

SMALL BUSINESS SOURCES SOUGHT NOTICE

Notice Number: HHS-NIH-NCI-SBSS-TSB-07009-65

Title: RECOVERY – Networks of Tissue Source Sites (TSS) Supporting NCI's 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 accelerate our understanding of the molecular basis of cancer through the application of genome analysis technologies. The National Cancer Institute (NCI) and the National Human Genome Research Institute (NHGRI) launched TCGA as a 3-year pilot. The second phase of the project is to study at least 20 additional cancers over five (5) years. This project aims to systematically explore the entire spectrum of genomic changes involved in human cancer. This project is designed to comprehensively analyze DNA copy number changes, including large and small scale rearrangements, transcription profiles, epigenetic modifications, sequence variation, and sequence in both tumor tissue and case-matched germline DNA. To successfully generate comprehensive data, TCGA will acquire in excess of 40,000 biospecimens over the course of this project.

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.

If a RFP is issued, the NCI anticipates that multiple awards may result from the issuance of the RFP.

The purpose of this project is to establish Tissue Source Site (TSS) networks capable of delivering clinically annotated biospecimens. The tissue and data shall be delivered to one of TCGA's Biospecimen Core Resource(s) (BCRs) for storage, quality control, processing into molecular analyses, and other research support efforts.

Project Requirements:

The contractor shall possess the requisite personnel and facilities for administratively and financially establishing, managing, coordinating and operating relationships with multiple TSS. Specifically, the contractor shall:

1. provide cancer biospecimens, including, but not limited to, those provided in Appendix B of this draft Statement of Work (SOW). This list is preliminary, and is subject to having cancers added or eliminated. NCI may over the course of the contract elect to approve the collection and banking of cancers not currently on the list.
2. provide biospecimens in accordance with the requirements identified in Section 2.1.3. of the draft SOW.
3. provide per-case biospecimen sets that comply with the criteria established in Section 2.1.3.1. of the draft SOW. Documentation that Institutional Review Board (IRB) has reviewed and approved participation is required.
4. comply with all data requirements outlined in Section 2.1.4. of the draft SOW.

Anticipated Period of Performance:

The period of performance for this requirement is five (5) years, consisting of an eighteen (18) month base period, plus three (3) one-year options and one six (6) month option. The anticipated start date is on/or about May 1, 2010. It is anticipated that the eighteen (18) month 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 325413 with a size standard of 500 employees is being considered.

Capability Statement/Information Sought:

Sources are expected to have personnel, facilities and corporate history in identifying and reviewing candidates for Tissue Source Site(s) (TSSs); developing accrual plans; delivering biospecimens and data, while complying with pertinent regulations, protocols, Standard Operating Procedures (SOPs) and all applicable laws.

Tailored Capability Statements shall demonstrate a clear understanding of all tasks specified in the draft Statement of Work (SOW), to include the process for proposing an existing TSS, or establishing a new TSS, as a network site for contributing biospecimens and data to TCGA and experience in identifying and acquiring both tumor and a source of germline DNA (blood or component, DNA, and/or adjacent normal tissue) samples for each case. Tailored Capability Statements for this requirement shall also address the following areas:

1. Document capabilities of Existing Tissue Source Sites (TSSs) networks:
 - Number of already established and operating TSS members;
 - Case and biospecimen number of accrual capabilities over 2 and 5 years; and
 - Previous experience of contractor setting up and/or managing sample accrual/networks.
2. Demonstrate the ability to provide retrospective biospecimens;
 - Number of cases and biospecimens available.
3. Demonstrate the ability in locating and identifying new categories/types of TSS not already providers to TCGA.
4. Demonstrate corporate capability in producing project management plans, quality management plans, and draft Accrual Plans.

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-07009-65. 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 20, 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).