Guide for Reviewers for 1R44 SBIR Direct Phase II Applications — Small Business Innovation Research (SBIR) Awards

Background

Section 5106 of the SBIR/STTR Reauthorization Act of 2011 authorized that NIH may ‘issue a Phase II award to a small business concern that did not receive a Phase I award for that research/research & development’. This ‘phase flexibility’ is called a ‘Direct-to-Phase II’ SBIR award. The original authority for this provision had expired on 9/30/2017. Recent legislation P.L. 115-232 re-instated this SBIR Direct Phase II provision through Fiscal Year 2022.

As such, NIH re-implemented the SBIR Direct-to-Phase II program. The prior program had specific SBIR Direct-to-Phase II funding opportunity announcements (FOAs). The transition to FORMS-E earlier this year now allows NIH to track SBIR Direct-to-Phase II applications at the Application level, as there is a new check-box on the SBIR/STTR Information Form for “Direct Phase II”. As a result of this, NIH does not need to issue separate SBIR Direct-to-Phase II FOAs as before, but can offer Direct-to-Phase II as an allowable Application Type on any SBIR FOA. SBIR Direct-to-Phase II applications are ‘New’ submissions and are not Renewals.

This authority permits SBCs to submit Direct-to-Phase-II SBIR applications, if the small business had performed the Phase I stage-type of research through other funding sources. The legislative rationale for permitting the Direct-to-Phase II award is to allow a SBC that has already built a technology prototype and tested its feasibility (i.e. completed Phase-I- type R&D) to move directly into a Phase-II-type R&D that tests the functional viability of the prototype according to scientific methods and potential for commercial development. The Direct-to-Phase-II SBIR mechanism eliminates the need for the SBCs to propose additional small feasibility studies, if the technology is ready for the Phase II stage of development.

The SBIR Direct-to-Phase II authority is not available to the STTR program and not available for the CDC and FDA SBIR programs.
Mechanics

SBIR Direct Phase II applications can be submitted to any SBIR FOA that allows the Direct Phase II Application Type, including the Omnibus SBIR FOAs. SBIR Direct Phase II applications will have a grant code ‘1 R44 IC123456-01’ which is identical to a Fast-track designation. The only way to tell a Direct Phase II is that “Direct Phase II” is checked on the SBIR/STTR Information Form.

A SBIR Direct Phase II is nearly identical to a regular Phase II with a few exceptions. Since there is no Phase I award prior, but applicants must have done the Phase I-equivalent work on their own, applicants must describe their Phase I-like work, similar to a Phase I progress report, in their application.

Direct Phase II applicants are given the following additional instructions:

**PHS 398 Research Plan**

All instructions in the SF424 (R&R) SBIR/STTR Application Guide must be followed, with the following additional instructions:

3. Approach - Research Strategy

**SBIR Direct Phase II (if this is an allowable application type):** Summarize the specific aims of the preliminary work that forms the basis for this Phase II application, quantitative milestones (i.e., a quantitative definition of success) for each aim, and the importance of the findings. Additionally, emphasize the progress made toward each aim’s achievement. Describe the technology developed, its intended use, and who will use it. Provide data or evidence of the capability, completeness of design, and efficacy, along with the rationale for selection of the criteria used to validate the technology, prototype, or method. Describe the current status of the product (e.g., under development, commercialized, in use, discontinued). If applicable, describe the status of FDA approval for your product, process, or service (e.g., continuing pre-IND studies, filed on IND, in Phase I (or II or III) clinical trials, applied for approval, review ongoing, approved, not approved). List the generic and/or commercial names of products. A list of publications, patents, and other printed materials should be included in Item 5 (Progress Report Publication List) – do not include that information here.
**Review**

Direct to Phase II SBIR applications will be reviewed in CSR SBIR/STTR study sections. Direct to Phase II SBIR applications should be reviewed with regular Phase IIs. Applicants must provide a separate Commercialization Plan as this is a Phase II.

The SBIR Direct to Phase II review criteria are nearly identical to the regular Phase II review criteria:

How well did the applicant demonstrate feasibility of the methodology or technology equivalent to meeting **Phase I (level)** objectives, and providing a solid foundation for the proposed Phase II activity?

These applications should be treated by-and-large like regular Phase II applications.