



Clinical Studies Monitoring Service (CSMS) National Center for Complementary and Integrative Health (NCCIH)

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Agency: Department of Health and Human Services

Office: National Institutes of Health

Location: National Cancer Institute, Office of Acquisitions

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Sources Sought

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NAICS Code:

541 -- Professional, Scientific, and Technical Services/541990 -- All Other Professional, Scientific, and Technical Services

Synopsis:

Added: Dec 04, 2015 10:24 am

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. The North American Industry Classification System (NAICS) code for this project is 541990 with a size standard of \$15.0 million.

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 Integrative Health (NCCIH) has developed a broad research portfolio focused on a variety of complementary and integrative medicine practices. These 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 new solicitation provides for the support of the NCCIH Clinical Studies Monitoring Services (CSMS) Contract to enhance clinical studies oversight by the NCCIH Office of Clinical and Regulatory Affairs (OCRA).

Over the past decade, the evidence base regarding efficacy and safety of integrative medicine practices have grown substantially in both quality and quantity. Basic research and clinical trials, both large and small, have yielded results-both "positive" and "negative"-that inform consumers' use of and health care providers' recommendations concerning integrative medicine. It is also apparent the nearly 40% of the US public practice some form of integrative therapy on a regular basis. Increasingly, the evidence base is permitting systematic reviews that point toward helpful conclusions regarding safety and efficacy or lack thereof, rather than simple statements that more or better quality research is needed. There is also evidence that this body of research has influenced consumers. For example, both NHIS data and industry sales figures suggest that the results of several large clinical trials have affected both the frequency of use and sales of non-vitamin/non-mineral dietary supplements. In addition, the U.S. Food and Drug Administration (FDA) has taken actions to address concerns about the safety of some complementary and integrative medicine products as a direct result of research.

Growth in the quality and quantity of the evidence base reflects substantial growth in complementary and integrative medicine research capacity, much of which is a direct result of NCCIH-led and -supported activities to attract scientists to the field, establish multidisciplinary research collaborations, and train investigators in research. In view of extensive use by the public, NCCIH is committed to further research on complementary and integrative medicine practices. State-of-the-art research methods and tools are being employed to assess and develop two broad categories of research funded by NCCIH-botanical products & dietary supplements and mind/body & manual therapies. Research is now a specific focus of several international organizations, including the Consortium of Academic Health Centers for Integrative Medicine, the International Society for Complementary Medicine Research, and the Society for Integrative Oncology, as well as various national governments (e.g., China and India) and the World Health Organization.

The NCCIH currently funds a broad portfolio of clinical studies that investigate complementary and integrative medicine practices with biologically-based or mind/body-based interventions <http://NCCIH.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 NCCIH 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 NCCIH-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, a few studies are conducted outside of the US, in Canada, and Peru.. NCCIH also supports an intramural clinical research program at the NIH Clinical Center. The NCCIH 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 NCCIH-funded clinical studies, the NCCIH/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 NCCIH funded studies.

NCCIH has a growing clinical research program that conducts research on promising complementary and integrative therapies for treatment or symptomatic relief of numerous diseases and conditions. Such studies of complementary and integrative practices involve varying degrees of risks to participants. This relative risk, as well as the scope and complexity of the research will influence the extent of external monitoring required by OCRA. The CSMS Contract will therefore provide support for ongoing site monitoring in NCCIH-funded clinical studies that are identified by OCRA, and addresses the compelling need to provide monitoring to insure that studies are conducted in the most scientifically valid, safe, and efficient manner possible.

Purpose and Objectives:

The purpose of this Small Business Sources Sought Notice (SBSS) is to identify qualified small business concerns that are interested in and capable of performing the work described herein. On behalf of NCCIH, 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 NCCIH 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 NCCIH which may be conducted independently or in conjunction with other clinical monitoring site visits.

Project Requirements:

1. SCOPE:

A. Scope of Clinical Site and Study Monitoring Functions: The Contractor shall provide comprehensive clinical site and study monitoring services for the NCCIH-funded (primary or secondary) extramural clinical studies research portfolio. The scope of activities to be performed includes:

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

2) Routine site monitoring visits for active select clinical studies to ensure compliance with NCCIH, 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 materials.

B. Scope of Clinical Studies Programs and Projects: The scope of NCCIH-supported clinical study programs and projects for which clinical site and study monitoring services shall be provided includes the following:

1) NCCIH Extramural Clinical Studies: On-site monitoring support for contractors, grantees and other clinical investigators conducting selected clinical trials, as well as selected observational and mechanistic clinical studies.

2) Other NCCIH-funded Investigator-initiated Projects: Expanded capability for conducting on-site monitoring to encompass the expanded scope of studies conducted under the auspices of the Intramural Research Program.

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 August 31, 2016.

Other Important Considerations:

Draft Statement of Work:

A copy of the draft Statement of Work (SOW), which is subject to revisions, is attached or it 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.

Capability Statement/Information Sought:

Respondents must be qualified and prepare tailored capability statements for all of the task areas in the attached draft Statement of Work. The capability statements will be evaluated based on the information provided in relation to the project requirement and current capability and capacity to:

1. Perform work in the task areas in the attached draft Statement of Work;
2. Staff education, training experience, expertise and knowledge;
3. Corporate experience and management capabilities.

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/Delivery Point:

All capability statements sent in response to this SMALL BUSINESS SOURCES SOUGHT notice shall be submitted electronically (via e-mail) to Mary Loesch, at mary.loesch@nih.gov in MS Word or Adobe Portable Document Format (PDF). The e-mail subject line must specify HHS-NIH-NCI-SBSS-TSB-57013-04. Facsimile responses or phone calls will not be accepted.

3. Common Cut-off Date:

Electronically submitted tailored capability statements are due no later than 12:00PM (Eastern Prevailing Time) on Monday, December 14, 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).

Sources Sought

Type: Other (Draft RFPs/RFIs, Responses to Questions, etc..)

Posted Date: December 4, 2015

[Statement of Work DRAFT NCCIH.pdf](#) (200.37 Kb)

Description: Draft Statement of Work

Contracting Office Address:

9609 Medical Center Drive, Room 1E128

Rockville, Maryland 20852

United States

Place of Performance:

Locations vary. Refer to Draft Statement of Work.

United States

Primary Point of Contact.:

Mary E. Loesch,

Contract Specialist

loeschme@mail.nih.gov

Phone: 3016248764

Secondary Point of Contact:

C. Timothy Crilley,

Contracting Officer

tcrilley@mail.nih.gov

Phone: 3016248743

ALL FILES

[Sources Sought](#) 

Dec 04, 2015

[Statement of Work DF](#)

Opportunity History

■ **Original Synopsis**

Dec 04, 2015

10:24 am