

Big changes are coming to grants submission at the National Institutes of Health and the Agency for Healthcare Research Quality. Both NIH and AHRQ will soon **require** all competing research grant applications to come in **electronically** via the web portal of Grants.gov on a new SF 424 Research and Related (R&R) application.

We are phasing in the changes by type of grant program (mechanism), beginning with the Dec. 1, 2005 submission date for small business (SBIR/STTR) applicants and culminating in May 2007 when all grant programs will be submitted electronically on the new form [see [Transition Plan](#)].

Applicants should carefully note the transition date for the grant mechanism for which they wish to apply.

- Once a grant mechanism is transitioned to the electronic mode and the grant opportunity is posted on Grants.gov, applicants will be able to download and begin working on their application package. For instance, if a grant opportunity is posted Oct. 17, applicants will be able to download and begin working on the application package on or after Oct 17. However, they cannot submit the application until the funding opportunity's open date. That grant opportunity may have an open date of Nov. 7 for a Dec. 1 submission deadline. In that case, the applicant can submit an application electronically to Grants.gov any time between the open and submission dates, i.e. any time between Nov. 7 and Dec. 1.
- An applicant must be cognizant of the fact that until a grant mechanism is transitioned, any

**NIH is ready for  
Electronic  
Submission.  
Are You?**

[Find out where to register](#)

# Getting Started with Grants.gov

GRANTS.GOV<sup>SM</sup>

Grantors Applicants EBiz About Us Resources P.L. 106-107 Privacy FAQs Site Map HELP

Get Started Find Grant Opportunities Apply For Grants Customer Support

Home > Get Started > Roles

## http://grants.gov/GetStarted

GET started

EBIZ POC AOR Individual Grant Researcher

Get Started with Grants.gov today! Begin your search for Federal grant opportunities and download application packages available on Grants.gov. In order to submit applications on Grants.gov, you must complete a **one-time registration process**. The registration process can take **three to five days** depending on your organization. **Registration checklists** are also provided to guide you through the entire process.

### Find Grant Opportunities

Grants.gov provides the ability to search for Federal government-wide grant opportunities.

- [Tips for Searching on Grants.gov](#)
- [Review available Application Packages](#)
- [Search for Grant Opportunities](#)
- [Receive Email Notifications](#)
- [Download an Application Package](#)

### Apply for Grants

Apply for grant opportunities online today.

- [Download PureEdge Viewer \[Required\]](#)
- [Download an Application Package](#)
- [Complete an Application Package](#)
- [Submit an Application Package](#)
- [How to address Application Errors](#)

### Register to Submit Applications [Required]

You must register to create a Grants.gov account and receive approval from your [organization](#) to submit applications. This also provides you with the ability to [track your application status](#).

- [Complete First-Time Registration \[Required\]](#)
- [Review Registration Checklist](#)
- [Manage Application Status and User Profile](#)

### Explore Grant Resources

The following links provide additional resources to help you write, prepare, and/or search for grant applications.

- [Sign-up to receive the Succeed Newsletter](#)
- [Resources for searching Grants.gov](#)
- [Learn about Grants.gov](#)

**GET STARTED**

- [For EBiz POCs](#)
- [For AORs](#)
- [For Individuals](#)
- [For Grant Researchers](#)

**QUICK LINKS**

Access the most requested information and features.

Select A Topic

**RESOURCES**

- [Install PureEdge on a Macintosh](#)
- [DUNS Number Information](#)
- [Posted Grant Opportunities within last 7 days](#)
- [Available Grant Application Packages](#)
- [Types of Grants](#)
- [Grant Making Agencies](#)
- [Additional Grant Resources](#)

**REGISTRATION CHECKLISTS**

- [For Organizations](#)
- [For EBiz POCs](#)
- [For AORs](#)
- [For Individuals](#)
- [Central Contractor Registry](#)

# Grants.gov: How It Works

## Before an applicant can Apply

- 1) Complete these registration steps:
  - a) Go to <http://grants.gov/GetStarted>
    - Obtain a DUNS number (DUNS=Data Universal Numbering System).
    - Register in Central Contractor Registry (CCR).
    - Register with Grants.gov.
  - b) Go to <https://commons.era.nih.gov/commons/>
    - Set up institution and PI profiles in eRA Commons.

# Grants.gov: How It Works

## Before an applicant can Apply

- 2) Establish capacity to fill out applications:
  - Download **PureEdge Viewer** (from Grants.gov site) OR
  - **Establish an electronic system** that allows the applicant to submit to Grants.gov using system-to-system (XML) datastream
    - Can be created by institution OR
    - Institution can establish an agreement with a commercial Service Provider to develop the system

# Finding Help:

## Grants.gov Registration & Submission

- Check the resources available on the Grants.gov website first (<http://grants.gov>)
- Contact Grants.gov Customer Support:  
Contact Center Phone: 1-800-518-472  
Business Hours: Monday - Friday  
7 a.m.- 9 p.m. Eastern Time  
Email [support@grants.gov](mailto:support@grants.gov)

# Finding Help:

## eRA Commons Registration & Validations Processes

eRA Commons registration process for the applicant organization and principal investigators, or with the application validation process in the eRA Commons after submission through Grants.gov, contact:

- eRA Commons help desk  
Phone: 301-402-7469/866-504-9552 (Toll Free)  
301-451-5939 (TTY)  
Business hours M-F 7am-8pm Eastern Standard Time  
Email [commons@od.nih.gov](mailto:commons@od.nih.gov)
- eRA Commons website:  
<https://commons.era.nih.gov/commons/index.jsp>  
eRA website: <http://era.nih.gov>

# Finding Help:

## Application Preparation

- Review Application Instruction Guide(s):  
<http://era.nih.gov/ElectronicReceipt/sf424.htm#1>
- Contact Grants Info:  
Grants Info  
Phone: 301-435-0714  
301-451-0088 (TTY)  
Email [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov)
- Resources Web site:  
<http://era.nih.gov/ElectronicReceipt/support.htm>



# Sites with important information:

<http://grants.nih.gov/grants/index.cfm>

<http://grants.nih.gov/grants/welcome.htm#introduction>

<http://deainfo.nci.nih.gov/funding.htm>

<http://deainfo.nci.nih.gov/extra/extdocs/grantrevprocess.htm>

<http://www.niaid.nih.gov/ncn/grants/default.htm>

<http://www.niaid.nih.gov/ncn/grants/charts/default.htm>

<http://www.niaid.nih.gov/ncn/glossary/default.htm>

# For More Information

[www.nih.gov](http://www.nih.gov)

**LISTSERV@LIST.NIH.GOV:**  
**subscribe SBIR-STTR Jane Doe**

Search Entire Site Active Funding Opportuni

# Small Business Funding Opportunities

- OER Home
- Funding Opportunities
- Applications & Forms
- Awarded Grants
- Grants Policy
- eRA
- About OER

## News Flashes [\(Current, 2005 Archive, 2004 Archive, 2003 Archive\)](#)

- **NEW** [Electronic Submission Alert \(12/15/2005\)](#)
- [Important Helpful Hints for SBIR/STTR Applicants](#)
- [NIH offers SBIR Niche Assessment Program to Phase I Awardees](#)
- [NIH Sets Up Website for Researchers Affected by Hurricane Katrina](#)
- [NIH offers Commercialization Assistance Program \(CAP\) for its Phase II SBIR Awardees](#)
- [NIH Announces SBIR Program and STTR Program Electronic Registration Notice Number: NOT-OD-05-068](#)
- [NIH Announces Initial Plans to Transition to the SF424\(R&R\) Application and Electronic Submission through Grants.gov. NOT-OD-05-067](#)

**Electronic Submission Alert (12/15/2005):** Organizations that submitted SBIR/STTR applications to Grants.gov on or before December 8, 2005 that have not yet been able to resolve NIH validation errors should continue to work with NIH to complete the submission process by December 22. [More...](#)

## Funding Opportunities

- SBIR and STTR Parent Funding Opportunity Announcements **NEW**
  - SBIR: [PA-06-006](#): Small Business Innovation Research Program Parent Announcement (SBIR [R43/R44]): Electronic Submission of Grant Applications through Grants.gov
  - STTR: [PA-06-007](#): Small Business Technology Transfer Program Parent Announcement (STTR [R41/R42]): Electronic Submission of Grant Applications through Grants.gov
  - Phase I NIH, CDC and FDA Program Description and Research Topics - ([PDF](#) or [MS Word](#))
- [Special Funding Opportunities & Announcements](#) - updated weekly
- SBIR Phase I Contract Solicitation PHS 2006-1 ([PDF](#) or [MS Word](#)) (**closed**)

## Electronic Submission Guidance **NEW**

- Registrations
  - [Grants.gov](#)
  - [eRA Commons](#)
- [Find opportunities](#)
- [Submit applications](#)

## Electronic Submission Helpful Tips **NEW**

- [Electronic Submission - Getting Started](#)
- [FAQ's](#)
- [Checkpoints](#)

## What Are the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs?

The Small Business Innovation Research (SBIR) program is a set-aside program (2.5% of the agency's extramural budget) that provides domestic small business concerns to engage in Research/Research and Development (R/R&D) that has the potential for commercialization.

The SBIR program was established under the Small Business Innovation Development Act of 1982 (P.

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

National Institute on Aging



National Institute of Environmental Health Sciences



Fogarty International Center

National Institute of Diabetes and Digestive and Kidney Diseases



National Institute of Child Health and Human Development

NIAAA

National Cancer Institute



National Eye Institute

National Institute on Drug Abuse

National Institute of Biomedical Imaging and Bioengineering

National Institute of Dental and Craniofacial Research



NIBIB



National Institute of Arthritis and Musculoskeletal and Skin Diseases

National Institute of General Medical Sciences

National Institute of Mental Health



National Human Genome Research Institute



National Institute of Nursing Research

National Center for Research Resources

National Institute on Deafness and Other Communication Disorders



National Institute of Neurological Disorders and Stroke

National Heart, Lung, and Blood Institute

National Institute of Allergy and Infectious Diseases

National Center on Minority Health and Health Disparities



National Library of Medicine



National Institute on Alcohol Abuse and Alcoholism



National Center for Complementary and Alternative Medicine

Largest SBIR/STTR set-asides

NIDCD

New!

# National Institutes of Health

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

***Jo Anne Goodnight***  
NIH SBIR/STTR Program Coordinator  
Phone: 301-435-2688  
Fax: 301-480-0146  
Email: [jg128w@nih.gov](mailto:jg128w@nih.gov)

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**SBIR/STTR Program Staff**

[http://grants.nih.gov/grants/funding/sbirsttr1/SBIR\\_STTR\\_ContactInfo.doc](http://grants.nih.gov/grants/funding/sbirsttr1/SBIR_STTR_ContactInfo.doc)