SMALL BUSINESS SOURCES SOUGHT NOTICE

Notice Number: HHS-NIH-NCI-SBSS-TSB-17001-02

Title: "Data Management for Cancer Diagnosis Program Activities"

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.

This National Cancer Institute (NCI), National Institutes of Health (NIH) project is for the renewal of contract HHSN261200422007C, N02-CM-42207 with Information Management Services, Inc. (IMS) that was awarded on a competitive basis for a five year period. Freedom of Information Act (FOIA) requests regarding the current contract with IMS Incorporated should be directed to Suzy Milliard at milliars@mail.nih.gov. This Small Business Sources Sought Notice (SBSS) is for information and planning purposes only and shall not be construed as a solicitation or as an obligation on the part of the National Cancer Institute (NCI).

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, the draft Technical Evaluation Criteria 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 role of the Cancer Diagnosis Program (CDP) is to facilitate transfer of concepts and technological developments from basic research into clinical applications for improved diagnosis and prognosis. Activities have included support for: specimen resources; marker studies in several organ systems; a molecular profiling study of lung cancer; and studies to evaluate the performance of clinical assays for 18qLOH in colon cancer and BCR-ABL in CML. The establishment and maintenance of secure websites has also become a significant portion of this effort.

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 National Cancer Institute (NCI) is an institute within the National Institutes of Health (NIH), one of eight agencies that compose the Public Health Service (PHS), Department of Health and Human Services (DHHS). The mission of the NCI is to plan, conduct, and coordinate the National Cancer Program and involves (a) research on the causes, detection, diagnosis, prevention, treatment, and palliative care of cancers and on rehabilitation of the cancer patient and (b) demonstration of the effectiveness of cancer control methods and techniques.

Project Requirements:

1. COORDINATION OF ACTIVITIES IN SUPPORT OF THE COOPERATIVE GROUP BANKS - The Cooperative Group Banks (CGB) resource is a national conglomerate of biorepositories operated by the NCI Clinical Cooperative Oncology Groups that collect, store and distribute a variety of specimens including blood, urine, buccal swabs, bone marrow, frozen tissues and formalin-fixed paraffin-embedded (FFPE) tissues. The specimens and associated clinical data are collected in the context of phase II and III NCI-supported clinical trials conducted by the Cooperative Groups. The Contractor shall support coordination of activities of the Group Banking Committee (GBC=Steering Committee of the CGB resource) and 5 GBC Subcommittees.

2. LOGISTICAL SUPPORT FOR THE COOPERATIVE HUMAN TISSUE NETWORK - The Cooperative Human Tissue Network (CHTN) was established by the Cancer Diagnosis Program in 1987 to improve access to human tissues for basic and applied research. It is a national network of institutions that provides specimens on a prospective basis in a format defined by the investigator.

3. SUPPORT FOR RECEIVING, RESPONDING TO, AND TRACKING INQUIRIES CONCERNING AVAILABILITY OF BIOSPECIMENS THROUGH THE TISSUE EXPEDITER - The Cancer Diagnosis Program has established the concept of the NCI Tissue Expediter to help investigators locate the tissue and

related data that they need for their research. The Contractor shall serve as the Tissue Expediter, fielding inquiries related to the biospecimens.

4. DATA MANAGEMENT AND LOGISTICAL SUPPORT FOR DISTRIBUTION OF TISSUE MICROARRAYS (TMAs) - The Cancer Diagnosis Program is building a collection of disease-specific TMAs to support discovery and translational research. Currently distribution of sections from each TMA has involved a separate data-management system. The Contractor shall build and maintain a new web-based database to consolidate the information concerning CDP's TMA inventory. This database must be searchable and expandable to accommodate more TMAs as they are added. The contractor shall assist in the development of new TMAs and add them to the same database.

5. DATA MANAGEMENT AND LOGISTICAL SUPPORT FOR THE SPECIMEN RETRIEVAL SYSTEM - The Cancer Diagnosis Program is establishing a specimen resource designed to provide appropriate archived community-based specimens for use in the NCI's Clinical Assay Development Program for biomarker assay evaluation studies. The Contractor shall effectively serve as the central coordinating office for this resource. The Contractor shall serve as the central data repository for the resource, coordinating and processing the NCI's requests for specimens, collecting data provided by the participating institutions, and providing the necessary data management support.

6. DATA MANAGEMENT SUPPORT FOR RESOURCE AND RESEARCH PROJECTS INITIATED BY THE CANCER DIAGNOSIS PROGRAM - The Cancer Diagnosis Program supports resource and research projects and networks under cooperative agreements and contracts to facilitate the evaluation of diagnostic and prognostic approaches. These projects may involve large numbers of specimens and data sets obtained from multiple institutions. Centralized support is required for the coordination of these projects. The Contractor shall effectively serve as the central coordinating office for these resource and research projects and networks. The Contractor shall coordinate collection of data from multiple institutions, serve as central data repository for the data, and provide the necessary data management support. Systems shall be designed and maintained for the management of study data, including data collection, quality-control checking, and routine data analysis. These systems shall be expanded and updated on a regular basis as needed with an expectation of 3-5 datasets per year.

7. **Transition: Phase-In/Phase-out** - The transition plan is to define the required activities and to lay out a schedule as to how the current organization will transition to a new contractor

Anticipated Period of Performance:

The period of performance for this requirement is five (5) years, consisting of a one-year base period plus four (4) one-year options. The anticipated start date is July 1, 2011.

Other Important Considerations:

Personnel Qualifications and Experience

1. Principal Investigator/Project Director

The PI shall possess overall management capabilities which would permit the effective implementation and coordination of all aspects of this project. The PI shall have at least three (3) years of direct experience within the past five (5) years in the management of a similar type project. The PI shall understand medical terminology, systems design, programming and statistics and shall be able to communicate with the biomedical research community and statisticians. The PI shall have some statistical training, preferably at the Masters level. The PI/PD must have a Bachelor's degree in a field related to the duties required. A M.S. is preferred for the PI/PD, but is required only if the PI/PD is also the statistician.

The PI shall have demonstrated ability in managing complex projects including setting priorities for completing tasks, assigning appropriate staff to the tasks, and providing the necessary follow-up for the successful completion of project activities within agreed-upon timelines.

2. Professional and Support Staff

a. Professional Personnel:

At least one (1) member of the project team shall have qualifications which equip him/her to serve as a Co-Principal Investigator. This individual shall have a technical background similar enough to that required for the principal investigator that the Co-PI is able to assume hands-on responsibility for supervising project activities during the absence of the Principal Investigator.

Professional staff shall have training and experience in system design, computer programming in high level languages (R, Matlab, C, Fortran), and the production of statistical tabulations and graphs and technical and user documentation. Professional staff shall have experience in using graphics packages such as SAS-GRAPH, and statistical packages such as Splus, SAS, and BDMP. Professional staff shall have experience in the design and maintenance of web-based computerized data storage and retrieval systems and in working with databases that require data security (password-protected). At least one (1) member of the professional staff must have statistical training at the Master's level. At least one (1) other member must have a B.S. in a biological science.

b. Support Staff:

Support staff shall have experience in data management activities, including data processing, text editing and quality control, interactive systems and in the use of medical terminology as well as training in the biological sciences.

Draft Statement of Work:

A copy of the draft Statement of Work (SOW) and draft technical evaluation criteria, which is subject to revisions, are attached to this sources sought announcement.

NAICS Code and Size Standard:

In the event an RFP is issued, North American Industry Classification System (NAICS) code 541519 with a size standard of 25.0 million dollars is being considered.

Capability Statement/Information Sought:

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:

In support of the efforts under Task 1, the Contractor shall:

a) Coordinate the activities of the GBC, gather materials and attend biannual face-to-face meetings, regularly scheduled conference calls, and write minutes.

b) Provide assistance with keeping track of versions and drafts of documents in preparation.

c) Maintain and update the secure internal portal (website) for the Group Banking Committee.

d) Assist the Marketing and Access Subcommittee of the GBC to develop a central website to provide marketing and access information about CGB specimens to the research community. Once this website has been developed, the Contractor shall be expected to maintain and update it as needed to maintain accuracy of the information.

In support of the efforts under Task 2, the Contractor shall:

a) Maintain and update a secure internal portal (website) for the CHTN.

b) Maintain the CHTN public website (http://chtn.nci.nih.gov/). This shall include updating data on a regular basis with the help of NCI staff and as directed by the COTR.

In support of the efforts under Task 3, the Contractor shall:

a) Serve as the Tissue Expediter to receive and respond to inquiries related to the resources.

b) Maintain the system(s) to receive and respond to inquiries about the availability of specimen and data resources. The system shall rely on information provided by participating biospecimen resources and NCI staff to identify the most appropriate resource(s). Following appropriate consultation with the COTR and CDP staff, contractor shall refer requests to the contact person(s) at the participating resource(s), or other resources as appropriate.

In support of the efforts under Task 4, the Contractor shall:

a) In consultation with the COTR and CDP staff, design, build and maintain a web-based database for tracking data concerning CDP TMAs. Such information shall include details of the samples present on each TMA (including the map of the TMA), current inventories, number of requests received, status of review and distribution.

b) Migrate data from the existing TMA websites to the new system, and receive and input data about new TMAs as they become available. The data shall be provided by the COTR and CDP staff and TMA manufacturers.

c) Establish a system to receive and respond to inquiries about the availability of TMAs. The system shall rely on the TMA website and additional information provided by the COTR and CDP staff and TMA manufacturers and distributors.

d) During the course of this contract, the Contracting Officer or his duly designated representative shall notify the Contractor to process applications for Tissue Microarrays (TMAs) submitted by researchers. The processing of applications includes reviewing letters of intent and relevant documentation, querying applicants for additional information, distributing documentation the CDP program directors, posting the documents to the secure CDP administrative website and drafting and distributing research evaluation letters to the applicants.

The Contractor shall bill recipients/applicants directly for costs associated with processing the TMA applications. The charges for processing the TMA applications shall be based upon the current National Cancer Institute price list for the item(s) listed on the CDP public website. Under no circumstances shall the Contractor bill prices other than those listed in the referenced price list. Prices listed are subject to change. Revised price lists will be issued by the Government when

appropriate without the concurrence of the Contractor.

The Contractor shall keep an accurate account of all payments received from TMA recipients/applicants and will separate this record of income from other fiscal aspects of the contract. The Contractor shall record as credits on monthly invoices to the Government all payments received from the processing of TMA requests. The actual collections from sales shall be offset against the gross billing, leaving a net amount due on the invoice.

The National Cancer Institute COTR may direct that processing of TMA applications be provided at Government expense.

The Contractor shall account for the contract-related income separately in accordance with its own double-entry accounting system. Each month the Contractor shall submit to the Government a monthly summary sheet of sales along with the monthly progress report.

The administration of the contract-related income shall be subject to the terms of this contract, including specifically and without limitation, FAR Clause 52.215-2, AUDIT-NEGOTIATION of the General Clauses, and the applicable cost principles of the Federal Acquisition Regulation.

The Contractor shall use the following procedures for collection of delinquent accounts:

Step 1 – Accounts 30 days past due. A copy of the invoice shall be sent to the recipient with a notation that the account is overdue and request payment.

Step 2 – Accounts 60 days past due. The Contractor shall turn the account over to the NCI COTR.

When the completion (final) invoice is submitted on this contract, a listing of all outstanding recipient invoices shall be provided along with details as to their dispositions.

e) Develop and maintain system(s) to track inquiries related to TMAs and requests for TMAs in consultation with the COTR. The Contractor shall prepare reports related to specimen requests as required by the COTR.

f) Consult with the COTR, study participants, NCI program staff and TMA manufacturers to effectively manage data.

In support of the efforts under Task 5, the Contractor shall:

a) Design, develop and customize a searchable database to contain the needed information about the specimens (the Specimen database). This database shall contain information concerning the collection inventory, including demographic, pathologic, and clinical outcome data on the cases. This

task shall be done in close consultation with the COTR. The Government estimates ten sets of data, each one containing data on five hundred to one thousand different cases, will be assembled over the course of the contract. It is projected that 3-5 sets will be assembled in the first two years of the contract.

b) Assist the NCI and contributing institutions, as requested by the COTR, in the development of data structures to allow collection of data electronically.

c) Receive completed electronic data, edit and screen for errors, correct errors per discussions with COTR and the NCI statistician and enter and store data into the database. These data shall be updated semi-annually or as requested by the COTR.

d) Develop appropriate data entry quality control programs in consultation with the COTR. These activities shall include routine edit checks to ensure the quality of the data, removal of duplicate data, internal checks to compare data among related databases to ensure that they are consistent, periodic reports to the NCI statisticians of subsets of data by site and reports and summaries of database problems.

e) Establish a system to receive and respond to NCI's inquiries about the availability of specimens. Work with the COTR and CDP statisticians to identify appropriate specimens to fill requests, and run routine statistical reports. The system shall rely on the database established by the Contractor.

f) Generate reports based on the information contained in the database as requested by the COTR. Prepare statistical reports required by Cancer Diagnosis Program statistician(s) as directed by the COTR using available statistical software and any routine modifications necessary to prepare the requested reports. The preparation of reports shall occasionally require high level programming support, including but not limited to coding computer simulations, writing routines to perform statistical tests which are not currently available as standard routines in statistical packages, and creating complex graphical displays of raw data or statistical analysis results. When requested to by the COTR, the Contractor shall be required to prepare these reports with very short deadlines, meaning deadlines that would require redirection of contractor resources (time and staff) to meet. All statistical support services provided by the Contractor shall be conducted under the guidance of Cancer Diagnosis Program statisticians.

In support of the efforts under Task 6, the Contractor shall:

a) Design, develop and maintain databases of laboratory data (the Laboratory databases) from NCI-generated studies of assay performance characteristics. These databases shall be developed under the guidance of the COTR and other involved personnel because the specific data generated will differ depending on the study. These databases could be in a simple format such as Excel or tab-delimited text files. The government estimates 2-3 studies in the first contract year, to increase in subsequent contract years depending on demand. Contractor shall consult with the COTR, study investigators, NCI program staff and statisticians to effectively manage data. This includes frequent

phone calls and e-mails and participation in conference calls and attendance at resource and research network meetings.

b) Design, develop and maintain databases of projects (the Project Tracking databases) from NCI-generated studies of assay performance characteristics. These databases shall be developed under the guidance of the COTR. These databases shall be capable of tracking all projects from the point of first consideration, through project performance to exit from the program. The government estimates 2-3 studies in the first contract year, to increase in subsequent contract years depending on demand and available NCI resources. Contractor shall consult with the COTR and NCI program staff to effectively manage data.

c) Provide data management support for research projects initiated by the Cancer Diagnosis Program, involving receipt of data and entry into a database. For example, these data may include molecular analysis data from different technical platforms and clinical annotation of the specimens analyzed. This shall also include programming to customize appropriate databases. It is anticipated that there will be 1-2 projects per year.

d) Assist the NCI and extramural investigators, as requested by the COTR, in the development of experimental and clinical data forms to allow collection of archival/existing data in a computer-ready format. As requested by the COTR, the Contractor shall duplicate and ship forms to the investigators with written instructions for completion of the forms, receive completed data forms or electronic data, edit and screen for errors, correct errors per discussions with COTR and NCI statistician(s) and enter data into the database. This includes development of appropriate data-entry quality-control programs in consultation with the COTR. These activities must include routine edit-checks to ensure the quality of the data, removal of duplicate data, internal checks to compare data among related databases to ensure that they are consistent, periodic reports to the NCI statisticians of subsets of data and reports and summaries of database problems.

e) Prepare statistical reports required by Cancer Diagnosis Program statistician(s) as requested by the COTR using available statistical software and any modifications necessary to prepare the requested reports. The preparation of reports shall occasionally require high level programming support, including but not limited to coding computer simulations, writing routines to perform statistical tests which are not currently available as standard routines in statistical packages, and creating complex graphical displays of raw data or statistical analysis results. When requested to by the COTR, the contractor shall be required to prepare these reports with very short deadlines, meaning deadlines that would require redirection of contractor resources (time and staff) to meet All statistical support services provided by the contractor shall be conducted under the guidance of Cancer Diagnosis Program statisticians.

f) Provide coded data sets in computer-readable storage medium in the format as directed by the COTR.

g) Establish and maintain secure document- and data-sharing websites for use by various working groups as requested by the COTR. The Government estimates that 10-20 such sites are needed over the course of the contract.

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 (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. Number of Copies:

All capability Statements 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 or Contract Specialist, Mandie White, at whitems@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-17001-02. Facsimile responses will not be accepted.

3. **Common Cut-off Date:**

Electronically submitted tailored capability statements are due no later than 2:00PM (Eastern Prevailing Time) on January 13, 2011. ***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).