

Supporting Statement A for

Title of Study: Application to be Accepted in the National Institutes of Health (NIH) Technical Assistance

Programs: Commercialization Accelerator Program (CAP)

Date: September 5, 2017

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Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Program Office

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Check off which applies:

- New
- Revision
- Reinstatement with Change
- Reinstatement without Change
- Extension
- Emergency

X Existing without OMB approval

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A. Justification

The National Institutes of Health (NIH) Commercialization Accelerator Program (CAP) has been offered annually since 2004 (previously known as the Commercialization Assistance Program), and is designed to help some of the agency's most promising small life science and healthcare Phase II awardees develop their commercial businesses and transition their SBIR/STTR-funded technologies into the marketplace. Applicants are selected via a competitive process for a limited number of slots in the program. Funded by NIH and managed through a contract, the CAP provides selected participants with individualized assistance toward accomplishing key commercialization goals. This is achieved through individual mentoring and consulting sessions, training workshops, access to domain experts, and focus on outcomes that will enhance the commercialization profile and readiness of participating awardees.

A.1 Circumstances Making the Collection of Information Necessary

The Small Business Innovation Research Program, codified at §9 of the Small Business Act, 15 U.S.C. §638, and extended through 2022, congressionally-mandates the SBIR and STTR Programs across federal agencies. These programs are implemented as part of the NIH's mission by supporting U.S. small businesses that conduct early-stage life sciences research, with the intention of developing lifesaving technology with commercial potential. The Commercialization Accelerator Program (CAP) is a three-track customized technical assistance program, conducted virtually and in-person as appropriate, and designed to serve the needs of up to 80 HHS/NIH SBIR/STTR Phase II awardees at different levels of commercialization experience and expertise.

This application will gather information from small businesses funded under Phase II NIH SBIR/STTR awards that want to participate in the NIH CAP. [See Attachment 1, Application]

A.2 Purpose and Use of the Information Collection

Information gathered will be used internally by the NIH SBIR/STTR staff to identify and select small businesses that would most benefit if selected as participants in the NIH Commercialization Accelerator Program (CAP) for 3 years. The data will not be used to formulate or change policies. Rather, it will be used to enable NIH SBIR/STTR staff to be responsive to its constituents by offering commercialization training to meet the goals of the Phase II small business NIH awardees. The form will be online for any potential CAP applicant companies and completed electronically.

A.3 Use of Information Technology and Burden Reduction

The application form will be administered through an Internet link to the NIH CAP contractor's website. The link will be available to interested companies via the NIH SBIR/STTR main website (<http://sbir.nih.gov>) and will include a webinar about CAP. The webinar will provide an overview and goals of the NIH Commercialization Accelerator Program (CAP), and will request interested parties to complete the application. The application provides straightforward instructions for filling-out the application form. NIH SBIR/STTR staff will be receiving and reviewing all applications. Using electronic application forms is less time intensive and burdensome than for NIH to mail paper forms and encourage the small business to mail them back. [See Attachment 3, PIA]

A.4 Efforts to Identify Duplication and Use of Similar Information

The NIH SBIR/STTR Office manages the Commercialization Accelerator Program and will be the only program to collect this data. The program managers will ensure that duplicative assessments are not conducted.

A.5 Impact on Small Businesses or Other Small Entities

This form will be available online to any small businesses that have received HHS/NIH Phase II SBIR awards and wish to be considered as a participant in the NIH CAP. Only small business seeking to be included in the CAP will access the form.

A.6 Consequences of Collecting the Information Less Frequently

This information has never been collected before and is essential for identifying and selecting qualified CAP participants from interested small business applicants.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This application will be implemented in a manner that fully complies with 5 C.F.R. 1320.5.

A.8.1 Comments in Response to the Federal Register Notice

The 60-day Federal Register notice was published on June 15, 2017, page 27516 (82 FR 27516). No public comments received.

A.8.2 Efforts to Consult Outside Agency

Judy Hsieh, Programs Director
Larta Institute
606 S. Olive Street, Suite 650
Los Angeles, CA 90014
Fax 213.622.6230

A.9 Explanation of Any Payment of Gift to Respondents

No gifts will be provided for participation.

A.10 Assurance of Confidentiality Provided to Respondents

All information will be private to the extent permitted by law. Although Personally Identifiable Information (PII) will be collected, the Privacy Act does not apply because none of the data elements will be retrieved to identify the individual. [See Attachment 2, Privacy Act Memo.]

A.11 Justification for Sensitive Questions

No sensitive information will be collected.

A.12 Estimates of Hour Burden Including Annualized Hourly Costs

Table 12-1 Estimated Annualized Burden Hours

Form Name	Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
A	SBIR Phase II Awardees	100	1	90/60	150
Total		100	100		150

A.12-2 ANNUAL COST TO RESPONDENT

Table 12-2 Annualized Cost to Respondents

Type of Respondents	Total Annual Burden Hours	Hourly Respondent Wage Rate*	Respondent Cost
Phase II Awardee	100	\$48.22	\$4,822.00
TOTAL	100		\$4,822.00

*Bureau of Labor Statistics: The General Public rate was obtained from the http://www.bls.gov/oes/2013/may/oes_nat.htm#00-0000

The Health Professionals wage rate was obtained from <http://www.bls.gov/oes/2013/may/oes290000.htm>
Occupation title "Healthcare Practitioners and Technical Occupations", occupation code 29-0000;

Health Educators wage rate was obtained from <http://www.bls.gov/oes/current/oes211091.htm>, occupation code 21-1091.

A.13 Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

None-N/A.

A.14 Annualized Cost to the Federal Government

The annualized cost to the federal government is \$27, 848.60.

Cost Descriptions	Grade/Step	Salary	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
Program Manager	GS 14-10	\$145,629	2%		\$2,912.58
Contractor Cost					
LARTA	N/A	1,246,801	2%		24,936.02
Travel					
Other Cost					
Total					\$27,848.60

A.15 Explanation for Program Changes or Adjustments

This program application is existing without approval as administrators were unaware that OMB Clearance was required.

A.16 Plans for Tabulation and Publication and Project Time Schedule

Annually and on average, the application will be made available to respondents in late July or early August and collection will end during the last business week of August. Applicants will be selected for program entry in September. The projected time between when the online application may be accessed, submitted, and respondents receive a response in no less than 60 days.

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

We are not requesting an exemption to the display of the OMB Expiration date.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

This application will comply with the requirements in 5 CFR 1320.9.