**Small Business Sources Sought Notice No.: HHS-NIH-NCI-SBSS-ETSB-11005-48**

**Title:** "Clinical Trials and Information Management Support"

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.**

The NAICS code for this project is 541990.
The small business size standard is $7,000,000.

**Background:**

The Cancer Therapy Evaluation Program (CTEP) is responsible for the administration, coordination, and scientific review of most of the extramural clinical trials supported by the Division of Cancer Treatment and Diagnosis (DCTD). These programs include the activities of the DCTD Clinical Trials Cooperative Group Program, the Early Drug Development Program cooperative agreement and contract holders, the recipients of investigator-initiated grants and cooperative agreements relating to cancer treatment and the recipients of investigational agents, as well as the Treatment Referral Center (TRC) and Special Exception programs. In addition, CTEP is implementing recommendations made by the National Cancer Advisory Board's Clinical Trials Working Group (CTWG) to restructure the NCI's clinical trials enterprise to realize the promise of molecular oncology in the 21st century. NCI's Coordinating Center for Clinical Trials (CCCT) guides the implementation of the CTWG recommendations. CTEP collaborates with CCCT in leading the implementation of Scientific Steering Committees to enhance scientific quality and prioritization of clinical trials. The project is for the re-competition of NCI Contract No. N02-CM-42205, which was awarded on a competitive basis for a four year base period with 3 award term option periods. This Small Business Sources Sought (SBSS) notice is for information and planning purposes only and shall not be construed as an obligation on the part of the NCI.

**Purpose and Objectives:**

The purpose of this project is to provide support to the CTEP and CCCT Professional Staff in the evaluation, coordination and oversight of clinical trial concepts and studies as they develop. The Contractor would also be involved with the acquisition, review and

analysis of data and information which result from CTEP-sponsored extramural clinical research. An additional component is to provide direct organizational and data management support for specific clinical trials as needs for TRC and Special Exception programs arise.

**Project Requirements:**

Major tasks required of the Contractor include the following:

1. Information Specialist Support: The Contractor shall provide support to the CTEP Professional Staff in the acquisition of information and review and analysis of data which result from extramural clinical research. These contract staff, referred to as Information Specialists, will also assist in analysis of clinical trials and other program management and analysis needs. These activities support CTEP's mission of evaluating, prioritizing, coordinating, and analyzing planned and ongoing clinical trials and clinical research through mechanisms such as concept evaluations, scientific strategy and program meetings, clinical trial planning meetings, and special drug development meetings. Examples of required support include, but are not limited to:

(a) Providing support for CTEP scientific meetings (including literature searches, preparation of tables, data synthesis, timelines and other material for preparation and distribution at meetings) and drafting meeting minutes. These meetings are often, but not always, held in the D.C. Metropolitan area.

(b) Attend meetings (e.g., clinical trial planning meetings, Cooperative Group Chairs meetings, and other scientific meetings), at the Contracting Officer's Technical Representative's (COTR's) direction, and preparation of meeting minutes. These meetings are often, but not always, held in the D.C. Metropolitan area.

(c) Perform literature and/or database searches and analysis, including, but not exclusively, Index Medicus, NLM data bases, PDQ, CLINPROT, and CTEP information systems, for purposes of concept reviews, preparation for scientific presentations, or publications.

(d) When necessary, the Contractor shall assist in the development of new Common Data Elements (CDE) as the scientific and/or trial need arises. NCI's CBIIT (Center for Biomedical Informatics and Information Technology) is leading an effort to create a comprehensive library of standardized electronic Case Report Forms (eCRFs) with associated CDEs to be utilized in all NCI-sponsored clinical trials as part of the cancer biomedical informatics grid (caBIG™) clinical trials tools. Depending on the timeline of completion for this large eCRF library, the contractor will provide continued review of CRFs for compliance with the CDE vocabulary. Investigators and Cooperative Groups are required to utilize the CDE Repository to develop protocol CRFs until the standardized eCRFs are available through caBIG™ tools. Specifically, the Contractor shall:

1) Provide support to CTEP to assist NCI-sponsored investigators in creating common data elements (CDEs) for CTEP-sponsored clinical trials that are consistent with ISO/IEC 11179 metadata standards and NCI/caBIG® best practices, when necessary (https://cabig.nci.nih.gov/workspaces/VCDE/Vocab-Standard-Governance-and-Review/ );

2) Be responsible for reviewing CDEs and eCRFs submitted by investigators for use in CTEP-sponsored clinical trials assuring that CDEs and eCRFs are consistent with the existing standards in the Cancer Data Standards Repository (caDSR). At the present time, there are about 30 phase 3 studies per year requiring this review. When CBIIT completes a significant portion of standardized eCRFs, the amount of time reviewing CDE compliance should decrease over time. The information specialists support of CDE review shall transition to become more of providing technical expertise to investigators to assist them in the creation of new data elements, when necessary, once the complete set of eCRFs are available. The contractor information specialists shall create an expert help desk to provide education and support to the investigator that may need to identify appropriate CDEs or eCRFS that would met their needs. When appropriate, the Contractor shall assist in the creation of new CDEs and eCRFs as directed by the COTR. Provision for education and support to investigators may be needed to assist in the implementation of CBIIT's standardized eCRFs once they are finalized. In addition, a provision to capture Investigator requests to extend existing eCRF standards and handle those requests appropriately. Requests such as the addition of permissible values to data elements with a choice list may be routed to CBIIT through change management mechanisms that shall version CDEs. Investigators may also have edits that need to be applied to existing eCRFs that shall improve the library of forms for the community. CBIIT will have a publicized Change Management plan with the release of additional finalized content that should be utilized for the benefit of our community;

3) Participate in relevant CDE and eCRF meetings, such as eCRF working groups, harmonization meetings, and appropriate CBIIT meetings. Provide input to ensure that the CTEP investigator community needs are well described and the implementation of standardized eCRFs include sufficient education of the NCI extramural community to facilitate adoption and ease of use of the new tools. Utilize training materials developed for the community adoption of eCRFs and data elements. Provide feedback to CBIIT to incorporate into training materials, a user instruction manual that shall guide the successful use of eCRFs; and

4) Serve as a resource to CTEP, Cooperative Group and other CTEP-

sponsored investigators, and CBIIT regarding development and implementation of CDE-compliant CRFs.

(e) Develop and maintain websites and/or databases for scientific committees:

1) The Contractor shall provide support for CTEP-sponsored activities, which shall include, but is not limited to, website development and maintenance, conference call organization and minutes, and tracking of scientific committee outcomes that may include clinical trial concepts that are reviewed outside the Scientific Steering Committee mechanism.

(f) Maintenance, entry, and/or retrieval of information in CTEP databases, which may include, but is not limited to:

1) The CTEP Enterprise System (CTEP-ESYS) including IPAD and CIBSCIT;

2) Secondary AML/MDS Database;

3) Funding Information and Accrual Tracking System Database (FIATS);

4) CGCB Grants Publications Database;

5) The IMPAC II Enterprise Program; and

6) NIH Population Tracking Database

(g) The contractor shall design data collection instruments (including databases) and develop data collection procedures for use in analysis of overall results of NCI-sponsored cancer clinical trials. Pertinent data might relate to any or all aspects of a subset (e.g. disease and stage specific) of cancer clinical trials, including study design, methodology, results, and quality of conduct. (OMB Clearance is not required). Databases must be compatible with databases developed within NCI and CTEP including the NCI's Scientific Information System (SIS), the CTEP Enterprise System, and the Cancer Informatics Infrastructure (CII), Oncology Patient Enrollment Network (OPEN), and Clinical Trials Reporting Program (CTRP).

(h) The contractor shall abstract, compile, collate, and analyze data utilizing a variety of resources available within and outside of the CTEP. Resources include, for example, published literature references, Cooperative Group minutes and agendas, research progress reports, scientific meeting proceedings and white papers, and research protocols.

(i) The contractor shall summarize or otherwise process compiled data, provide assistance to CTEP in developing a comprehensive understanding of past, current, and future research strategies and establishing research priorities.

(j) The contractor shall assist in the review of Cooperative Group Concepts including analysis of ongoing activities and assistance in the form of literature searches and a listing of similar ongoing studies.

(k) The contractor shall prepare drafts of reports for use by staff in carrying out CTEP's mission of coordinating and maintaining an effective network of clinical trials organizations.

(l) Assist the CTEP staff in the preparation of manuscripts, abstracts, posters or other publications for scientific publication including literature searches, preparation of initial drafts, copy editing, reference checking, and preparation of graphics.

(m) Assist the CTEP staff in the retrieval and analysis of information on Phase III clinical trials necessary for entry of data into the NIH Population Tracking Database.

(n) Assist the CTEP staff in the retrieval and analysis of information from:

1) Phase I/II meetings;

2) Special drug development sessions; and

3) Development of plans for high priority drugs

2. Scientific Steering Committee Support:

The Contractor shall:

(a) Provide support for CCCT scientific steering committee in-person meetings and steering committee specific Clinical Trials Planning Meetings (CTPMs). This involves, working with NCI staff and steering committee leadership to establish agendas, distribute meeting materials, draft meeting minutes, perform literature searches from available data bases, prepare tables, data synthesis, timelines and other material as needed. These meetings are often, but not always, held in the D.C. Metropolitan area.

(b) Provide support for monthly steering committee and task force teleconferences. This involves coordinating conference calls, working with CCCT staff and steering committee leadership to establish agendas, draft meeting minutes, distribute meeting materials, perform data synthesis, prepare data tables, supply needed reports from the relevant data bases and other information as

specified by CCCT staff responsible for facilitating the specific steering committee.

(c) Attend in-person meetings and all conference calls associated with steering committee activities at the direction of the responsible CCCT staff. The meeting minutes shall be submitted to appropriate CCCT staff within the three work days for conference calls and within two weeks after each in-person meetings for comments and corrections and revised accordingly.

(d) Perform literature and/or data base searches and analysis including, but not exclusively, Index Medicus, NLM data bases, PDQ, CLINPROT, and CTEP information systems for purposes of assisting NCI with concept evaluation, preparation for scientific presentations, or publications.

(e) Develop and maintain websites and/or databases for scientific committees. The Contractor shall provide support for steering committee-sponsored activities which shall include but is not limited to, website development and maintenance, conference call organization and minutes, and tracking of scientific committee outcomes that may include clinical trial concepts that are reviewed outside the Scientific Steering Committee mechanism.

(f) Summarize or otherwise process compiled data, provide assistance in developing a comprehensive understanding of past, current, and future research strategies and establish research priorities.

(g) Assist in the review of Cooperative Group concepts including analysis of ongoing activities and assistance in the form of literature searches and a listing of similar ongoing studies.

(h) Prepare drafts of reports for use by staff in carrying out the mission of the scientific steering committees, coordinating and maintaining an effective network of scientific steering committees.

3. The Contractor shall participate, as needed, with NCI staff and other designated contractors in software updates, development, and maintenance and as subject matter experts involving the CTEP Enterprise System. At the direction of the COTR, the contractor's systems supporting CTEP projects may need to share data electronically with other CTEP systems. Any systems developed by the Contractor shall be consistent and compatible with CTEP Enterprise models and caBIG standards (i.e. web services).

4. Procedures Manual: The Contractor shall maintain and update a Policy and Procedures Manual. This manual shall contain detailed operational procedures used in accomplishing the tasks described above.

5. The Project Manager and/or his or her representative shall be available for consultation and planning with the COTR or other NCI staff on a short turnaround basis,

such as within 48 hours, to discuss data management and procedures, protocol and/or forms revisions, planning meetings, problems encountered in clinical trials management, procedures employed and other matters relating to the central management of the clinical trials and for information management, review and analysis support. The contractor shall implement a project management and task approval system to track tasks and subtasks.

6. Transition:

In the event this project is re-competed during the life of this contract and the successor award is not made to the incumbent Contractor, a transition period shall be utilized. This transition period shall encompass the final sixty days of this contract.
During this period, the Contractor shall proceed with the phase-out process, as stated below in cooperation with the successor Contractor:

1) The Contractor shall prepare and submit a Transfer/Phase-Out Plan to the Contracting Officer and COTR [to be determined during negotiations]. Upon review and approval by the Contracting Officer and COTR of the Contractor's Transfer/Phase-Out Plan, the Contractor shall provide the successor Contractor with detailed briefings regarding the policies and procedures for managing all aspects of the project. The successor Contractor shall also work in an apprentice capacity with this Contractor to insure that work operations are fully understood.

2) Transfer of filed material and documents: The schedule for transfer of project materials from the Contractor to the successor shall proceed at the direction of the Contracting Officer at a rate, and in a manner mutually agreed to by the NCI COTR and the CTEP staff. All data transfer shall be completed by a date to be determined by the COTR and shall include provision by the Contractor of accurate and complete data files and pertinent documentation.

3) The Contractor shall ensure that the Procedures Manual is accurate and up-to-date and is provided to the new Contractor.

4) The Contractor shall carry on operations at full staffing levels until contract expiration.

Optional Work:

Any of the following options may be exercised, per the Government's decision:

Option 1 - CLINICAL TRIALS MANAGEMENT SUPPORT: The Contractor shall provide clinical trials management (trial design, development, data management, statistical and operations office, regulatory oversight and reporting, auditing, etc.) support for the following clinical trials programs when the need arises at CTEP:

(a) Treatment Referral Center (TRC) Protocols:

The Treatment Referral Center (TRC) is a means for NCI to provide information to community oncologists about therapeutic options for cancer patients with emphasis on referral to Cooperative Group studies or Cancer Centers. The TRC uses the PDQ, ClinicalTrials.gov, CTEP information systems databases, data supplied by the NCI-designated Comprehensive or Clinical Cancer Centers, CTRP, and consultations with CTEP physicians to maintain a referral list of the most current active research protocols. For certain high-priority diseases or agents, NCI identifies those stages and amount of prior therapy situations for which it is felt investigational treatments should be available. For each of these patient populations, the TRC will provide a Treatment Referral Center Protocol to the Cancer Centers. If any one of the Cancer Centers feels there are no commercially available treatment options or there is no active clinical trial available for such patient populations, the Cancer Center may choose to use the Treatment Referral Center Protocol as a treatment option.

1) The Contractor shall support the development and conduct of TRC protocols during the performance period as appropriate agents are identified.

(b) Other Clinical Trials:

The Contractor shall provide support for selected CTEP and/or NCI-coordinated studies as designated by the COTR.

(c) Clinical Trials Support: The support required for the clinical trials programs described in the TRC item above shall include all of the following, although not all may be included in each task. Specific tasks required will be identified by the CTEP Senior Investigator(s) and COTR at the initiation of each clinical trial or program:

1) Assist in development of protocols: Prepare the written document from a brief outline agreed upon by the investigators and COTR; revision of the document after circulation of appropriate drafts to the investigators and the COTR; submission of protocols to the CTEP Protocol and Information Office for review and approval; prepare responses to the NCI Protocol Review in collaboration with the involved investigators and/or COTR; and distribute approved protocols, as appropriate.

2) Assist in the preparation and design of data forms, beginning with a list of CDEs and/or requirements provided by the COTR and/or the study chairperson; circulation of drafts of proposed forms to investigators and the COTR for comment/concurrence/revision; revision, duplication, and distribution of data forms to the appropriate investigators. caBIG™ standardized CDEs and CRFs will be used as much as possible in these trials.

3) Provide statistical input into all aspects of protocol design, including critique of study design from a statistical perspective, and calculation of appropriate sample size requirements.

4) Design and implementation of procedures for patient registration including procedures for randomization; maintenance of logs of patient randomization and/or registration; design and implementation of procedures for confirming registration.

5) Design and implementation of procedures to track the submission of forms as indicated by the requirements of specific protocols.

6) Design and implementation of procedures to ensure that the studies and investigators conform to regulatory guidelines.

7) Design of appropriate computer databases for the storage and analysis of patient data submitted to the central office, based upon the elements contained on data forms specific to each protocol.

8) Provide instruction and orientation in the conduct of clinical trials (when deemed necessary by the COTR) to the data management personnel located at the research facilities conducting the clinical trials; this would include preparation of instructional materials and conduct of orientation sessions as needed to maintain a high standard of submitted materials.

9) Receive and process all data submitted from the research groups and/or organizations; this includes review for timeliness, completeness and accuracy.

10) Query the investigators and/or research site for missing data.

11) Maintain computer files and back-up files of pertinent clinical trial data in a manner representing current best standards which permit utilization of appropriate analytical methods. Maintain back-up copy of electronic files of data which make up the data base when requested by the COTR.

12) Maintain accurate and up-to-date electronic copy documentation of the structure and maintenance of all computer files, as well as data management procedures.

13) Provide interim, final, and other necessary data analyses; capabilities and requirements in this regard should include all standard statistical techniques utilized in the analysis of cancer clinical trials (e.g., response rates, actuarial survival curves, multivariate analysis of prognostic factors, and other standard statistical techniques).

14) Prepare regular (as defined by the COTR) study status reports by protocol for use by the clinical trials organization. Analyses must include as a minimum, trial accrual, eligibility, and evaluability information, as well as comprehensive reporting of treatment-related toxicity. As indicated by specific protocols, presentation of outcome data (open or blinded) may also be required.

15) Maintain electronic records of protocol compliance, timeliness of forms submission, and quality of data submission, when appropriate by institution, as measures of quality of investigator participation.

16) Report promptly toxicities of investigational agents to the Investigational Drug Branch (IDB), in accord with IDB policies.

17) Receive electronic files from incumbent and promptly carry out all procedures to ensure continuity of management of the studies and data bases involved.

18) Identify and promptly report protocol violations to the study chair.

19) Arrange meetings of working groups associated with particular clinical trials for the purpose of data review (e.g., pathologists, surgeons, medical oncologists, etc.). It is anticipated that most meetings will be held in the Bethesda, Maryland area.

20) Maintain electronic lists/files of investigators, study reports and publications. Maintain documentation of all procedures employed in the conduct and analysis of clinical trials supported under this contract.

21) Assist the COTR and/or investigators in the preparation of manuscripts, abstracts or other presentations related to specific clinical trials supported by this contract, including preparation of drafts, revision of drafts, and preparation of final copy.

22) Provide scientific and administrative information relevant to the clinical trials supported by this contract to the COTR or involved investigators upon request.

23) Conduct site visits and audits upon request of the investigators.

Option 2 – CTEP Project Management:

Each 1 of the 6 Project Management options (Options 2A – 2F) will conduct similar work and are separated into blocks of hours of support to enable CTEP to have the flexibility to

increase the effort in project management for CTEP trials as the CTWG components are implemented. Project Management tasks include:

1) Coordinate, track and manage CTEP-sponsored protocols in development to assure timely completion of required activities from Concept/LOI approval through protocol activation, accrual, and closure. Target timelines are 210 days from LOI receipt to protocol activation for phase 2 studies and are 300 days from concept receipt to protocol activation for phase 3 studies. Note the contractors will NOT be directly responsible for safety, scientific, regulatory or administrative review of the protocol, but rather will facilitate and manage the protocol development and review process to assure that it is completed in a timely and efficient fashion. It is anticipated that this requirement will be completed by non-physician trial coordinators. These managers will have responsibility for a specific grouping of trials to be determined by the COTR(s). As a frame of reference, 122 LOIs (90 from non-Groups and 32 from Groups), 27 Concepts (all from Groups) and 176 protocols (130 from Groups and 46 from non-Groups) were approved during FY09. To support the protocol development process the Contractor shall:

a) Interface with all trial development participants including NCI and extramural professional and support staff; NCI contractors; and FDA and pharmaceutical company personnel to shepherd a study through the protocol development process in the most efficient, effective and timely fashion possible.

b) Establish a project timeline for each protocol and identify/track key and appropriate sub-task milestones and responsible study development participants and their contact information (i.e. telephone, fax, e-mail).

c) Utilize existing NCI and site databases to capture and or track relevant milestones, key-words and study development participants (i.e. CTEP-ESYS, CTSU RSS, CIRB IRB Manager, Group databases).

d) As necessary capture pertinent information in a local database suitable to meet the project needs.

e) Collaborate with other NCI contractors involved in the protocol development process (i.e. PIO, CTSU, CIRB) to minimize redundancy and gaps in supporting the protocol development process. It must be emphasized that Project Managers are not intended to replace or duplicate activities currently being performed by other CTEP contractors or government staff, but rather it is intended to provide proactive coordination and oversight to assure that protocol development and implementation timelines are met.

f) Communicate with study development participants (i.e. professional reviewers, support staff, study coordinators) via email, telephone, fax or other suitable mechanisms.

g) Arrange teleconferences and or meetings to resolve critical issues.

h) Participate in appropriate meetings to maintain 'situational awareness' of current or upcoming trials (i.e. PRC, Concept Review, IDB LOI Review).

i) Prompt and/or remind study development participants to address issues in a timely fashion.

j) Develop prompts or triggers to alert appropriate personnel (i.e. study participants, NCI/extramural site leadership) regarding any potential or actual delays.

k) As needed, escalate awareness of any issues that might delay trial development to the appropriate NCI and extramural site leadership.

l) When approved by NCI leadership, adjust/modify protocol development timelines to accommodate unforeseen delays.

m) Develop standardized procedures to optimize protocol development process.

n) Recommend policies to streamline the protocol development process. All policies must be approved by the NCI.

o) By collecting information regularly, maintain up to date electronic reports documenting current status of each protocol, which shall be a working/living document that gets updated in real-time and can be accessed on the share drive. The reports shall be user friendly and highlight and prioritize any potential or actual delays in protocol development or accrual. The reports shall be able to be sorted by trial type (i.e. phase, lead site participant, disease, CTEP coordinator). Reports shall reflect actual versus expected timelines. Project Managers will review these reports at least weekly with CTEP lead investigator/reviewer.

p) Develop metrics to assess overall performance of the project based on trial type to identify trends, bottle-necks and successes.

q) Identify potential roadblocks or impediments to the clinical trial development process and recommend solutions.

r) Identify and implement any other tasks and or processes that will facilitate and improve the protocol development process.

s) Monitor accrual and provide reports that reflect actual versus planned accrual rates.

t) Identify potential impediments to achieve accrual goals (i.e. eligibility criteria, drug supply, scientific interest/results from other trials, Pharma contracts).

u) Provide suggestions to address protocol specific and global impediments to patient accrual.

v) Monitor and track patient demographics (race, ethnicity, gender, age) compared to the expected study patient population.

w) Monitor protocol amendment development, review and decision timelines.

x) Develop standardized procedures to optimize protocol amendment process.

**Government Furnished-Information (Reference Websites):**

The following websites are being provided for use as a reference for this requirement:

Cancer Therapy Evaluation Program: http://ctep.cancer.gov/

Coordinating Center for Clinical Trials: http://ccct.cancer.gov/

Clinical Trials Working Group: http://restructuringtrials.cancer.gov/

caBIG™ : https://cabig.nci.nih.gov/

Glossary of Terms:
http://gforge.nci.nih.gov/docman/view.php/401/12075/CTMS_glossary_v2.doc

Common Data Elements (CDEs):
https://cabig.nci.nih.gov/workspaces/VCDE/Data_Standards/

CDE Browser: https://cdebrowser.nci.nih.gov/CDEBrowser/

CTSU: https://www.ctsu.org/public/

CTSU/ RSS: https://www.ctsu.org/public/rss2_page.aspx

**Anticipated Period of Performance:**

The anticipated period of performance, inclusive of options for this proposed acquisition is March 1, 2011 through February 28, 2018 (if awarded to a new Contractor), or May 1, 2011 through April 30, 2018 (if awarded to the incumbent Contractor).

**Capability Statement/Information Sought:**

Interested, qualified small business organizations should submit a tailored capability statement for this requirement, not to exceed 20 single-sided pages (including all attachments, resumes, charts, etc.), presented in single-space and using a 12-point font size minimum, that clearly details the ability to perform the aspects of the notice described above. 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, as well as the eligible small business concern's name, point of contact, address and DUNS number.

**Information Submission Instructions:**

All capability Statements sent in response to this Small Business Sources Sought notice must be submitted electronically (via email) to John R. Manouelian, Contracting Officer, at manouelj@mail.nih.gov in either MS Word or Adobe Portable Document Format (PDF), by April 8, 2010, 3:00PM, EST. All responses must be received by the specified due date and time in order to 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 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. Respondents will be added to the prospective offerors list for any subsequent solicitation. 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 information in any resultant solicitation(s).