

# SMALL BUSINESS SOURCES SOUGHT NOTICE

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**Notice Number:** HHS-NIH-NCI-SBSS-TSB-07030-36

**Title: RECOVERY** – Quality Management System (QMS) 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 responses 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 initiated in 2006 focused on three tumor types (brain, ovarian, and lung), established the scientific infrastructure and demonstrated the “proof of concept” needed to mount a large-scale cancer genome mapping project. Based on the success of the pilot, TCGA announced in September 2009 that it will map the genomes of at least 20 additional cancers over the next five years.

During the pilot phase TCGA generated almost 7 terabytes of data, spanning biospecimen information, patient information, and genome, exome and epigenetic data for both tumor and

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normal specimens per patient. The ability to ensure data completeness associated with each specimen required a coordinated effort across numerous institutions and information systems. This coordination will become increasingly difficult and important as the program grows by 8 fold in the coming five years. The value of the data generated in TCGA will lie in its quality, as all subsequent analyses and research outcomes will be dependent on the quality of the information generated. The Quality Management System (QMS) will serve as the basis by which the quality and value of the TCGA data may be measured.

Key to the program will be the establishment of a process and system to ensure data completeness and quality. To facilitate expansion of the program, TCGA will focus on quality as a best management practice.

The NCI is seeking to establish a QMS congruent with the guidelines described by the Clinical and Laboratory Standards Institute (CLSI) document HS1-A2, "*A Quality Management System Model for Healthcare; Approved Guideline – Second Edition*" ([http://www.clsi.org/source/orders/index.cfm?section=Online\\_Store&task=3&CATEGORY=QM&PRODUCT\\_TYPE=SALES&SKU=HS01A2E](http://www.clsi.org/source/orders/index.cfm?section=Online_Store&task=3&CATEGORY=QM&PRODUCT_TYPE=SALES&SKU=HS01A2E)). CLSI document HS1-A2 proposes Quality Management guidelines for organizations in the medical disciplines and these guidelines are based on a common set of 12 quality elements established by ISO 9001, typically referred to as Quality System Essentials (QSE)

It is the intent of the TCGA Program office to employ a minimal QMS based on 9 of the 12 QSEs (see draft Statement of Work).

### **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, women-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 received.

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 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.

If a RFP is issued, the NCI anticipates that one (1) award may result from the issuance of the RFP.

The objective of this project is to establish a Quality Management System (QMS) across the funded activities of the TCGA program, with the goal of identifying non-conforming data in a timely fashion to ensure data released to the public is of the highest quality possible.

### **Project Requirements:**

The contractor shall possess the necessary labor, services, equipment, materials, supplies, and facilities, except as otherwise specified herein, as needed to perform the work as set forth below:

- Establish TCGA-Quality Management (QM) policies, processes and procedures in line with the program organization and goals
- Implement the QMS and train the staff within the Biospecimen Core Resources (BCR) and the Data Coordinating Center (DDC)
- Provide a means to identify, track and report non-conforming data
- Establish and implement internal audit policies, processes, and methods to verify compliance with the QMS
- Provide regular and detailed reports of the status of data quality at all stages in the TCGA workflow

### **Anticipated Period of Performance:**

The period of performance for this requirement is five (5) years, consisting of an eighteen month base period, three (3) one-year options, and one (1) six month option. The anticipated start date is on or about August 16, 2010. It is anticipated that the eighteen month base period will be funded utilizing American Recovery and Reinvestment Act 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 <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 Size Standard (NAICS) code 541990 with a size standard of \$7 million is being considered.

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## **Capability Statement/Information Sought**

Sources are expected to have the personnel, facilities, equipment, and experience to outline a strategy and propose the specifications for the development of a program-wide QMS. The proposed QMS shall meet the needs of the Quality Management Goals of the TCGA Program, as well as support the program management requirements for oversight and reporting.

Tailored capability statements shall demonstrate a clear understanding of all tasks specified in the draft Statement of Work (SOW), to include documented understanding of the nine (9) quality system elements outlined in the draft SOW and how these elements will establish the backbone of the TCGA QMS. Tailored Capability Statements for this requirement shall also address the following areas:

1. Documented understanding of laboratory workflows, the purpose and content of the Quality Manual, the structure of QMS Policy documents, the QMS IMS, and internal auditing based on the QMS.
2. Approach and documented history of leveraging an electronic information management system (IMS) to manage the quality policy documents, manage non-conforming data, and generate reports of program status and non-conforming data.
3. Demonstrated knowledge of and ability to handle biomedical laboratory data, spanning clinical information to biospecimen data, to molecular and genomic data.
4. Documented track record of senior personnel with the experience to implement an effective QMS, proven to improve quality of the output of biomedical related programs. Documented experience of senior personnel in successfully managing or serving in leadership positions on multimillion dollar, national biomedical programs on the size and magnitude of the TCGA program.
5. Documented current facilities and equipment, capability and past experience in managing a large QMS Information Management System that is employed at multiple physical locations, and informatics capacity to identify/track/report non-conforming data obtained from disparate data systems.
6. Documented experience in the development and management of a project of this magnitude. Documented history of training staff on QMS information management processes.

## **Information Submission Instructions:**

1. Page Limitations:

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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 (preferably 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. Delivery Point:

All capability statements sent in response to this Small Business Sources Sought notice must be submitted electronically (via email) to Stanley A. Knight, Contracting Officer, at [knights@mail.nih.gov](mailto:knights@mail.nih.gov) in MS Word or Adobe Portable Document Format (PDF). The email subject line must specify HHS-NIH-NCI-SBSS-TSB-07030-36. Facsimile responses will not be accepted.

3. Common Cut-Off Date:

Electronically submitted tailored capability statements are due no later than 2:00 PM (Eastern Prevailing Time) on May 7, 2010. 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 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).