# NCI Guidance for Administrative Supplements for SBIR/STTR Workforce Enhancement to Accelerate the Commercialization of Novel Cancer-Related Innovations

Title: Requests for an NCI SBIR/STTR administrative supplement under the Recovery Act must address the requirements stated in the documents below:

Announcement Number: NOT-09-056 NIH guidance on preparing an administrative supplement request under the Recovery Act.

The document below (information that follows below), which lists important additional items which must be included in all NCI SBIR/STTR administrative supplement requests.. Please see <a href="NCI General Guidance for ARRA Funded Administrative Supplements">NCI General Guidance for ARRA Funded Administrative Supplements</a> for submission instructions.

## **Program Overview**

NCI SBIR/STTR Phase II awardees are encouraged to apply for administrative supplements that will meet the goals of the American Recovery and Reinvestment Act (ARRA) by specifically targeting job creation and accelerating the commercialization of novel cancer products currently being developed under NCI SBIR/STTR Phase II awards. Applicants are strongly encouraged to hire individuals that have been most impacted by the economic recession.

#### **Funds Available**

The NCI will commit up to \$10 million in fiscal year 2009 to fund awards under this program.

## **Eligibility**

- Applicants may receive a maximum of ONE supplement per small business concern (SBC) from one of two active NCI ARRA SBIR/STTR supplement programs. The current program (described herein) is for administrative supplements, which may NOT be used to expand the scope of a project. The other program is for NCI ARRA Competing Revision Supplements, which may be used to expand the scope of a project (e.g., by adding one specific aim). An SBC seeking a supplement to an active NCI Phase II award may apply to only one of these two supplement programs (i.e., only one application per SBC is allowed).
- Active NCI SBIR and STTR Phase II grants in all scientific areas are eligible for supplements administrative supplements to SBIR and STTR Phase I grants will not be considered

# **Receipt Date**

• Applications must be submitted electronically no later than **June 30, 2009**, and can be submitted on a rolling basis starting immediately

### **Budgets and Project Periods**

• Applicants may propose budgets up to \$200K (total costs) per year for 1-2 years (\$400K maximum)

- Eligible costs include salary, fringe, and indirect costs for new FTEs (i.e., personnel costs only). Requests in cost categories other than personnel will not be considered
- Individual supplements should support 50-100% effort for 1-3 FTEs
  - o Supplements can be used to convert employees from part-time to full-time
- Competitive preference and funding priority will be given to supplements that support a minimum of 50% effort for at least one FTE for at least one year
- The duration of the supplement must not exceed the existing project period of the parent Phase II award

# **Application Review**

- Administrative supplement requests will not undergo peer review. They will be reviewed for technical and commercialization content by program staff from the NCI SBIR Development Center with expertise relevant to the supplement request (including the Program Director assigned to the parent grant). Requests will undergo administrative review by grants management staff from the NCI Office of Grants Administration (including the Grants Management Specialist assigned to the parent grant)
- Specific review criteria will include the following:
  - o Qualifications, experience, and expertise of the proposed new personnel
  - o Demonstration that the new FTE(s) will help to accelerate the commercialization of a product or service for the characterization, diagnosis, treatment, or prevention of cancer
  - o Clarity of the revised timeline for completing the original research plan, which shows how new personnel will accelerate activities and commercialization
  - Overall quality of the updated commercialization plan, which effectively addresses key milestones and challenges in bringing a product or service to the marketplace
- All applicants will receive within 6-8 weeks of application submission a brief written response from NCI staff describing the outcome of the review

# **Selection Factors (Funding Criteria)**

Among the overarching goals of the ARRA are to preserve and create jobs and promote economic recovery, as well as provide investments to increase economic efficiency by spurring technological advances in science and health. As such, applications will be critically evaluated based on the applicant's **overall plan** to accomplish the following:

- To accelerate commercialization of the technology in order to achieve a significant benefit for cancer patients, physicians and/or researchers
- To effectively leverage this one-time supplement by establishing critical strategic partnerships and/or securing third-party investments (i.e., non-federal funding) that will be necessary to achieve long-term commercialization goals

Supplements that propose to hire individuals from minority and disadvantaged populations will be viewed favorably

#### **Award Date**

Awards will be made by September 30, 2009

## **Preparing an Administrative Supplement Request**

In addition to the forms and documents requested in the NIH notice (NOT-OD-09-056), the NCI SBIR/STTR Program requests the following additional information be e-mailed to the NCI Points of contact:

- 1) An updated Commercialization plan (not to exceed 10 pages) that addresses the following questions:
  - Has the applicant SBC identified a realistic market niche for their product/technology which addresses an unmet need?
  - Is the value proposition compelling and does the discussion clearly demonstrate a market-pull?
  - Has the applicant identified market-based milestones that are expected to be achieved over the next five years?
  - Does the applicant SBC demonstrate an understanding of the competitive environment and the market in which they plan to sell their product?
  - Does the SBC have a plan for establishing critical strategic partnerships that will be necessary to achieve long-term commercialization goals?
  - Have the customers been identified?
  - Has the company addressed potential hurdles that may delay or prevent acceptance of their product?
  - If appropriate, are the applicant SBC's plans for generating a revenue stream reasonable, and are the revenue projections realistic?
  - How strong is the applicant SBC's intellectual property (IP) portfolio/position (pertinent to the proposed project)?
  - Does the company have a reasonable strategy to protect its IP and build a sustainable business?
  - Does the team have a track record in successfully commercializing technology in this area?
- 2) A fundraising plan (to be included within the commercialization plan) that addresses the applicant's **current** or **future** plans for raising additional third party funds (separate from SBIR/STTR funds) to move the project towards commercialization. This plan is expected to include the following information:
  - A summary of any third-party funding raised to date
  - A specific plan or strategy for securing substantial, independent third-party investor funds
  - The **type(s)** of independent third-party investor funds (i.e., cash, convertible debt, etc.) that will be secured
  - The **source(s)** of independent third-party investor funds (e.g., strategic partners, angel investors, venture capital, state funds) that will be secured

- The **anticipated timing or schedule** for receiving independent third-party investor funds
- 3) A summary of all Previous Phase I and Phase II SBIR/STTR awards received from any Federal agency within the last 5 years **AND** a summary of products or services commercialized as a result of previous SBIR/STTR funding.

# **NCI SBIR Development Center Points of Contact**

Dr. Greg Evans: <a href="mailto:evansgl@mail.nih.gov">evansgl@mail.nih.gov</a>
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The NCI SBIR Development Center staff can be reached by telephone at 301-594-7709.