

# **R41, R42, R43, R44 GUIDE FOR REVIEWERS**

Small Business Innovation Research (SBIR) Awards

Small Business Technology Transfer (STTR) Awards

## **EXECUTIVE SUMMARY**

Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Awards (R41), (R42), (R43), and (R44)

Visit parent SBIR FOA at [PA-09-080](#), and parent STTR FOA at [PA-09-081](#).

### **Objectives of SBIR/STTR programs:**

- Stimulate technological innovation in the private sector
- Strengthen role of small business in meeting Federal Research/Research & Development needs
- Increase private sector commercialization of innovations developed through Federal SBIR/STTR R&D
- Increase small business participation in Federal Research/R&D
- Foster and encourage socially and economically disadvantaged small business and women-owned business concerns in the areas of technological innovation

### **The SBIR and STTR programs differ in significant ways:**

#### ***Project Director/Principal Investigator (PD/PI):***

- The SBIR program stipulates that the PD/PI must have his/her primary employment with the small business. Note: Agencies are permitted to grant waivers to PD/PIs who are not primarily employed by the small business. These however, are given infrequently for extraordinary circumstances.
- The PD/PI on an STTR may be from the small business or the research institution, provided an official relationship exists between the small business and the research institution.
- Both programs may have multiple PD/PIs on individual applications/grants. If an SBIR application has more than one PD/PI, only one of the PD/PIs must be primarily employed by the small business.

#### ***Research Collaborator:***

- STTR requires the applicant small business organization to formally collaborate with a U.S. research institution in both Phase I and Phase II.
- For STTR:
  - The small business must perform at least 40% of the work/R&D.

- The single partnering U.S. research institution must perform at least 30% of the work/R&D.
- These percentages are in statute and deviations are not allowed.
- SBIR grants are not required to have research collaborators, but they may; collaborators may perform up to 33% of the work/R&D for Phase 1 and up to 50% for Phase 2.

Visit the PHS 2009-02 Omnibus Solicitation and special SBIR/STTR funding opportunity announcements at <http://grants.nih.gov/grants/funding/sbir.htm>.

## **SBIR/STTR PROGRAMS**

### ***Phase I: Feasibility [type 1 R41 (STTR) and type 1 R43 (SBIR) applications]***

The objective of Phase I is to establish the technical/scientific merit and feasibility of the proposed R/R&D efforts and to determine the quality of performance of the small business grantee organization prior to providing further Federal support in Phase II.

- Preliminary data are not required.
- SBIR Phase I awards normally may not exceed \$100,000 total costs for a period normally not to exceed 6 months. The total amount of all contractual costs and consultant fees normally may not exceed 33% of the total costs requested.
- STTR Phase I awards normally may not exceed \$100,000 total costs for a period of 1 year.
- These award levels for duration and total costs are statutory guidelines, not ceilings. Deviations from the guidelines are acceptable, but must be justified in the application.
- Note: The mean Phase I award (FY 2006 – 2008) for SBIR and STTR projects is \$170,000.
- For STTR awards, at least 40% of the work must be performed by the small business and 30% of the work must be performed by the single partnering U.S. research institution.
- For STTR awards, the principal investigator must spend a minimum of 10% effort on the research effort.

### ***Phase II: Full Research/R&D Effort [type 2 R42 (STTR) and type 2 R44 (SBIR) applications]***

The objective of the Phase II is to continue the research or R&D efforts initiated in Phase I. Evaluation is based on the results of Phase I, scientific and technical merit, and commercial potential and societal impact of the Phase II application. Reviewers may access additional information on Phase II applications.

- SBIR Phase II awards normally may not exceed \$750,000 in total costs for an entire period normally not to exceed 2 years. The sum of the consultant costs and contractual costs normally may not exceed 50% of the total costs requested.

- STTR Phase II awards normally may not exceed \$750,000 in total costs for an entire period normally not to exceed 2 years.
- These award levels for duration and total costs are statutory guidelines, not ceilings. Deviations from the guidelines are acceptable, but must be justified in the application.
- Note: The mean Phase II award (FY 2006 – 2008) for SBIR and STTR projects is \$850,000.
- For an STTR award, at least 40% of the work **must** be performed by the small business and 30% of the work **must** be performed by the research institution.
- These percentages **are** in statute and deviations are not allowable.
- For STTR awards, the principal investigator must spend a minimum of 10% effort on the grant.
- All Phase II SBIR/STTR applications must include a succinct Commercialization Plan (Section I.D., below) within the application.

### ***Phase II Competing Renewal Applications***

- Some NIH Institutes/Centers (ICs) offer Phase II SBIR/STTR awardees the opportunity to apply for Phase II Competing Renewal awards.
- These are available for those projects that require extraordinary time and effort in the R&D phase and may or may not require FDA approval for the development of such projects, including drugs, devices, vaccines, therapeutics, and medical implants related to the mission of the IC. In addition, some ICs will accept competing renewal Phase II SBIR grant applications to continue the development of technologies that do not require FDA approval, but are intended to continue the process of developing complex instrumentation, clinical research tools, or behavioral interventions and treatments.
- Some ICs have used targeted announcements in the NIH Guide for Grants and Contracts and some are using the Omnibus SBIR/STTR Grant Solicitation, a.k.a. parent announcements. (All FOAs are available from <http://grants1.nih.gov/grants/funding/sbir.htm>)
- Only those small business concerns who have been awarded a Phase II are eligible to apply for a Phase II Competing Renewal award. Prospective applicants are strongly encouraged to contact NIH staff prior to submission.
- Additional requirements and instructions (e.g., submission of a letter of intent) are available in the specific IC research topics section and in the specific [IC Program Funding Opportunity Announcements](http://grants.nih.gov/grants/funding/sbir_announcements.htm); [http://grants.nih.gov/grants/funding/sbir\\_announcements.htm](http://grants.nih.gov/grants/funding/sbir_announcements.htm).
- The following NIH ICs will accept applications for Phase II Competing Renewal awards: **NCRR** (SBIR only), **NIA**, **NIAAA**, **NIAID**, **NICHD** (SBIR only), **NIDA**, **NIDCD**, **NIDDK**, **NIGMS** (SBIR only), **NEI** (SBIR only and only Competing Renewals of NEI-supported Phase II awards), **NHLBI** (SBIR only and only Competing Renewals of NHLBI-supported Phase II awards), **NIMH** (SBIR only), and **NINDS**.

### ***Fast-Track Applications (type 1R42 and type 1R44 applications)***

- Expedite the award of SBIR and STTR Phase II funding for scientifically meritorious applications that have a high potential for commercialization. (Closes the funding gap between phases.)
- Incorporate a parallel review option, in which the Phase I and Phase II grant applications are submitted and reviewed together.
- The Phase I of a Fast Track must specify clear, measurable criteria for success (milestones) that should be achieved prior to initiating Phase II work. It is expected that the Phase I portion of a Fast-Track will include preliminary data.

### ***Commercialization Plan***

Phase II and Fast-Track and Phase II Competing Renewal applications must include a succinct Commercialization Plan within the application. The Commercialization Plan (limited to fifteen pages) should address:

- The value of the SBIR/STTR project, expected outcomes, and societal and educational benefits including: a description of key technology objectives, the commercial applications of the research, and the advantages compared to competing products or services.
- Company information including: corporate objectives, core competencies, present size, products/services with significant sales, history of previous Federal and non-Federal funding, regulatory experience, and how the company plans to develop from a small technology R&D business to a successful commercial entity.
- Market, customer, and competition including: the market/market segments being targeted, plans to gain customer acceptance of the product/service, and analysis of potential competition.
- Intellectual property protections: patent or provisional patent status.
- Finance plan including: letters of commitment or intent of funding, letters of support, and specific steps being taken to secure Phase III funding.
- Production and marketing plan including: manufacturing, marketing, licensing, and internet sales.
- Revenue stream generation including: manufacture and direct sales, distributors, joint ventures, licensing, and staffing expectations.
- Reviewers should use the commercialization plan when evaluating the "significance" core review criteria and comment on the plan's strengths and weaknesses in this section.

### ***Just-in-Time Considerations***

Certain items required for funding a grant application are termed "Just-in-time." These items are not required prior to the review of the application, but will be routinely requested by the awarding component prior to making the grant award.

- Eligibility for an SBIR or STTR is considered at the time of award, not at the time of application. Small Business Concerns must complete a Verification Statement to verify they meet the SBA's eligibility criteria as a small business concern for an award.
- Human Subjects Assurance and Institutional Review Board (IRB) approval.
- Institutional Animal Care and Use Committee (IACUC) approval date. Animal welfare assurance numbers are not required for the review of an application.
- Documentation to establish the "primary employment" of the PD/PI with the applicant small business concern (SBIR only).
- Documentation regarding the performance site(s) of the applicant small business concern as shown on the Face Page of the application, if that site(s) is not owned by the applicant organization.
- "Other support" for the PD/PI and the other Senior Key Personnel, excluding consultants, named in the Senior/Key Person profile.

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### **MORE INFORMATION**

To read more about the review criteria and considerations for SBIR-STTR applications, visit <http://grants.nih.gov/grants/peer/critiques/sbir-sttr.htm>.

Please see the following documents for more information on scoring and critique templates: [Scoring System and Procedure](#), [Critique Template Instructions](#). A comprehensive list of Guidelines for Reviewers is available at [http://grants.nih.gov/grants/peer/reviewer\\_guidelines.htm](http://grants.nih.gov/grants/peer/reviewer_guidelines.htm).