Small Business Funding Opportunities

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 Advancing Translational Sciences (NCATS), one of NIH’s 27 Institutes and Centers, aims to transform the translational science process so that new treatments and cures for disease can be delivered to patients faster.

NCATS seeks to increase small business participation in federally supported research and development (R&D) as well as private-sector commercialization of technology developed with federal support. The Center also is interested in the application of clinical technology, instruments, devices and related methodologies that may have broad application to clinical research and patient care.

NCATS participates in two federal grant programs that provide funding to small businesses — the Small Business Technology Transfer (STTR) program and the Small Business Innovation Research (SBIR) program. Both of these programs provide opportunities to integrate public and private initiatives.

Small Business Technology Transfer

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.

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.

To be eligible for the STTR program:

1. The small business must be a for-profit U.S. business.
2. The U.S. research institution must be a nonprofit.
3. An agreement must identify the allocation of intellectual property rights.
4. 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.
5. The PI’s primary employment may be with either the small business or the research institution.
Small Business Innovation Research

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. 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.

To be eligible for the SBIR program:

1. The small business must be organized for-profit U.S. business.
2. The small business must be an individual proprietorship, partnership, limited liability company, corporation, joint venture, association, trust or cooperative, except that where the form is a joint venture, there must be less than 50 percent participation by foreign business entities in the joint venture;
3. (i) The small business must be more than 50 percent directly owned and controlled by one or more individuals (who are citizens of or permanent resident aliens in the U.S.), other business concerns (each of which is more than 50 percent directly owned and controlled by individuals who are citizens or permanent resident aliens of the U.S.), or any combination of these;
   OR
   (ii) SBIR only: The small business must be more than 50 percent owned by multiple venture capital operating companies, hedge funds, private equity firms or any combination of these. No single venture capital operating company, hedge fund or private equity firm may own more than 50 percent of the concern;
   OR
   (iii) The small business must be a joint venture in which each entity to the joint venture meets the requirements above.
4. The small business must have, including its affiliates, no more than 500 employees.

STTR and SBIR Program Structure

The STTR and SBIR programs are structured in three phases.

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<th>Phase</th>
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| Phase 1 | • Establish technical merit, feasibility and potential for commercialization.  
          • **STTR**: Support may not exceed $225,000 in total costs for one year.  
          • **SBIR**: Support may not exceed $225,000 in total costs for six months. |
| Phase 2 | • Continue research and R&D efforts initiated in Phase I.  
          • Funding will be based upon Phase I results and may not exceed $1.5 million in total costs for a two-year period.  
          • Commercialization plan required. |
| Phase 3 | • Commercialization stage using non-STTR/SBIR funds to pursue Phase I and II goals. |