Small Business Innovation Research and Small Business Technology Transfer Programs

NIH is required by statute to reserve a portion of its annual extramural budget for projects under the SBIR and STTR programs. These programs primarily are intended to encourage private-sector commercialization of technology and to increase small business participation in federally funded R&D.

Both the SBIR and STTR programs consist of the following three phases; however, individual projects may not be eligible for all three phases:

- *Phase I.* The objective of this phase is to establish the technical merit and feasibility of proposed research or R&D efforts and to determine the quality of performance of the applicant (small business concern or SBC) before providing further Federal support in Phase II.

- *Phase II.* The objective of this phase is to continue the research or R&D efforts initiated in Phase I. Funding will be based on the results of Phase I and the scientific and technical merit and commercial potential of the Phase II application. Only Phase I grantees are eligible to receive Phase II funding. Unless submitted as a Fast-Track application (see below), Phase II applications may be submitted only after the Phase I award is made. NIH expects non Fast-Track Phase II applications to be submitted within the first six receipt dates following expiration of the Phase I budget period, i.e., normally 2 years beyond the expiration date of the Phase I award.

- *Phase III.* The objective of this phase, where appropriate, is for the SBC to pursue, with non-Federal funds, the commercialization of the results of the research or R&D funded in Phases I and II.

There are two major differences between the SBIR and STTR programs:

- The STTR program requires that the SBC formally partner with a single, non-profit research institution in the collaborative conduct of a project that has potential for commercialization. To be eligible for an STTR award, at least 40 percent of the research must be performed by the SBC and at least 30 percent of the research must be performed by a domestic non-profit research institution through a formal, cooperative arrangement. Such organizations include universities, non-profit hospitals, and other non-profit research organizations as well as Federally Funded Research and Development Centers. (The same requirement applies to Phase I and to Phase II.) STTR grants are awarded to the SBC, which will receive all of the funding for the project and disperse the appropriate funding to the research institution. The SBIR program does not have this requirement; therefore, the SBC may conduct the entire SBIR project without outside collaboration.

- The SBIR program requires that the primary employment of the PI (greater than 50 percent of the individual's time) be with the SBC at the time of award and during the conduct of the project. The STTR program does not have this requirement, i.e., the PI may have his or her primary employment with an organization other than the SBC, including the collaborating research institution. However, there must be an official relationship between the PI and the SBC. As an eligibility criterion, NIH also requires the PI to devote at least 10 percent of his or her time to the STTR project.

The NIH Fast-Track application process expedites award decisions and funding of SBIR and STTR Phase II applications for scientifically meritorious projects that have a high potential for commercialization. The Fast-Track process allows Phase I and Phase II grant applications to be submitted and reviewed together. Typically, Fast-Track applications will receive a single rating. NIH determines whether to allow SBCs to use the Fast-Track review option. Therefore, before submitting applications for Fast-Track review, applicants are strongly encouraged to consult

with cognizant NIH program staff. SBIR/STTR Phase I and Phase II applications submitted concurrently without prior consultation with NIH may be redirected for review under NIH's normal review procedures. For additional information on the submission of Fast-Track applications, see the SBIR/STTR program solicitations and instructions at http://grants.nih.gov/grants/funding/sbir.htm.

Eligibility

Qualification as a Small Business Concern

Each organization receiving a grant under the SBIR/STTR programs must qualify as a U.S.-owned SBC—an entity that, at the time of the Phase I and Phase II awards, meets all of the following criteria:

- The entity is organized for profit, with a place of business located in the United States, which operates primarily within the United States, or which makes a significant contribution to the U.S. economy through payment of taxes or use of American products, materials or labor.

- It is in the legal form of an individual proprietorship, partnership, limited liability company, corporation, joint venture, association, trust, or cooperative. If the entity is a joint venture, there can be no more than 49 percent participation by foreign business entities.

- As provided by the express terms of 13 CFR 121.702(a), it is at least 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States. In the case of a joint venture, each party to the venture must be 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States. Under these regulations, corporations or artificial entities cannot quality as individuals who are U.S. citizens. Further, indirect ownership of the entity by a U.S. citizen does not satisfy the requirements of 13 CFR 121.702(a).

  - *Example 1.* An entity applying for an SBIR/STTR grant is 100 percent owned by Company A. Company A is 100 percent owned by U.S. citizens. The entity is not eligible for support under the SBIR/STTR program because it is not 51 percent directly owned and controlled by citizens of, or permanent resident aliens in, the United States.

  - *Example 2.* An entity applying for an SBIR/STTR grant is 51 percent owned by U.S. citizens of and permanent resident aliens in the United States and 49 percent owned by a corporation. The entity is eligible for support under the SBIR/STTR program, assuming it meets the other eligibility criteria (e.g., size), because 51 percent of the ownership rests directly with U.S. citizens and permanent resident aliens of the United States.

- The entity, including its affiliates, cannot have more than 500 employees. In accordance with 13 CFR Part 121.103, affiliation exists when, either directly or indirectly, (1) one concern controls or has the power to control the other, or (2) a third party or parties controls or has the power to control both. One of the circumstances that would lead to a finding that an organization is controlling or has the power to control another organization involves sharing common office space, employees, and/or other facilities (e.g., laboratory space). The research and analytical work performed by the grantee organization under an SBIR/STTR award is to be conducted in research space occupied by, available to, and under the control of, the grantee. However, when required by the project activity, access to special facilities or equipment in another organization is permitted, as in cases where the SBIR grantee has entered into a consortium arrangement with another organization for a specific, limited portion of the research project. See 13 CFR 121.3-2(a) and 13 CFR 121.3-2(t) for additional information concerning this criterion.

All appropriate factors will be considered in determining whether an entity qualifies as an SBC, including common ownership, common management, and contractual relationships.

Place of Performance

For both Phase I and Phase II SBIR/STTR awards, the research or R&D project activity must be performed in its entirety in the United States. (The United States is defined as the 50 States, the territories and possessions of the United States, the Commonwealth of Puerto Rico, the Federated States of Micronesia, the Republic of Palau, the Republic of the Marshall Islands, and the District of Columbia.)

In those rare instances where the study design requires use of a foreign site (e.g., to conduct testing of specific patient populations), the investigator must thoroughly justify in the application the need for use of a foreign site. Similarly, in those rare instances where it may be necessary to purchase materials from other countries, investigators must thoroughly justify the request. NIH will consider these instances on a case-by-case basis, and they should be discussed with cognizant NIH staff before submitting an application. Whether the request is approved or disapproved, it will be explicitly addressed in the NGA if an award is made. Whenever possible, work outside the United States, which is necessary to the completion of the project, should be supported by funding other than SBIR/STTR grants.

Minimum Level of Effort

Generally, under SBIR Phase I awards, a minimum of two-thirds or 67 percent of the research or analytical effort must be carried out by the SBC. In addition, payments, in the aggregate, to consultants, consortium participants and contractors for portions of the scientific/technical effort generally may not exceed 33 percent of the total requested amount.

Generally under SBIR Phase II awards a minimum of one-half or 50 percent of the research or analytical effort must be carried out by the SBC. In addition, payments, in the aggregate, to consultants, consortium participants, and contractors for portions of the scientific/technical effort generally may not exceed 50 percent of the total requested amount.

For STTR awards (both Phase I and Phase II), at least 40 percent of the work is to be performed by the SBC and at least 30 percent of the work is to be performed by the single, non-profit research institution. The basis for determining the percentage of work to be performed by each of the cooperating parties is the total of direct and F&A costs attributable to each party, unless otherwise described and justified in the “Contractual Arrangements” portion of the “Research Plan” section of the grant application.

Public Policy Requirements and Objectives

The requirements concerning disclosure of financial conflicts of interest (see “Public Policy Requirements and Objectives—Ethical and Safe Conduct in Science and Organizational Operations—Financial Conflict of Interest”) do not apply to applications or awards under Phase I of the SBIR/STTR programs.

Allowable Costs and Fee

Profit or Fee

A reasonable profit or fee may be paid to a SBC receiving an award under Phase I or Phase II of the SBIR and STTR programs. The profit or fee is not considered a “cost” for purposes of determining allowable use, program income accountability, or audit thresholds. The profit or fee may be used by the SBC for any purpose, including additional effort under the SBIR/STTR

award. It is intended to provide a reasonable profit consistent with normal profit margins for for-profit organizations for R&D work; however, the amount of the profit or fee normally will not exceed seven (7) percent of total costs (direct and F&A) for each phase of the project. The profit or fee should be drawn from PMS in increments proportional to the drawdown of funds for direct and F&A costs. The profit or fee applies solely to the SBC receiving the SBIR/STTR award and not to any other participant; however, in accordance with normal commercial practice, the SBC may pay a profit or fee to a contractor providing routine goods or services to the SBC under the grant.

Facilities and Administrative Costs (Indirect Costs)

Phase I

If the applicant SBC has a currently effective indirect cost rate(s)[18] with a Federal agency, such rate(s) should be used when calculating proposed F&A costs for an NIH application. (However, the rates(s) must be adjusted for IR&D expenses, which are not allowable under HHS awards.) If the applicant SBC does not have a currently effective negotiated indirect cost rate with a Federal agency, the applicant should propose estimated F&A costs at a rate not to exceed 40 percent of the total direct costs. However, SBCs are reminded that only actual F&A costs are to be charged to projects. (If awarded at a rate of 40 percent or less, the rate used to charge actual F&A costs to projects cannot exceed the awarded rate unless the SBC negotiates an indirect cost rate(s) with a Federal agency.) NIH will not negotiate indirect cost rates for Phase I awards.

Phase II

If the applicant SBC has a currently effective negotiated indirect cost rate(s) with a Federal agency, such rate(s) should be used when calculating proposed F&A costs for an NIH application. (However, the rates(s) must be adjusted for IR&D expenses, which are not allowable under HHS awards.) If the applicant SBC does not have a currently effective negotiated indirect cost rate with a Federal agency, the applicant should propose an estimated F&A rate in the application. If the requested F&A cost rate is 25 percent of total direct costs or less, no further justification is required at the time of award, and F&A costs will be awarded at the requested rate. However, SBCs are reminded that only actual F&A costs may be charged to projects. If awarded at a rate of 25 percent or less of total direct costs, the rate used to charge actual F&A costs to projects cannot exceed the awarded rate unless the SBC negotiates an indirect cost rate(s) with DFAS. DFAS—the office authorized to negotiate indirect cost rates with SBC's receiving NIH SBIR/STTR awards—will negotiate indirect cost rates for SBCs receiving Phase II awards that requested a rate greater than 25 percent of total direct costs.

Upon request, the applicant SBC should provide DFAS with an indirect cost proposal and supporting financial data for its most recently completed fiscal year. If financial data is not available for the most recently completed fiscal year, the applicant should submit a proposal showing estimated rates with supporting documentation. Further information about DFAS is available at its website or by telephone (see Part III of the NIHGPS).

Administrative Requirements

Market Research

NIH will not support market research, including studies of the literature that lead to a new or expanded statement of work, under the grant. For purposes of the SBIR/STTR programs, "market research" is the systematic gathering, editing, recording, computing, and analyzing of data about problems relating to the sale and distribution of the subject of the proposed research. It includes various types of research, such as the size of potential markets and potential sales volume, the identification of consumers most apt to purchase the products, and the advertising media most likely to stimulate their purchases. However, "market research" does not include activities under a research plan or protocol that include a survey of the public as part of the objectives of the project to determine the impact of the subject of the research on the behavior of individuals.

Intellectual Property

Rights to data, including software developed under the terms of any funding agreement resulting from an NIH award, shall remain with the grantee except that any such copyrighted material shall be subject to a royalty-free, nonexclusive and irrevocable license to the Federal government to reproduce, publish or otherwise use the material, and to authorize others to do so for Federal purposes. In addition, under the SBIR/STTR programs, in contrast to awards to for-profit organizations under other support mechanisms, such data shall not be released outside the Federal government without the grantee's permission for a period of 4 years from completion of the project under which the data were generated.

The STTR program requires that the small business grantee and the single, non-profit research institution execute an agreement allocating between the parties intellectual property rights and rights, if any, to carry out follow-on research, development, or commercialization of the subject research. (A model agreement, entitled "Allocation of Rights in Intellectual Property and Rights to Carry Out Follow-On Research, Development, or Commercialization," is available at the NIH website at http://grants.nih.gov/grants/funding/sbir.htm.) By signing the face page of the grant application, the SBC's AOO certifies that the agreement with the research institution will be effective at the time the grant award is made. A copy of the agreement must be furnished upon request to the NIH awarding office.

SBIR/STTR grantees are covered by 37 CFR 401 with respect to inventions and patents (see "Grants to For-Profit Organizations—Administrative Requirements—Intellectual Property" in this section).

Data Sharing

Applicants for SBIR Phase II funding of $500,000 or more of direct costs in any single year must comply with the NIH policy on data sharing as modified by the Small Business Act. If the final data would not be amenable to sharing, e.g., proprietary data, the SBC should explain that in the application. In addition, as indicated under "Intellectual Property" in this subsection, whether or not the award meets the threshold for data sharing, NIH will not release data outside the Federal government without the grantee's permission for a period of 4 years from completion of the project under which the data were generated. The entire policy may be found at http://grants.nih.gov/grants/policy/data_sharing.