

Translating Research from Basic Discovery to Improved Patient Care

NCRR FACT SHFFT

Small Business Grant Program

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Overview

The National Institutes of Health (NIH) provides grant opportunities for small businesses in any biomedical or behavioral research area that falls within NIH's mission to improve human health. The National Center for Research Resources (NCRR), one of the 27 institutes and centers at NIH, provides laboratory scientists and clinical researchers with the resources and tools they need to understand, detect, treat, and prevent a wide range of diseases. Through the small business program, NCRR supports research to create and develop critical resources, models, and technologies.

NCRR participates in two federal grant programs that provide funding to small businesses—the Small Business Innovation Research (SBIR) program and the Small Business Technology Transfer (STTR) program. Both programs seek to increase the participation of small businesses in federally supported research and development (R&D) and to increase private-sector commercialization of technology developed through federally supported R&D. Both of these programs provide opportunities to integrate public and private initiatives.

Clinical and Translational Research Resources

NCRR fosters collaboration between small businesses and academic researchers through its Clinical and Translational Science Award (CTSA) program. This program aims to reduce the time it takes for laboratory discoveries to become treatments for patients as well as to train the next generation of clinical and translational researchers. A national consortium, funded through CTSAs, will link together about 60 institutions by 2012 with a budget of \$500 million per year to energize the discipline of clinical and translational science.

The CTSA consortium is designed to stimulate alliances in medical research and research training by identifying opportunities via collaboration among CTSA members and private-sector, nonprofit, and government partners. Specific efforts related to private-public partnerships, translational research, and other CTSA committees can be found at www.CTSAweb.org/ppp.

NCRR is also interested in the development of clinical technology, instruments, devices, and related methodologies that may have broad application to clinical research. In particular, NCRR funds applications that enhance the ability to perform clinical research and improve patient care. To help facilitate clinical research, NCRR supports R&D focused on:

- Patient-centered technologies and systems.
- Methods and tools used for clinical and translational research.
- Medical and health care computer and communication technologies.
- Research informatics and information systems.

- Miniaturization of existing biomedical technologies for adaptation to pediatric use.
- Vehicles for drug delivery, vectors for gene therapy, high-throughput technologies, and methods and techniques for studies of human diseases.
- Techniques, instruments, and reagents to optimize the recovery and quality of cells for subsequent use in either basic research or clinical protocols.

Instrumentation and Specialized Technologies for Biomedical Research

NCRR supports research to discover, create, and develop innovative technologies for biomedical research. It is especially interested in funding R&D in topic areas such as:

- New or improved instrumentation, including but not limited to mass spectrometry; nuclear magnetic resonance; imaging; fluorescent, kinetic, or laser spectroscopies; X-ray absorption/diffraction; electron or confocal microscopies; flow cytometry; synchrotron; and detection technologies.
- Computer science and technology designed to study biomedical or behavioral research problems, such as computer visualization, computer modeling and simulation, and structure-based drug design.
- New bioinformatics technology infrastructure, such as data management and analysis tools, networking infrastructure, and collaborative tool development.
- Novel technologies for proteomics and glycomics discovery, such as sample handing; separations; mass spectrometry; and computational tools for protein identification, data curation, and mining.

Comparative Medicine

NCRR helps meet the needs of biomedical researchers for high-quality, disease-free animals and specialized animal research facilities. Of particular interest to scientists are a variety of sources for genetic analysis services, such biological materials as cultures and reagents, and online information about model organisms. Other areas include:

- Control of selected laboratory animal diseases.
- Technologies for preservation or management of laboratory animals.
- Methods for identification or production of new mammalian or nonmammalian animal models.
- Improvement of culture and culture conditions.

Additional high-priority needs are for the development of innovative methods and tools to control and prevent herpes virus B in nonhuman primates and the development of effective means of accessing and using disease models-related data.

Discovery-Oriented Software and Tools for Science Education

NCRR is working to improve the public's understanding of health and biomedical research, to generate interest in science-related careers, and to train the next generation of biomedical and behavioral researchers. To meet these goals, NCRR is interested in funding discovery-oriented, user-friendly educational software and applying technology and tools on health science topics for K-12 and undergraduate students.

Topics can range from basic molecular and cellular biology to human diseases. This effort is intended to generate efficient and easy-to-follow educational materials for students that can then be extended to enhance the health science literacy of the general public.

Definitions of the NIH SBIR and STTR Programs

The *NIH SBIR program* is a set-aside program for domestic small businesses to engage in biomedical R&D that has the potential for commercialization.

The *NIH STTR program* is a set-aside program to facilitate cooperative R&D between small businesses *and* U.S. research institutions, with the potential for commercialization.

Differences between SBIR and STTR

Under the *SBIR program*, the principal investigator's (PI) primary employment must be with the small business. However, if multiple PIs are applying for a grant, the second PI need not be primarily employed by the small business.

Under the *STTR program*, primary employment is not stipulated. The STTR program requires research partners at universities and other nonprofit research institutions to have a formal collaborative relationship with the small business.

Structure of the SBIR and STTR Programs

The SBIR and STTR programs are structured in three phases:

Phase I

- Establish technical merit, feasibility, and potential for commercialization.
- SBIR: Support may not exceed \$100,000 in total costs for six months.*
- STTR: Support may not exceed \$100,000 in total costs for one year.*

Phase II

- Continue research and R&D efforts initiated in Phase I.
- Funding will be based upon Phase I results and may not exceed \$750,000 in total costs for a two-year period.*
- Commercialization plan required.

Phase III

- Commercialization stage using non-SBIR/STTR funds to pursue Phase I and II goals.
- * Deviations from the indicated Phase I/Phase II statutory award amount and project period guidelines are acceptable but must be well justified.

Eligibility

SBIR Requirements

- The small business must be an organized for-profit U.S. business.
- It must have 500 or fewer employees, including affiliates.
- It must be at least 51 percent U.S.-owned by individuals and independently operated or at least 51 percent owned and controlled by another (one) business that is at least 51 percent owned and controlled by one or more individuals.
- The PI's primary employment must be with the small business at the time of award and for the duration of the project period.

STTR Requirements

- The small business must be a for-profit U.S. business.
- A formal cooperative R&D arrangement must exist with a 40 percent minimum effort by small business and a minimum 30 percent effort by a U.S. research institution.
- The U.S. research institution must be a nonprofit.
- There must be an agreement identifying the allocation of intellectual property rights.
- The PI's primary employment may be with either the small business or the research institution.

NIH Small Business Grant Program Information http://grants1.nih.gov/grants/funding/sbir.htm

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