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**NCI SBIR & STTR Bay Area Forum**  
**Stanford University, Clark Center Auditorium**  
**September 6, 2006**



- **Overview**
- **Eligibility Requirements**
- **SBIR Funding Opportunities**
- **PHS 2007-1, Solicitation for SBIR Contract Proposals**
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- **Grantsmanship**

# Overview



- 1. Stimulate technological innovation**
- 2. Use small business to meet federal research and development needs**
- 3. Increase private-sector commercialization of federal R&D**
- 4. Foster participation by minority and disadvantaged firms in technological innovation**

**Since 1992, there has been increasing focus on  
Goal 3: Increasing commercialization**

## Set Aside

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

**2.5%**

**0.3%**

**1. SBIR Contract Solicitation (NIH, CDC)**

*Release:* August

*Receipt Date:* Early November

**2. SBIR/STTR Omnibus Grant Solicitation**

*Release:* January

*Receipt Dates:* April 1, August 1, and December 1

**3. NIH Guide for Grants and Contracts**

*Release:* Weekly

*Receipt Dates:* Various

**Information at:**

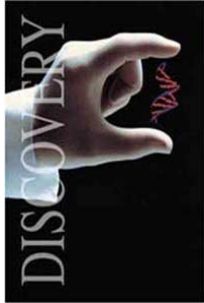
**<http://grants.nih.gov/grants/funding/sbir.htm>**

- **Grants:** Applicant determines the research and product to be designed or developed (SBIR & STTR)
- **Contracts:** NCI determines the research and general product to fill prioritized need (SBIR only)
- **Cooperative Agreements:** Similar to grants, and NCI has significant involvement in carrying out the project's activities



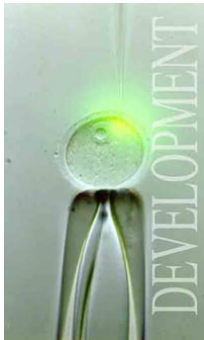
- **Provides seed funding for innovative technology development projects**
- **Provides recognition, verification and visibility**
- **Can be a leveraging tool to attract other funding (VC, etc)**
- **No repayment is required**
- **Doesn't impact stock or shares in any way. No dilution of capital.**
- **Intellectual property rights are usually retained by the small business concern**





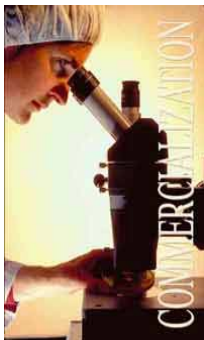
## PHASE I – R41, R43

- 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

Note: Actual funding levels may differ by topic.

## Projects by Fiscal Year

	FY 2003	FY 2004	FY 2005	FY 2006 (estimate)
SBIR Grants Phase I	182	205	84	110
SBIR Grants Phase II	146	139	147	126
SBIR Contracts Phase I	21	16	21	18
SBIR Contracts Phase II	21	17	28	37
STTR Phase I	19	37	18	33
STTR Phase II	9	16	16	3

## Successful NCI-Supported Projects

37 products commercialized — In areas ranging from devices, to research tools, to software, to educational materials:

### MarkPap® Test Kit (System)

- Based on a unique biomarker that in clinical trials has improved the cytoscreeners' ability to detect abnormal specimens (50% more than control) and has assisted them in reducing false negative readings (50% less than control)

### Image Guided Cancer Therapy

- A system for the accurate localization and fixation of the prostate during the planning and treatment of prostate cancer using radiation therapy

### Interactive multimedia CD- ROM entitled "Kidz with Leukemia: A Space Adventure"

- For 4- to 11-year-old youth with leukemia, their friends, and families. With the help of games, voiceover, videos, animation, graphics, and music, children learn about their illness, diagnosis, treatment, as well as some helpful coping skills

# Eligibility Requirements and Funding Opportunities



- **Organized for-profit U.S. business**
- **500 employees or fewer, including affiliates**
- **PI's primary employment must be with the small business concern at the time of award and for the duration of the project period**
- **Small business concern must be:**
  - **At least 51% U.S.- owned by individuals and independently operated**
  - or**
  - **At least 51% owned and controlled by a for-profit business concern that is at least 51% owned and controlled by one or more individuals**

- **Applicant is a 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 and STTR Programs (Critical Differences)



## SBIR

- **Permits** research institution partners (e.g., universities)
- Small business concern may outsource ~33% of Phase I activities and 50% of Phase II activities

## STTR

- **Requires** research institution partners (e.g., universities)
- 40% of the work must be conducted by the small business concern (for profit) and 30% by a U.S. research institution (non-profit)

**Award always made to small business**



## Solicitation Topics

- NCI describes topics in solicitation

## Proposal Submission

- Small business concerns prepare short (usually 25-page) proposals
- Unsolicited proposals are not accepted

## Evaluation

- NCI evaluates proposals based on technical merit, applicant qualifications, and commercial potential/societal benefit

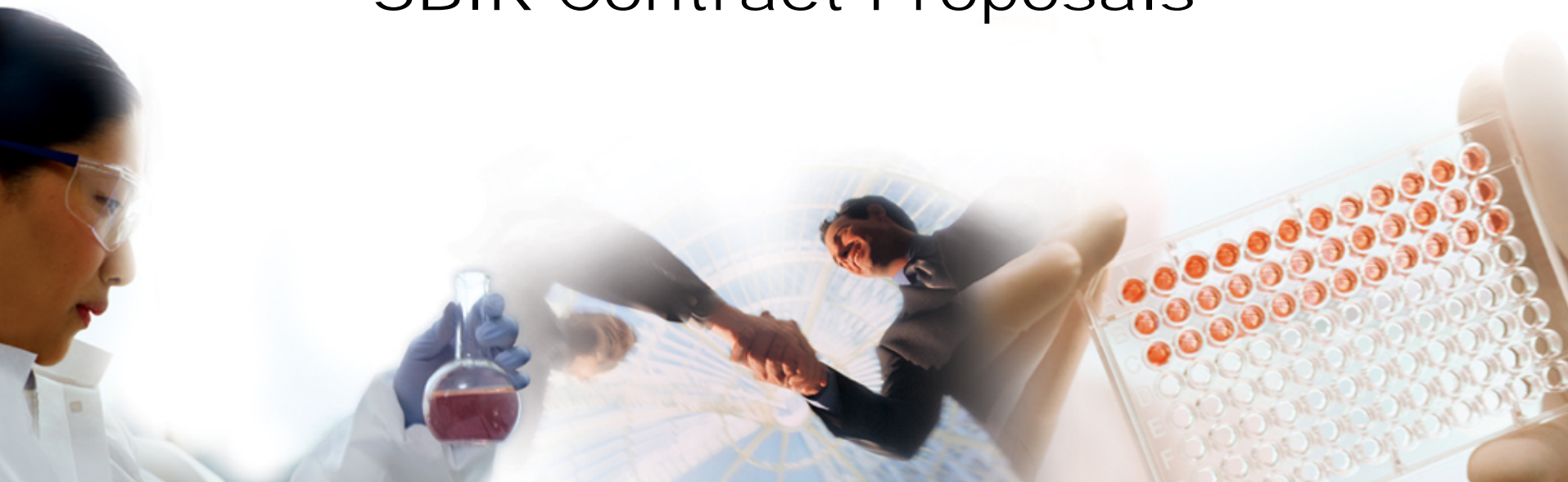
## Award

- NCI makes awards

About 6-9 months

## New Funding Opportunities

PHS 2007-1, Solicitation for  
SBIR Contract Proposals



## Alliance for Nanotechnology in Cancer

### 1 Early Diagnostics Using Nanotechnology-Based Imaging and Sensing

- Develop nanotechnology-based sensors with improved sensitivity and specificity for early detection and post-treatment monitoring of cancer signatures
- Sensor platforms should monitor genomic or proteomic signatures and operate in both *in vitro* and *in vivo* environments

### 2 Multifunctional Therapeutics Based on Nanotechnology

- Develop nanodevice-based therapeutic delivery vehicles for high efficacy, low side effects therapies
- Projects may focus on the discovery and demonstration of novel delivery platform concepts or may involve further development of existing nanodevice platforms that have demonstrated improved therapeutic efficacy in at least one animal model

## Clinical Proteomic Technologies for Cancer

### 3 Development of Clinical Automated Multiplex Affinity Capture Technology for Detecting Low Abundance Cancer-related Proteins/Peptides

- Develop a quantitative automated high-throughput multiplex affinity/protein capture technology for detecting low abundance cancer related proteins/peptides from bodily fluids
- Proposed technologies should be highly specific, highly selective and have ultra-sensitive detection capabilities with limited sample preparation

### 4 Development of Alternative Affinity Capture Reagents for Cancer Proteomics Research

- Develop reproducible, highly qualified/characterized alternative protein capture reagents for the cancer research community
- Capture reagents are expected to effectively compete against ELISA-based antibody technologies in terms of protein recognition, binding affinity, and detection and should be reproducibly produced in a cost-effective and efficient manner

## Cancer Treatment and Diagnosis

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### 5 Development of Anti-Cancer Agents

- Investigate candidate therapeutic agents to establish the rationale for continued development to the point of filing an IND
- Compounds may be chosen from a list provided by NCI or by the small business
- Work scope may include animal efficacy testing, structure-activity relationship (SAR), medicinal chemistry, formulation, production of GMP bulk drug and clinical product, pharmacokinetic, pharmacodynamic, and toxicological studies

### 6 Development of Molecular Pharmacodynamic Assays for Targeted Therapies

- Development of pharmacodynamic assays that measure molecular targets relevant to oncology therapeutics development
- Molecular targets may be chosen from a list provided by NCI or by the small business
- Provides a mechanism to determine earlier in the development process if the intended target is modulated and whether this corresponds with either tumor stasis or regression

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For more information about molecular targets and compounds of interest to NCI, please visit:

<http://sbir.cancer.gov>

## Cancer Prevention

### 7 Antibody Array for Cancer

- Develop high throughput antibody arrays for the quantitative analysis of multiple biomarkers for early detection and diagnosis of cancer
- Arrays may include biomarkers based on the applicants research and knowledge of the literature and/or biomarkers identified in collaboration with extramural investigators from NCI's Early Detection Research Network (EDRN)

### 8 Glycan Arrays for Biomarker Discovery and Validation

- Develop technologies to characterize glycan moieties of glycoproteins to enhance the diagnostic capability of protein-based biomarkers
- Arrays may include glycans based on the applicants research and knowledge of the literature and/or glycans identified in collaboration with extramural investigators from NCI's Alliance of Glycobiologists for Cancer Detection and Diagnosis



## Cancer Epidemiology and Genetics

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### **Synthesis of Stable Isotope-Labeled Steroids as Internal Standards for the Measurement of Endogenous Steroid Hormones in Biologic Samples by Liquid Chromatography – Mass Spectrometry (LC-MS)**

- Development of chemical syntheses for specific steroids labeled with stable isotopes (deuterium, C-13, or O-17)
- Demonstrate that products meet defined criteria for use as internal standards in LC-MS measurement of endogenous steroid hormones
- Scientific community will be able use these methods to ask important questions about the roles of endogenous estrogens, androgens, and progesterones in specific cancers

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### **Quantitative Assay for O<sup>6</sup>-Carboxymethyl Guanine DNA Adducts**

- Develop and commercialize a kit for quantitatively measuring O<sup>6</sup>-carboxymethyl guanine adducts in human DNA samples
- Produce a kit for the large-scale testing for O<sup>6</sup>-carboxymethyl guanine concentrations in samples from epidemiologic studies



## Cancer Control and Population Sciences

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### **Development of Software Systems to Facilitate the Use of Electronic Data Records in the Collection of Population-Based Cancer Surveillance Data**

- Expand on the present utilization of electronic pathology records in the collection of population-based cancer surveillance data
- Develop standards for the transmission of the electronic health records from their source to a central cancer registry

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### **Develop Automated Methods to Identify Environmental Exposure Patterns in Satellite Imagery Data**

- Develop an automated process to apply existing pattern recognition algorithms to satellite image data
- Develop capabilities to present results to the researcher using a user-friendly, interactive geovisualization tool

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### **Home Centered Coordinated Cancer Care System**

- Develop an automated cancer care coordination tracking program that will track health status and outcomes data, symptom management recommendations, interventions, and decision points in real time
- Program is not a stand alone product but should be integrated into a larger system of home based coordinated cancer care

# More Information on NCI SBIR & STTR Website



The screenshot shows the NCI SBIR & STTR website homepage. At the top, the National Cancer Institute logo and name are on the left, and "U.S. National Institutes of Health | www.cancer.gov" is on the right. Below this is a dark blue header with the SBIR & STTR logo, navigation links for "Contact Us", "Site Map", and a search box, and a secondary navigation bar with links for "About", "Funding Opportunities", "Resource Center", "News & Events", and "Success Stories". A large banner image depicts a scientist in a lab coat and safety glasses working with a petri dish, overlaid with a handshake, symbolizing research and commercialization. Below the banner are two main content areas: "What are SBIR & STTR?" and "Latest Announcements". The "What are SBIR & STTR?" section contains text explaining the program's purpose and a "Learn More" link. The "Latest Announcements" section lists three contract topics with links for more information. Below this is a "Sign up for Updates" section with an email input field and a "Go" button. At the bottom is an "Ask a Question" section with a link to ask the NCI SBIR & STTR staff a question.

National Cancer Institute U.S. National Institutes of Health | www.cancer.gov

**SBIR & STTR** Contact Us | Site Map | Search

About | Funding Opportunities | Resource Center | News & Events | Success Stories

**Small Business:**  
Leading for cancer research, innovation, and commercialization.

What are **SBIR & STTR**? Latest Announcements

<http://sbir.cancer.gov>

research and development projects involving a small business and a research institution.

SBIR & STTR are the largest source of early-stage technology financing in the United States. In 2005, the National Cancer Institute (NCI) made SBIR & STTR awards totaling over \$100 million to organizations that proposed innovative ideas to meet specific research and development needs of the NCI.

[Learn More](#)

Click here for more information.  
Specific information about three contract topics:

- [229: Development of Molecular Pharmacodynamic Assays for Targeted Therapies](#)
- [232: Development of Anti-Cancer Agents](#)
- [237: Glycan Arrays for Biomarker Discovery and Validation](#)

Sign up for **Updates**

Sign up to receive updates and news about the NCI SBIR & STTR Program and upcoming opportunities.

Enter your email  Go

Ask a **Question**

Ask the NCI SBIR & STTR staff a question. [Click here](#)

## SBIR Omnibus Solicitation

PHS 2006-02 Omnibus Solicitation of the NIH, CDC, and FDA for Small Business Innovation Research Grant Applications (Parent SBIR [R43/R44])

<http://grants.nih.gov/grants/guide/pa-files/PA-06-120.html>

Receipt Dates: April 1, August 1, December 1, 2006

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## STTR Omnibus Solicitation

PHS 2006-02 Omnibus Solicitation of the NIH for Small Business Technology Transfer Grant Applications (Parent SBIR [R41/R42])

<http://grants.nih.gov/grants/guide/pa-files/PA-06-121.html>

Receipt Dates: April 1, August 1, December 1, 2006

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## Program Announcements

An SBIR Initiative for Image-Guided Cancer Interventions (R43/R44)

<http://grants.nih.gov/grants/guide/pa-files/PA-06-032.html>

Receipt Dates: April 1, August 1, December 1, 2006

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Novel Technologies for *In Vivo* Imaging (SBIR [R43/R44])

<http://grants.nih.gov/grants/guide/pa-files/PA-06-046.html>

Receipt Dates: April 1, August 1, December 1, 2006

# Innovative Molecular Analysis Technologies (IMAT)



The screenshot shows the top portion of the IMAT website. At the top left is the National Cancer Institute logo and name. To the right is the text "U.S. National Institutes of Health | www.cancer.gov". Below this is the IMAT logo and name, followed by a search bar and links for "Contact Us" and "Site Map". A navigation menu includes "About IMAT", "Programs", "Funding Opportunities", "Electronic Submission Process", and "News & Events". The main banner features a molecular structure image and the text: "Developing Innovative Technologies In The Fight Against Cancer".

<http://imat.cancer.gov>

(IMAT) was established in 1998 to meet the challenge goal of reducing suffering and death due to cancer. IMAT supports research projects aimed at developing creative methods and tools by which to understand, prevent, diagnose, and treat cancer. Through solicitation, outreach, and communication with the investigator community, the IMAT Program has been successful in promoting cancer-relevant applications of a diverse spectrum of new and emerging technologies. [more](#)

## ◦ IMAT Programs

### [Innovative Technologies for the Molecular Analysis of Cancer](#)

IMAT funding opportunities are designed to encourage

Technologies (IMAT) program now encompasses an array of 14 closely related Funding Opportunity Announcements (FOAs). Each FOA is segregated based on theme and type of funding mechanism. Click on the links below to view the FOAs by IMAT Program.

### [Innovative Technologies for the Molecular Analysis of Cancer](#)

### [Application of Emerging Technologies for Cancer Research](#)

### [Innovations in Cancer Sample Preparation](#)

### [Small Business Funding Opportunities](#)

- 1** Innovative Technologies for Molecular Analysis of Cancer (SBIR [R43/R44])  
<http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-07-006.html>  
Receipt Dates: February 22, May 26, September 26, 2006

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- 2** Application of Emerging Technologies for Cancer Research (SBIR [R43/R44])  
<http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-07-008.html>  
Receipt Dates: February 22, May 26, September 26, 2006

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- 3** Innovations in Cancer Sample Preparation (SBIR [R43/R44])  
<http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-07-010.html>  
Receipt Dates: February 22, May 26, September 26, 2006

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- 4** Innovative Technologies for Molecular Analysis of Cancer (STTR [R41/R42])  
<http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-07-007.html>  
Receipt Dates: February 22, May 26, September 26, 2006

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- 5** Application of Emerging Technologies for Cancer Research (STTR [R41/R42])  
<http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-07-009.html>  
Receipt Dates: February 22, May 26, September 26, 2006

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- 6** Innovations in Cancer Sample Preparation (STTR [R41/R42])  
<http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-07-011.html>  
Receipt Dates: February 22, May 26, September 26, 2006



# Preparing to Submit an Application or Proposal



- **Understand NCI's mission and needs**
- **Explore the funding opportunities on our web site**
- **Seek guidance from SBIR & STTR Program Directors**
- **Don't depend solely on SBIR funding**
- **Don't go it alone: Use support systems, such as the Commercialization Assistance Program (CAP)**
- **Have an outcome**
- **Win or lose, request and review evaluations**
- **If you're new to the NIH SBIR program and the peer review process, consider collaborating with someone who has been successful in receiving awards**



- **Significant Product Potential**
  - **A product-focused application is more likely to have support of business reviewers**
  - **A project with sound financial projections is more likely to attract a partner**
- **Significant, innovative science**
  - **A scientifically focused application is more likely to have a knowledgeable reviewer**
  - **Translational research/clinical applications projects should involve the appropriate collaborators (e.g., oncologists, pathologists, statisticians)**

## Significance

- Does the study address an important problem and have commercial potential?

## Approach

- Are design and methods well-developed and appropriate? Are problem areas addressed?

## Innovation

- Are there novel concepts or approaches? Are the aims original and innovative?

## Investigator

- Is the investigator appropriately trained and capable of managing the project?

## Environment

- Does the scientific environment contribute to the probability of success? Is the environment unique?

# NIH SBIR/STTR Fast-track: Bridging the Phase I – Phase II Funding Gap



## Phase I + Phase II

- Simultaneous submission and concurrent review

## Completion of Phase I

- Phase I final report submitted
- Program staff assess completion of specific aims and milestones

## Phase II Award

- Phase II award is made only if the applicant has met the aims and milestones in Phase I

## Fast-track applicants should demonstrate:

- Convincing preliminary data
- Clear, measurable, achievable milestones
- Well-conceived commercialization plan
- Letters of Phase III support/interest
- Track record of commercializing

- **Have you assessed the commercial viability of your technology?**
- **Do you have a talented professional to be a PI?**
- **Is the PI supported by the right team?**
- **Do you have the resources to write the grant application/ contract proposal?**
- **Do you have the resources and capabilities to execute?**
- **Do you have the business resources needed for a successful launch?**

**Plan this before writing**

# Grantsmanship



- **Your specific aims are the milestones of your research project, driven by your hypothesis or research objective**
- **Specific aims are the criteria by which success will be judged**
- **Choose specific aims that can be easily assessed by the review committee**
- **Include concrete specific aims that reviewers will expect**

- **Describe the state of knowledge in your research area, gaps and roadblocks, and opportunity you have identified**
- **Use citations to demonstrate the breadth of your knowledge of both published and unpublished work**
- **Tell why your proposal will increase knowledge and improve public health**
- **Identify how the proposed Phase I research milestones will justify Phase II**



- **Preliminary Data**
  - **Solicitation states “Preliminary data are not required”**
  - **Reviewers like to see preliminary data**
  - **Preliminary data should support your proposal and the feasibility of the project**
  - **Preliminary data may consist of your own publications and unpublished data from your laboratory**
  - **Interpret results critically (e.g., evaluate alternative meanings)**

- **Describe your research design and methods in parallel to your specific aims, including for each experiment:**
  - **Timelines**
  - **Rationale, innovation, supporting data, and references**
  - **Expected results, limitations, potential difficulties, and planned statistical analysis if relevant**
  - **Criteria for evaluating success, failure, or other possible interpretations**
  - **Hazards anticipated – precautions proposed**
  - **Reagents, animals, human subjects, equipment, etc.**
  - **Collaborators – purpose & letters of agreement**

- **Value of the SBIR/STTR Project, Expected Outcomes, and Impact**
- **Company**
- **Market, Customer, and Competition**
- **Intellectual Property Protection**
- **Finance Plan**

- **Protection of Human Subjects**
- **Inclusion of Women and Minorities**
- **Targeted/Planned Enrollment Table**
- **Inclusion of Children**
- **Data and Safety Monitoring Plan**
- **Vertebrate Animals**
- **Consortium/Contractual Agreements “Select Agent Information”**
- **Resource Sharing Plans**
- **Letters of Support**

# Electronic Submission Process (Grants Only)



- The PHS398 grant application form is being phased out and replaced with the SF424 [Research and Research-related (R&R)] application
- NIH has transitioned from paper submission of SBIR/STTR grant applications to electronic submission via the web portal of [Grants.gov](https://www.grants.gov)
- Applicants must first register for application submission:
  - Company and company official must be registered in [Grants.gov](https://www.grants.gov)
  - PI and company official must be registered in the [eRA Commons](https://www.eRA Commons)

**Contract proposals are received  
via paper submission ONLY**

<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](#)
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### 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](#)



# More Information on NCI SBIR & STTR Website



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<http://sbir.cancer.gov>

**Questions?**  
[ncisbir@mail.nih.gov](mailto:ncisbir@mail.nih.gov)



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