DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

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To: Office of Management and Budget (OMB)

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DHHS Report Clearance Officer

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Office of Extramural Programs (OEP)/Office of Extramural Research (OER)/ Office of the Director (OD)/National Institutes of Health (NIH)

Subject: **Change Request to a Currently Approved Form (OMB # 0925-0002, Expiration date 08/31/2015) for "Tracking of SBIR and STTR Commercialization Assistance Program (CAP) Participants"**

In August, 2012 NIH received approval of post-award forms in OMB Collection 0925-0002, modifying the NIH SBIR and STTR Phase II Final Progress Report (RFPR) among other forms that are part of the NIH-wide Research Performance Progress Report (RPPR). The NIH SBIR/STTR Office proposes non-substantive changes to the questions asked in the SBIR/ STTR RFPR in order to follow commercialization progress of SBIR and STTR Phase II awardees that participate in the NIH Commercialization Assistance Program (CAP). Specifically, NIH proposes to conduct a tracking effort of SBIR and STTR CAP participants under the OMB Control Number. This tracking effort will gather feedback from CAP participants about their commercialization activities and progress for eighteen (18) months after the conclusion of the program in order to comply with new statutory requirements for agencies to collect and report on commercialization outcomes of SBIR and STTR awardees.

Use of the Information Collected

Information from the tracking effort will be evaluated and analyzed internally by the NIH SBIR/STTR Office, which in turn will provide the data to the Small Business Administration per new congressionally mandated requirement. Depending on the results, the information gleaned from the data may be used to help us improve and refine our funding strategy and potentially refocus our CAP services that are used to accomplish the NIH mission as related to the SBIR and STTR mandates to support commercialization of high-risk, innovative technologies. This tracking effort will be used to enable the NIH SBIR/STTR Programs to be responsive to the expectations of its stakeholders, which include the US taxpayers, the small business community and US Congress.

Background

The mission of the National Institutes of Health (NIH) is to improve human health through biomedical and behavioral research. The NIH SBIR and STTR Programs implement this mission by supporting U.S. small businesses that conduct innovative, early-stage life sciences research and development in their own laboratories and facilities, with the intention of developing or improving lifesaving technology solutions that have a viable commercial potential. Supporting innovation toward ultimate commercialization of innovative technologies is one of four congressionally mandated goals for the SBIR and STTR Programs. Public Law (P.L.) 112-81 authorizes the SBIR and STTR administering agencies like the NIH to provide business technical assistance programs to its awardees; the Commercialization Assistance Program is one of them and delivers specialized services to Phase II SBIR and STTR awardees. The overarching goal of the program is to leverage NIH's initial investment through grants and contracts intended to bring innovative technologies closer to a commercializable and market ready technology development stage. Furthermore, the most recent re-authorization of the Programs enacted by P.L. 112-81 gives SBIR and STTR programs the directive to request information from awardees about their commercialization progress. To this end, the SBIR and STTR Office proposes to conduct a tracking effort of all small business awardees that participated in the Commercialization Assistance Program, in this case seeking feedback about commercialization activities and progress over a period of 18 months since completing the CAP.

OER/OD/NIH exercises overall oversight for the policies and procedures governing the award of extramural program financial support. This represents more than 80% of the total NIH budget ($31 billion in FY 2013) to the extramural scientific community and academic research institutions through a variety of mechanisms including the SBIR and STTR grants and contracts awarded to the U.S. small business community, representing 3% of the extramural budget. The goal of the SBIR/STTR programs is to encourage promising early-stage life sciences small business to pursue innovation and develop important health solutions and products for the benefit of the general public. Frequently, early-stage life science companies lack the necessary financial and human resources to be able to organically develop untested, high-risk ideas and inventions. Therefore, the funding and technical assistance provided under the SBIR and STTR programs provides these small business and entrepreneurs with critical support and de-risking platform that can help them survive and thrive in a very competitive environment. Specifically, by training and mentoring US small businesses on how to develop sound business practices and strategies through the CAP, the NIH further supports its biomedical mission, and simultaneously enables these firms to turn innovative ideas into tangible products and services while becoming self-sustaining and profitable businesses.

Plan

NIH proposes to modify the approved SBIR and STTR Phase II Final Progress Report (FPR) by changing the title and question format in order to seek input from the SBIR or STTR small business participants in the CAP. For this change request, we would like to seek approval to use the subject tracking forms for up to 100 SBIR/STTR participants in the CAP programs because we anticipate the number of participants to fluctuate from year to year. For the 2013 CAP, we plan to contact all 68 program participants who are the representatives for the SBIR or STTR awarded small business selected for the CAP. It is also important to note, that the CAP is comprised of two distinct tracks, which customize the type of business assistance delivered based on the level of maturity and business experience of the participating small business. Therefore,

the participants go through either the Accelerated Commercialization Track (ACT) or the Commercialization Training Track (CTT). However, NIH is interested in the same commercialization outcomes information for all CAP participants irrespective of the track they were in. Accordingly, please see Attachments A and B for the tracking forms for each track, which are identical except for the titles specifying the program track.

Regarding the change request to the approved SBIR and STTR Phase II FPR, the information sought through the new CAP tracking forms is not different in its intent and is directly related to the objectives and reasons why the FPR asks for example, sources of funding, or information about sales and revenues.

We plan to initially email these participants with a request to complete a tracking form at the conclusion of the CAP, thus establishing a baseline for the commercialization outcomes data. Then we plan to contact these same individuals with the same forms nine (9) months later to provide us with an update on their commercialization activities, and finally contact these same individuals again nine (9) months later for a final update on their commercialization progress. These two nine-month intervals will complete the proposed 18-month tracking period since the conclusion of the CAP.

The email will provide an overview and goals of the tracking effort. We will include straightforward instructions for filling-out the tracking form, as well as the OMB clearance number. NIH SBIR/ STTR office staff will be receiving and reviewing all responses electronically. Individuals who do not complete the tracking form within two weeks of the invitation email will be sent a reminder email. These individuals will then have another week to complete the tracking form and submit to NIH.

Participation in the tracking effort is voluntary. All participant-identifying information from the forms will be kept private to the extent allowed by law. All electronic information will be kept on secure NIH servers and hard copy information will be kept in locked cabinets in locked facilities.

Estimates of Annualized Hour Burden and Cost					
Time Period	Number of Respondents	Frequency of Response	Average Time Per Response (Hours)	Annual Hour Burden	Cost
Baseline	100	1	20/60	33	0
9 month Follow-up	100	1	10/60	17	0
18 month Follow-up	100	1	10/60	17	0
Total				67	

Thank you for your consideration of this study proposal.