SMALL BUSINESS SOURCES SOUGHT NOTICE

Notice Number: HHS-NIH-NCI-SBSS-TSB-17003-64

Title: – Clinical Studies Monitoring Service (CSMS) for National Center for Complementary and Alternative Medicine (NCCAM)

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:

Since its creation as an independent Center in 1998, the National Institutes of Health (NIH) National Center for Complementary and Alternative Medicine (NCCAM) has developed a broad research portfolio focused on a variety of complementary and alternative medicine (CAM) practices. CAM practices are a group of diverse medical and health care systems, interventions, and products that are not generally considered part of conventional medicine. In view of its expanding portfolio of clinical research, this project provides for the support of the NCCAM Clinical Studies Monitoring Services (CSMS) Contract to enhance clinical studies oversight by the NCCAM Office of Clinical and Regulatory Affairs (OCRA).

The NCCAM currently funds a broad portfolio of clinical studies that investigate CAM practices with biologically-based or mind/body-based interventions http://nccam.nih.gov/research/results/spotlight/atoz.htm. The biologically-based interventions include those such as dietary supplements (i.e., omega-3 fatty acids, creatine), probiotics, and botanical products (i.e., silymarin, saw palmetto extract). As many of the biologically-based studies funded by NCCAM focus on a specific disease or condition of use, many such studies are conducted under an IND issued by the FDA. By contrast, the mind/body-based intervention studies include modalities such as yoga, Tai Chi, meditation, acupuncture, massage therapy and chiropractic manipulation. The majority of NCCAM-sponsored clinical research is conducted in single-site studies, and is conducted at academic medical centers, hospitals, clinics and physician

offices through a variety of funding mechanisms such as cooperative agreements, grants, and contracts. In addition, several studies are conducted outside of the US, in Canada, Hong Kong, Peru and South Africa. NCCAM also supports an intramural clinical research program at the NIH Clinical Center. The NCCAM clinical research portfolio therefore incorporates many scientific disciplines and includes studies of diverse design, clinical setting, size and complexity.

In view of the diverse scope of NCCAM-funded clinical studies, the NCCAM/OCRA plays a primary role in clinical studies oversight for the approximately 150 ongoing clinical projects. Monitoring of clinical sites is one element of a larger program of clinical studies oversight developed by OCRA to fulfill its responsibilities of ensuring the safety and welfare of participants, of maximizing adherence to appropriate clinical research regulations and guidelines and maximizing data quality from NCCAM-funded studies.

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. On behalf of NCCAM, 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 provide comprehensive clinical site and study monitoring services for the NCCAM extramural clinical studies research portfolio and other support efforts as outlined in the draft SOW. The Contractor would also perform specialized clinical site visits as needed by NCCAM which may be conducted independently or in conjunction with other clinical monitoring site visits.

Project Requirements:

The contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities as needed to perform comprehensive clinical site and study monitoring services for the NCCAM extramural clinical studies research portfolio. The scope of activities to be performed includes, but is not limited to the following:

(1) Site initiation visits prior to clinical study implementation to ensure compliance with NCCAM, U.S. and, where appropriate, country-specific regulatory requirements and guidelines.

(2) Routine site monitoring visits for active select phase 0, phase 1, and phase 2 clinical studies to ensure compliance with NCCAM, U.S. and, where appropriate, country-specific regulatory requirements and guidelines, verify the accuracy and completeness of clinical study data, and assess adherence to protocol-specific requirements.

(3) Specialized site monitoring visits for a variety of purposes, including regulatory audits, assessments of overall and protocol-specific research pharmacy operations and management of investigational products, and remedial or for cause site visits to implement and ensure adherence to corrective actions required to address site or study deficiencies identified through routine site monitoring.

(4) Site closeout visits to ensure appropriate completion of clinical studies, storage of clinical records and disposition of investigational products.

(5) Preparation of written reports of all site monitoring visits, including identification of problems and deficiencies and recommendations for remedial actions.

(6) The development and implementation of Standard Operating Procedures for the conduct of clinical site and study monitoring functions, including the components to be reviewed/assessed and the processes to be used for each type of site visit.

(7) The development and implementation of a training plan for site monitors on staff and new hires and for evaluating the effectiveness and efficiency of training activities conducted.

(8) The development and implementation of a Quality Assurance/Quality Control (QA/QC) Plan to ensure the efficient and effective performance of monitoring functions and the appropriate management of the project.

(9) The development and implementation of an Integrated Master Project Plan to provide for the overall management, integration and coordination of all contract activities.

(10) Other technical and administrative support to coordinate meetings, teleconferences, review and/or preparation of study-related documents and material.

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 on or about May 30, 2011.

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 541990 with a size standard of $7.0 million 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 draft SOW. Tailored Capability Statements for this requirement shall also address the following four (4) areas:

1. TECHNICAL PLAN / APPROACH

A. Clinical Site Monitoring and Reporting

(1) Organizational experience in planning and conducting the breadth of routine and specialized clinical site and study monitoring visits required, including experience in the identification and resolution of site performance problems and deficiencies.

(2) Proposed Standard Operating Procedures (SOPs) for both routine and specialized clinical site monitoring visits.

(3) The proposed approach to scheduling clinical site monitoring visits, the cost/resource efficiencies of the proposed approach, and experience in and approaches implemented to resolve scheduling problems and conflicts.

(4) The plans and approaches for accommodating urgent and/or unanticipated site monitoring needs.

(5) Organizational experience with and proposed plans and procedures for coordinating clinical site monitoring functions.

B. Training

(1) The proposed training plan for all training activities to be conducted for site monitors on staff as well as newly hired monitors.

(2) The proposed plan for evaluating training activities, including performance metrics.

(3) The organizational experience in planning and conducting training for site monitors.

C. Quality Assurance/Quality Control (QA/QC)

(1) The proposed QA/QC Plan for standardizing contract processes, ensuring compliance with domestic and country-specific regulations and Good Clinical Practice (GCP) and International Conference on Harmonization (ICH) guidelines, and assessing Contractor performance and the quality of clinical site monitoring functions performed.

(2) The results of independent audits conducted over the past 5 years, problems/deficiencies identified, and correct/remedial actions implemented to resolve identified problems and deficiencies.

2. CLINICAL AND TECHNICAL PERSONNEL

A. The offeror shall demonstrate the qualifications, experience, training, and availability of proposed clinical and technical personnel to accomplish the requirements specified in the Statement of Work, particularly with respect to large and complex clinical trial programs involving both domestic and foreign clinical sites, including clinical sites in resource-limited countries with respect to the following:

(1) Site Monitors - includes training and experience in clinical site monitoring for (i) clinical trials conducted at both domestic and foreign sites in resource-limited countries, (ii) clinical trials conducted in a variety of community- and hospital-based settings, and (iii) proficiency in the language of countries where clinical records are not maintained in English.

(2) Supervisory Site Monitor - includes experience and training in performing clinical site monitoring functions as well as experience and expertise in coordinating, tracking, managing and assessing the performance and quality of clinical site monitoring activities and personnel.

(3) Information Technology Manager – includes training, experience and capabilities to ensure appropriate adherence to FIMSA policy and regulations.

B. The appropriateness and adequacy of proposed plans for the identification and recruitment of the number of additional site monitors proposed to be hired to ensure that 100% of site monitors are on board and trained within 4 months of the contract effective date.

C. The adequacy of documentation of the ability to recruit and retain site monitors based on organizational performance over the past 5 years.

D. Appropriateness of plans for cross-training and replacement of proposed staff throughout the course of the contract, including back-up and fill-in personnel.

3: FACILITIES, EQUIPMENT AND OTHER RESOURCES

Demonstrate the adequacy and availability of the proposed facilities, equipment and other resources necessary to carry out the functions specified in the Statement of Work. The offeror shall demonstrate they have the available space/facility with regard to the following:

A. Location and features of office space and facilities, including lease or ownership information.

B. Proposed plans and procedures to accommodate the need for NCCAM to have easy and rapid access to contract staff and documents housed at the offeror's main facility or satellite office and the cost-effectiveness of the proposed plans and procedures.

C. The rationale for the number and locations of proposed regional or local field offices outside of the U.S., including how such arrangements are expected to contribute to cost-effectiveness and efficiency in the use of contract resources and to ensure adequate access to site monitoring staff expertise and assistance by foreign sites.

D. Adequacy of security arrangements for protecting the confidentiality of the records.

4. PROJECT MANAGEMENT

A. Project Management Personnel.

Demonstrate through documentation the adequacy and appropriateness of the training, experience, qualifications and availability of the proposed project management personnel, particularly with respect to the coordination, management and oversight of clinical site monitoring functions for large and complex clinical studies or programs involving both domestic and foreign clinical sites, including clinical sites in resource-limited countries with respect to the following:

(1) Program Director - includes training and experience in overall project management and communications, tracking, monitoring and reporting on project status and progress, recommending modifications to project requirements, timelines and procedures, and directing and ensuring the quality of site monitoring functions carried out by in-house staff as well as subcontractors, and implementing corrective/remedial actions to resolve problems and deficiencies.

(2) Senior Project Manager - includes training and experience in overseeing the daily operations of large and complex projects, tracking assignments, ensuring adherence to internal policies and procedures, and assisting in the resolution of deficiencies and problems.

(3) Administrative Personnel - includes training and experience in financial management and reporting on all contract activities, including activities carried out by subcontractors.

B. Integrated Master Project Plan. The appropriateness, adequacy, feasibility and soundness of the proposed Integrated Master Project Plan with respect to the following Plan components:

(1) Management Structure - including roles and responsibilities of proposed staff of the offeror and all subcontractors, lines of authority and plans for achieving appropriate and ongoing communications among project staff.

(2) Project Implementation and Management - encompasses proposed plans for implementing and managing all contract activities, including project management systems and procedures and proposed plans for assessing the efficiency of internal project management procedures in the following areas: (i) internal timelines for planning and implementing contract assignments and metrics for assessing efficiency and timeliness; (ii) personnel and other resources required and methods to assess the adequacy of contract resources; (iii) project risks and risk management/mitigation strategies; (iv) initial and ongoing training of clinical, technical and project management staff on Project Implementation and Management procedures and timelines; and (v) procedures to ensure that all Contractor and subcontractor staff safeguard intellectual property, the confidentiality of human subjects and other data, and other information provided by third parties or by the Government, as well as data generated through this 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 (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 James D. Carder, Contracting Officer, at carderj@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-17003-64. 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 October 20, 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 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).