News from the National Institute of General Medical Sciences (NIGMS) Small Business Research Grants Update

Small businesses form an integral part of the current pharmaceutical and biotechnology scene. The National Institutes of Health (NIH) offers two programs to help support small business research: the Small Business Technology Transfer Grant Program (STTR) and the Small Business Innovation Research Grant Program (SBIR). Table 1 provides a detailed comparison between these programs. The STTR program exists to encourage the spin-off of academic research into commercial enterprises and requires an academic research component. The SBIR program is primarily intended to support research by small businesses, although the work may involve substantial academic collaborations. In both cases, the objectives are to support research with potential for commercialization and to utilize small businesses to accomplish research important to the NIH mission.

STTR and SBIR grants support a staged R&D program. Phase I grants are awarded to establish the technical merit and feasibility of the proposed research and the capabilities of the grantee organization. Phase II grants are awarded to continue the R&D effort established during Phase I. Phase III is the commercialization of the results using non-SBIR funds. A "Fast-track" mechanism exists to apply for Phase I and Phase II funding at the same time. The award levels and project durations shown in Table 1 are considered guidelines, not ceilings. Applicants may propose longer periods of time and greater amounts of funds if necessary and justified to complete the work.

Eligible applicant organizations are companies with at least 50% U.S. ownership and with fewer than 500 employees. The research must be conducted entirely in the U.S., in facilities under control of the company or its sub-contractors. The PI must be employed at least part time by the company during the award period. Title to equipment and supplies acquired under the grant lies with the grantee. Rights to data, software, inventions, patents, and other intellectual property reside with the company, although the government does retain some limited and extremely rarely exercised rights. Confidentiality of proprietary information is protected. The proposed budget can include the reimbursement of indirect costs and a fixed fee (profit), as well as direct costs of the research.

Each year the government publishes a booklet, "Omnibus Solicitation of the National Institutes of Health, Centers for Disease Control and Prevention, and Food and Drug Administration for Small Business Innovation Research Grant Applications" and a comparable booklet for the STTR program. A third booklet is published soliciting SBIR contract proposals. These books are available on-line (see below) or by telephone request: 301-206-9385. The books include descriptions of the interests of each of the agencies and long lists of topics of potential interest to small businesses. However, the NIH is even more interested in investigators' own ideas about innovative research. Applicants should not feel that they are obliged to figure out where their ideas fit into the NIH organizational structure. NIH staff will assign the application to the appropriate institute (and in many cases will give it a secondary assignment as well). An important distinction between NIH and many other small business programs in the government is that most of the NIH funds are distributed as research grants, to enable investigators to do the work they want to do, rather than as contracts. Nonetheless, contacting a relevant program director before submitting your application may be useful.

Areas of recent NIGMS interest that are especially relevant to AAPS include: pharmacogenetics; pharmacogenomics; bioinformatics; combinatorial chemistry; rational and computer aided drug design; structures of membrane receptors and transporters; structural genomics; high-throughput methods; screens for bioavailability, metabolism, activity, and toxicity; complex systems analysis; physiology of stress responses, sepsis, shock, trauma and burn injury; wound healing; tissue engineering; mechanisms of anesthesia and pain management; genetics of newly emerging infectious diseases;

Table 1. Features of NIH Small Business Programs

	STTR	SBIR
% Set-aside of NIH budget	0.15%	2.5%
FY99 NIH SBIR/STTR budget	$18 million	$307 million
FY98 NIH SBIR/STTR budget	$17 million	$264 million
Phase I FY98 applications (Awards)*	339 (88)	2678 (696)
Phase II FY98 applications (Awards)*	65 (20)	585 (224)
Award guidelines phase I	$100K/12 months	$100K/6 months
phase II	$500K/2 years	$750K/2 years
Subcontract limits phase I	<60%	<33%
phase II	<60%	<50%
Academic component	>30%	Not required
Business employment of PI	>0%	>50%
Receipt dates	12/1, 4/1, 8/1	12/15, 4/15, 8/15
Receipt date for contracts	N/A	11/1, only, inquire

* Applications reviewed in FY98. New and competing continuation awards in FY98.

Table 2. Review Criteria for STTR/SBIR Applications

1) Soundness and technical merit of the proposed approach.
2) Qualifications of the proposed principal investigator, supporting staff, and consultants.
3) Scientific, technical, or technological innovation of the proposed research.
4) Potential of the proposed research for commercial application or societal impact.
5) Appropriateness of the budget.
6) Adequacy and suitability of the facilities and research environment.
7) Appropriate means for safeguarding human or animal subjects.

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microbial biofilms; genetic tools and model systems for discovery research. For text of NIGMS program announcements, see: http://www.nih.gov/nigms/funding/pa. See the Omnibus Solicitation for a complete description of the interests of NIGMS and other institutes.

SBIR/STTR applications are reviewed by Special Emphasis Panels (*ad hoc* study sections) organized by the NIH Center for Scientific Review *de novo* for each receipt date to accommodate the incoming workload. These panels usually include members from small businesses, as well as members from big business and academia. Many applications in areas of interest to AAPS are reviewed by the "drug development and drug delivery" study section. The current Scientific Review Administrator responsible for this area is Dr. Ronald Manning (E-mail: manningr@csr.nih.gov). He was part of an NIH grantsmanship workshop held at 12:00 noon, Tuesday, November 19, at the 1999 AAPS Annual Meeting in New Orleans (http://www.aaps.org/annualmeet/tue.html).

Many AAPS members have participated in the SBIR/STTR programs as applicants, consultants, or reviewers; however, many more could potentially benefit by becoming involved with these NIH programs. Many of the companies who exhibit at the AAPS annual meetings have participated in the NIH small business programs at some stage in their development. NIH is interested in hearing from previous awardees about how past NIH support has contributed to the development of their business. The small business programs are currently undergoing reauthorization by Congress. Your input is particularly useful at this time.

Detailed information on the NIH small business programs, including downloadable application forms, can be found on the NIH web site. (See http://www.nih.gov/grants/funding/sbir.htm).

Detailed information on areas of NIGMS interest and specific recent initiatives can be found on the NIGMS web site. (See http://www.nih.gov/nigms).

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