

SMALL BUSINESS SOURCES SOUGHT NOTICE

Notice Number: HHS-NIH-NCI-SBSS-TSB-57019-02

Title: Clinical Proteomics Tumor Analysis Consortium (CPTAC) Biospecimen Core Resource

Introduction:

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 overall objective of the Clinical Proteomic Tumor Analysis Consortium (CPTAC) is to improve our understanding of cancer biology by conducting proteogenomic analysis on selected cancer types (*anticipated up to 10 cancer types, 200 cases each; see Tumor Types of Interest*) where unanswered questions remain about the molecular biology of the disease. This analysis will add a complementary layer of protein molecular biology that facilitates refinement of driver genes, enhances understanding of the pathogenesis through proteomic subtyping, and illuminates dynamic alterations in posttranslational modifications responsible for the dysregulation of cancer signaling networks and pathways.

Purpose and Objectives:

The purpose of this Small Business Sources Sought Notice (SBSS) 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 a single award may result from the issuance of the RFP.

The purpose of this project is to utilize a pipeline to collect, process, qualify, genomically characterize, and distribute biospecimens for CPTAC and to collect, analyze, review, store, and distribute the data associated with this research.

The project involves several components, including:

- Tissue Source Sites (TSS)
- Biospecimen Core Resource (BCR)
- Genome Characterization Center (GCC)
- Quality Management System (QMS)
- Comprehensive Data Resource (NCI-OTS CDR)
- Proteome Characterization Centers (PCC)
- Proteo-Genomic Data Analysis Centers (PGDAC)
- Proteogenomic Translational Centers (PTC)
- Data Coordinating Center (DCC)

The pipeline of these components will supply high-quality biospecimens and data to a network of Proteome Characterization Centers (PCC), Proteogenomic Translational Centers (PTC), and Proteogenomic Data Analysis Centers (PGDAC). Ultimately, the samples will be characterized for copy number variation, single nucleotide polymorphisms, DNA, RNA, and protein expression and mutation analysis. De-identified data will be made available through the CPTAC Data Coordinating Center and other NIH data resources. Overall quality for the entire project will be the responsibility of the QMS.

Tumor Types of Interest

- #1. Thoracic: Non-Small Cell Lung Carcinoma (Lung Adenocarcinoma)
- #2. Gastrointestinal: Pancreatic Ductal Adenocarcinoma (PDA)
- #3. CNS: Glioblastoma Multiforme (GBM)
- #4. Hematologic: Acute Myeloid Leukemia (AML)
- #5. Urologic: Clear Cell Renal Cell Carcinoma (ccRCC)
- #6. Head And Neck: Head And Neck Squamous Cell Carcinoma (HNSCC)
- #7. Skin: Cutaneous Melanoma
- #8. Soft Tissue: Sarcomas
- #9. Thoracic: Lung Squamous Cell Carcinoma (SQCC)
- #10. Gynecologic: Uterine Corpus Endometrial Carcinoma (UCEC)

CPTAC Biospecimen Core Resource

A major prerequisite of the CPTAC Program will be the acquisition of high quality biospecimens. To meet this need, NCI is establishing a network of Tissue Source Sites (TSS) to provide high quality, clinically annotated biospecimens for submission to a centralized quality control and processing facility. The TSSs will be procuring tumor tissue, normal tissue (when feasible) and blood (plasma and buffy coat/packed red cells) from patient volunteers suffering from breast, colon, and ovarian cancer. The BCR will be the primary interface between the CPTAC Program and the TSSs.

It must be noted that the term “high quality” refers not only to the histological and molecular properties of the tissue, but also to characteristics such as degree and quality of clinical annotation, the existence of appropriate informed consent provisions for the intended use of the biomolecules and data, collection and subsequent distribution to CPTAC participants under an Institutional Review Board (IRB) approved protocol, as well as unencumbered access for research use (e.g., intellectual property restrictions).

CPTAC project management chose to establish a centralized tissue processing model to standardize procedures such as histopathology, DNA/RNA isolation, sequencing, and other sample preparation processes. This centralization specifically means that all operations to process tissue for any single cancer studied by CPTAC occur at the BCR, utilizing SOPs. This standardization refers to the processes of biospecimen receipt, logistical and physical management, processing into analytes (the molecular extracts from tissue such as DNA and RNA), the subdivision of tissue or analytes, and dissemination to the research sites with rigorous QC of all intermediate and final products along the workflow.

The BCR will work closely with the Comprehensive Data Resource (NCI-OTS CDR), which will manage biospecimen and clinical data, including sample identifiers.

The objective of this SOW is to establish a core resource providing comprehensive logistical support for the CPTAC Program facilitating tissue sample and clinical data collection, histopathological analysis, storage, and internal dissemination. It is envisioned that the contractor will put in place a seamless pipeline for accepting clinical samples and associated data, analyzing frozen-section slides (or images) for pathological analyses, storing the samples and data, preparing DNA and RNA from the samples, distributing the tissue samples to the PCCs and the DNA/RNA to the GCC, and conveying the clinical and sample data to the NCI-OTS CDR. It is further envisioned that the BCR will employ rigorous quality control and assurance practices for all aspects of the work in collaboration with the QMS. Finally, it is envisioned the BCR shall actively engage in routine communication regarding all aspects of the work with the CPTAC leadership and the other components of CPTAC.

Project Requirements:

The Contractor shall function as a fundamental resource and play a central logistical role in the CPTAC Program. Specifically, the Contractor shall be able to perform the below task areas and all subtasks. See the attached draft Statement of Work for the subtasks under the below ten (10) task areas.

1. Coordinating the procurement of biospecimen collection and shipping from the CPTAC TSSs,
2. Coordinating clinical data procurement and transmission from the CPTAC TSSs,

3. Storing and managing the CPTAC biospecimen collection,
4. Managing and storing the CPTAC clinical data associated with the biospecimens,
5. Processing biospecimens for pathology review,
6. Processing the biospecimens for DNA and RNA,
7. Distributing biospecimens and analytes to the PCCs and GCC,
8. Coordinating with and distributing clinical and biospecimen data to the NCI-OTS CDR,
9. With the QMS, developing and implementing comprehensive quality control and assurance regimens for all aspects of the work,
10. Managing the operations of the BCR.

The Contractor shall be able to perform as a single entity all the biospecimen and data processing capabilities described in this SOW. Currently, the goal of the program is to accumulate 200 qualified tissues from each of 8-10 cancer types. The Program estimates a qualification rate of 60% with a total of 333 consented patients enrolled in each of the eight tumor studies. Tissues shall be received by the Contractor from contributing CPTAC Tissue Source Sites (TSSs) that will be vetted by the NCI to meet a set of preliminary evaluation criteria. To account for the more rigorous tissue collection protocols needed for proteomic analyses, the tissue procurement will be prospective in all cases.

Anticipated Period of Performance:

The period of performance for this requirement is five (5) years, consisting of a twelve (12) month base period, plus four (4) one-year options. The anticipated start date is on/or about September 8, 2015. A single award is anticipated.

Other Important Considerations:

Draft Statement of Work: A copy of the draft Statement of Work (SOW), which is subject to revisions, may be accessed at the end of this document.

NAICS Code and Size Standard: In the event an RFP is issued, North American Industry Classification System (NAICS) code 541990 with a size standard of \$15.0 million dollars is being considered.

Capability Statement/Information Sought:

Sources are expected to have the expertise, personnel, protocols, systems, and technology to meet requirements of the draft SOW. Tailored Capability Statements shall demonstrate a clear understanding of all tasks specified in the attached draft Statement of Work (SOW). Tailored Capability Statements for this requirement shall also address the following five (5) areas:

Technical Approach

- The amount of time required for the Offeror to be prepared to receive and process the first biospecimen and associated clinical data; the amount of time required for the Offeror to become fully functional.
- The Offeror's understanding of the scope, objectives, and challenges of this project.
- The Offeror's proposed approaches to the Tasks and Subtasks are capable of meeting project objectives as stated in the SOW.
- The Offeror's proposed approach is consistent with the CPTAC Tissue Procurement Protocols.
- The Offeror's proposed approach is within the scope of the effort.
- The Offeror's capabilities/facilities for receiving, processing, storing, and shipping biospecimens.

Team and Key Personnel

- Project Organization covers all skills needed to execute this project.
- Key personnel have demonstrated experience in the technical evaluation factors given above that are applicable to their role, and have performed successfully in similar roles in the past.

Experience and Past Performance

- The Offeror has demonstrated experience in the technologies and procedures required to execute this project.
- Past performance examples are for projects of similar size, scope, and technical objectives.
- Evidence of successful performance on these projects has been provided.

Management

- Project Management Approach is sufficient to meet the objectives in the SOW.
- Mechanism by which project, and budget and costs are controlled has been described.
- Project risks have been identified and risk mitigation strategies have been identified.
- Any contractor roles are defined and management controls are adequate.

Cost Reasonableness

- Costs proposed are commensurate with the technical tasks bid.

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:

One (1) electronic copy of the capability statement submitted electronically (via e-mail) to Mandie S. White, Contracting Officer, at whitem@mailto.nih.gov in MS Word or Adobe Portable Document Format (PDF).

3. Delivery Point:

Electronic copy of the capability statements sent in response to the SMALL BUSINESS SOURCES SOUGHT notice must be submitted electronically (via email) to Mandie S. White, Contracting Officer, at whitem@mailto.nih.gov in MS Word or Adobe Portable Document (pdf). The e-mail subject line must specify HHS-NIH-NCI-SBSS-TSB-57019-02. Facsimile responses will not be accepted.

4. Common Cut-off Date:

Electronically submitted tailored capability statements are due no later than 2:00PM (Eastern Prevailing Time) on May 1, 2015. ***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).*