

ADVANCING

Small Business Innovation



NCATS works to transform the translational science process so that new prevention, detection and treatment technologies can be delivered sooner to people who need them. Through its **Small Business Innovation Research (SBIR)** and **Small Business Technology Transfer (STTR)** programs, NCATS fosters small business participation in research and development (R&D) as well as private-sector technology commercialization. These programs are engines of innovation, offering grants, contracts and technical assistance to small businesses and research organizations.

SBIR & STTR Programs

support entrepreneurial researchers as they engage in R&D and seek to commercialize new products that will have public benefit

SBIR

Small Business Innovation Research supports early-stage R&D projects at small businesses Small Business

Technology Transfer helps small businesses formally collaborate with a research institution in Phase I and Phase II

SBIR & STTR Benefits

One of the **largest sources of stable and predictable funding** for early-stage life sciences

IP rights are retained by the small business

Non-dilutive capital, not a loan

Projects undergo rigorous peer review, which awardees leverage to attract other funding and collaborations

SBIR and STTR Program Structure

Phase I

- Establish technical merit, feasibility and potential for commercialization.
- Support: May not exceed \$306,872 in total costs over six months (SBIR) or one year (STTR). With proper justification, applicants can propose more time and funding to establish the technical merit and feasibility of the project.

Phase II

- · Continue R&D efforts initiated in Phase I.
- · Requires a commercialization plan.
- Support: May not exceed \$2,045,816 in total costs over two years.

Note: Small businesses can apply for SBIR Direct to Phase II if they have performed Phase I research using other funding. Extended research periods and higher funding limits may be available for approved waiver topics.



Apply for Fast Track consideration by submitting one application for Phase I and Phase II for a combined application review.

Phase III

 Uses non-STTR/SBIR funds to pursue Phase I and II goals in the commercialization stage.

Funding Types

Omnibus Grant Solicitation Applications due January 5,

April 5 and September 5

Contracts

Applications typically due in October/November

Grants in Targeted AreasApplication deadlines vary

Direct to Phase IIApplication deadlines vary

Eligibility Requirements

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 primary employment of the principal investigator (PI) must be with the small business. However, if multiple PIs are applying for funding, the second PI need not be primarily employed by the small business.

To be eligible for the SBIR program:

- The small business must be an organized for-profit U.S. business.
- The small business must be an individual proprietorship, partnership, limited liability company, corporation, joint venture, association, trust or cooperative, except when the structure is a joint venture, there must be less than 50% participation by foreign business entities in the joint venture:
 - i. The small business must be more than 50% directly owned and controlled by one or more individuals (who are citizens or permanent resident aliens in the United States), other business concerns (each of which is more than 50% directly owned and controlled by individuals who are citizens or permanent resident aliens of the U.S.), or any combination of these;
 - ii. SBIR only: The small business must be more than 50% 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% 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.
- The small business must have, including its affiliates, no more than 500 employees.

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:

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

Tips for Applying

- Confirm your small business meets the eligibility requirements.
- Confirm your innovative research idea aligns with NCATS' research priorities.
- Review the solicitation carefully for application requirements; contact NCATS to discuss your project idea.
- 4. **Submit your application** electronically.
- 5. Get started with the four required **registrations**:
 - 1. <u>SAM.gov/Unique Entity</u> <u>Identifier</u>
 - 2. Grants.gov
 - 3. eRA Commons
 - 4. SBA Registry

Online Resources

Small Business Opportunities ncats.nih.gov/smallbusiness

Research Priorities ncats.nih.gov/smallbusiness/ priorities

Current Funding Opportunities ncats.nih.gov/smallbusiness/funding/open

Have Questions? Need Help?

Schedule a one-on-one meeting to discuss a project idea. Email NCATS-SBIRSTTR@mail.nih.gov to get started.