

SMALL BUSINESS SOURCES SOUGHT NOTICE

Notice Number: HHS-NIH-NCI-SBSS-TSB-07005-65

Title: RECOVERY – Sequencing for The Cancer Genome Atlas (TCGA) Program

This is a Small Business Sources Sought notice. This is **NOT** a solicitation for proposals, proposal abstracts, or quotations. The purpose of this notice is to obtain information regarding: (1) the availability and capability of qualified small business sources; (2) whether they are small businesses; HUBZone small businesses; service-disabled, veteran-owned small businesses; 8(a) small businesses; veteran-owned small businesses; woman-owned small businesses; or small disadvantaged businesses; and (3) their size classification relative to the North American Industry Classification System (NAICS) code for the proposed acquisition. Your response to the information requested will assist the Government in determining the appropriate acquisition method, including whether a set-aside is possible. **An organization that is not considered a small business under the applicable NAICS code should not submit a response to this notice.**

A determination by the Government not to compete this requirement as a set-aside based upon responses to this Notice is solely within the discretion of the Government.

Interested parties are expected to review this Notice and the **draft** *Statement of Work* to familiarize themselves with the requirements of this project; failure to do so will be at your firm's own risk.

Background:

The Cancer Genome Atlas (TCGA) is a comprehensive, collaborative effort led by the National Institutes of Health (NIH) to map the genomic changes that occur in major types and subtypes of cancer. Researchers throughout the nation are using various genome analysis technologies, including high through-put DNA sequencing, to carry out this effort.

A pilot project was initiated in 2006 established the scientific infrastructure and demonstrated the "proof of concept" needed to mount a large-scale cancer genome mapping project. Based on this success, TCGA will map genomes of at least 20 cancers over the next five years.

Purpose and Objectives:

The purpose of this Small Business Sources Sought Notice is to identify qualified small business concerns including HUBZone small businesses; service-disabled, veteran-owned small businesses; 8(a) small businesses, veteran-owned small businesses; woman-owned small businesses; or small disadvantaged businesses that are interested in and capable of performing the work described herein. The NCI does not intend to award a contract on the basis of responses received nor otherwise pay for the preparation of any information submitted.

As a result of this SBSS Notice, the NCI may issue a Request for Proposal (RFP). THERE IS NO SOLICITATION AVAILABLE AT THIS TIME. However, should such a requirement materialize, no

basis for claims against NCI shall arise as a result of a response to this Small Business Sources Sought Notice or the NCI's use of such information as either part of our evaluation process or in developing specifications for any subsequent requirement.

The purpose of this project is to perform genomic DNA sequencing and initial analysis for the comprehensive characterization of sequence from the genomes of cancer specimens and associated normal tissues in support of The Cancer Genome Atlas (TCGA) program. This project will catalog comprehensively somatic DNA changes that are associated with cancer. Under this project, the contractor shall utilize the most advanced DNA sequencing technologies and genomic analysis computational methods to investigate at least 400 and as many as 1,000 cancer cases (specific types to be identified by NCI) during the two-year base period. During the option periods, the number of cancer cases will be expanded. A case includes DNA from tumor and case-matched normal tissue. In addition, the contractor shall sequence entire exomes, deposit the sequenced data according to the TCG rapid data release policies, efficiently and accurately analyze the data to initially detect >80% of true mutations and polymorphisms and at the same time minimize the false positive discovery rate including complete analysis, and have an established and integrated bioinformatics capability sufficient to support production, including systems and database administration, laboratory information management, data handling and deposition.

Project Requirements:

The contractor shall possess the requisite personnel and facilities in order to perform genomic DNA sequencing and initial analysis for the comprehensive characterization of sequence from the genomes of cancer specimens and associated normal tissues.

1. **Sequencing** - The contractor shall possess the requisite experience and capacity to sequence entire exomes from at least ten (10) cases per month and whole genomes from at least two (2) cases per month. At contract inception, the contractor shall produce one hundred (100) gigabases alignable DNA sequence per month and generate and analyze at least two (2) whole human genome sequence data sets. Within six (6) months of contract award, the contractor shall sequence three hundred (300) gigabases of alignable DNA sequence per month and shall maintain this minimum and/or exceed this minimum throughout the entire contract period. The contractor shall deposit the sequence data according to TCGA rapid data release policies that specify primary data within one (1) week of being generated. Within the first year, the contractor shall achieve sequencing and analysis capacity to characterize comprehensively the exomes of at least twenty (20) cases per month and whole genomes of at least three (3) per month.
2. **Analysis** - The contractor shall efficiently and accurately analyze the data to initially detect >80% of true mutations and polymorphisms and at the same time minimize the false positive discovery rate. The contractor shall prioritize and validate putative mutations derived from primary analyses and shall design the analysis pipeline. The contractor shall complete the analysis, including putative variation calls, within four (4) weeks of data generation.

3. **Bioinformatics and Data Disposition** - The contractor shall use an established and integrated bioinformatics capable to support production, including systems and database administration, laboratory information management, data handling and disposition.

Anticipated Period of Performance:

The period of performance for this requirement is five (5) years, consisting of a two-year base period plus three (3) one-year options. The anticipated start date is on/or about May 1, 2010. It is anticipated that the two-year base period will be funded utilizing ARRA Funding. The option periods, if exercised will be supported by appropriated funds.

Other Important Considerations:

Draft Statement of Work:

A copy of the draft Statement of Work (SOW), which is subject to revisions, may be accessed on the NCI Office of Acquisitions Website at URL: <http://rcb.nci.nih.gov/> . Once there, click on Current Requests for Proposals.

NAICS Code and Size Standard:

In the event an RFP is issued, North American Industry Classification System (NAICS) code 541380 with a size standard of \$12.0 million dollars is being considered.

Capability Statement/Information Sought:

Sources are expected to have personnel, facilities and corporate history in performing genomic DNA sequencing and initial analysis for the comprehensive characterization of sequence from the genomes of cancer specimens and associated normal tissues in support of The Cancer Genome Atlas (TCGA) program.

Tailored Capability Statements shall demonstrate a clear understanding of all tasks specified in the draft Statement of Work (SOW). Tailored Capability Statements for this requirement shall address the following areas:

1. The organization's awareness of project needs and approach to performance in meeting the objectives of the attached draft SOW. Specifically, address the following:
 - Demonstration of meeting the Sequencing and Analysis requirements described in the draft Statement of Work.
 - Demonstration of experience in high-throughput, state-of-the art second-generation sequencing technologies and the bioinformatics approaches necessary for generation of sequence data, data analysis, data integration and data sharing.
 - Demonstration of ability to perform complete whole genome sequencing for multiple genomes.
 - Documentation of existing partnerships/relationships in the cancer genomics and high-throughput sequencing communities, demonstrating ability to work

- collaboratively and integrate data with other sources of high-throughput sequencing data.
 - Demonstration of security of system to store, update, backup, track and release data.
 - Demonstration of quality control needs and protocols used to increase reproducibility, efficiency, scalability, capacity and success rate.
 - Demonstration of experience incorporating technical advances to significantly increase production.
2. Demonstrate the ability to provide knowledgeable staff to meet the objectives of the attached draft SOW. Specifically, addressing that proposed staff have experience in the following areas:
- Demonstration of personnel experience in sequencing, genomics, informatics and data management. Description of proposed administrative structure/management necessary for successful oversight, budgetary operation and communications with other sequencing sources and NCI personnel.
 - Demonstration of providing cost effective solutions for needed sequencing and demonstrated plans for additional personnel for scaling.
 - Demonstration of training personnel for the Statement of Work tasks.
 - Demonstration of successful track-record of senior personnel in improving technology and/or methodology for state-of-the-art production level sequencing.
 - Demonstration of successful performance in and establishment of collaborative cancer genome characterization programs.
 - Demonstration of replacing key staff due to turnover.
3. Demonstration of the availability, suitability and accessibility of current facilities and equipment. Documented capability to provide cost effective sequencing efforts in quantity required, including accuracy, capacity and turnaround time. Documentation of availability and acceptability of equipment to perform the efforts under the statement of work, including robotics, computers for informatics and data management, and appropriate sample storage. Demonstrated plan to replace equipment or for maintenance and repair of equipment.
4. Demonstration of corporate capability in sequencing at this level of production. Demonstration of ability in product management experience, including ability to meet deadlines and re-assign staff. Description of the priority of this project in relation to other corporate projects.

Information Submission Instructions:

1. Page Limitations:

Interested qualified small business organizations should submit a tailored capability statement for this requirement not to exceed twenty (20) single sided pages including all attachments, resumes, charts, etc. (single spaced, 12 point font minimum) that clearly details the firm's

ability to perform the aspects of the notice described above and in the draft SOW. Tailored capability statements should also include an indication of current certified small business status; this indication should be clearly marked on the first page of your capability statement (preferable placed under the eligible small business concern's name and address) as well as the eligible small business concern's name, point of contact, address and DUNS number.

2. Number of Copies:

All capability Statement sent in response to this SMALL BUSINESS SOURCES SOUGHT notice must be submitted electronically (via e-mail) to C. Timothy Crilley, Contracting Officer, at tcrilley@mail.nih.gov in MS Word, WordPerfect or Adobe Portable Document Format (PDF). The e-mail subject line must specify HHS-NIH-NCI-SBSS-TSB-07005-65. Facsimile responses will not be accepted.

3. Common Cut-off Date:

Electronically submitted tailored capability statements are due no later than 3:00PM (Eastern Prevailing Time) on November 9, 2009. ***CAPABILITY STATEMENTS RECEIVED AFTER THIS DATE AND TIME WILL NOT BE CONSIDERED.***

DISCLAIMER AND IMPORTANT NOTES: This notice does not obligate the Government to award a contract or otherwise pay for the information provided in this response. The Government reserves the right to use information provided by respondents for any purpose deemed necessary and legally appropriate. Any organization responding to this notice should ensure that its response is complete and sufficiently detailed to allow the Government to determine the organization's qualifications to perform the work. Respondents are advised that the Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted. After a review of the responses received, a pre-solicitation synopsis and solicitation may be published in Federal Business Opportunities. However, responses to this notice will not be considered adequate responses to a solicitation.

CONFIDENTIALITY: No proprietary, classified, confidential, or sensitive information should be included in your response. The Government reserves the right to use any non-proprietary technical information in any resultant solicitation(s).