Notice Number: HHS-NIH-NCI-SBSS-ETSB-11000-77

Title: Inherited Bone Marrow Failure Syndrome Support Services Contract

This is a Small Businesses Sources Sought notice (SS). 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 business; HUBZone small businesses; service-disabled, veteran-owned small businesses, 8(a) small businesses; veteran-owned small businesses; women-owned small businesses; or small disadvantaged business; 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.**

The NAICS code for this project is 541990.

The small business size standard is $7M.

Background:

The Division of Cancer Epidemiology and Genetics (DCEG's) research focuses on discovering genetic and environmental determinants of cancer and identifying new approaches to cancer prevention. This project is for the re-competition of contract N02-CP-65501 with Westat, Inc., which was awarded on a competitive basis for a five year period. This Small Business Sources Sought (SBSS) is for information and planning purposes only and shall not be construed as an obligation on the part of NCI

Purpose:

The purpose of this support will be to provide support services for the Inherited Bone Marrow Failure Syndromes (IBMFS) Program which involves large numbers of families in which there is proband with a cancer-prone IBMFS, and includes both family studies at the NIH Cancer Center and field studies of members of large families. The NCI is seeking capability statements from all eligible small businesses concerns in performing the tasks/duties herein. Based on the responses received from this SBSS notice, the proposed project may be solicited as a Small Business Set-Aside. 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.

Project Requirements:

The project will require a contractor to provide support services for the Inherited Bone Marrow Failure Syndrome (IBMFS) Program within the Clinical Genetics Branch, Human Genetics Program, Division of Cancer Epidemiology and Genetics, National Cancer Institute. The IBMFS Program encompasses several rare, well-characterized bone marrow disorders, each with a high degree of neoplasia. It involves large numbers of families in which there is a proband with a cancer-prone IBMSF, and includes both family studies at the NIH Clinical Center and field studies of members of large families. The Contractor shall perform some or all of the following activities as may be specified by the NCI Project Officer in the conduct of each study.

A. Study Initiation and Liaison

1. Determine parties whose cooperation and approval is necessary for implementation of the study (e.g., federal or state agencies, universities, hospitals, medical offices, laboratories, other NCI Contractors, etc.).

2. Arrange for communication and meetings between the NCI research investigators and agents for those parties whose cooperation or approval is needed.

3. Attend such meetings, provide background information required, and take appropriate action on recommendations as applicable. Document proceedings and action items as requested by NCI staff.

4. When multiple institutions are involved in a multi-center study, develop procedures to insure that the investigation is being conducted in a standardized manner at all sites.

5 Obtain information required to determine the capabilities of potential collaborating institutions and/or investigators, number of eligible study subjects, etc.

6. Make arrangements for document translations as necessary to initiate studies in foreign settings or to enroll family members from foreign sites.

7. Negotiate and manage with collaborating centers, institutions or companies all financial and administrative matters related to the collection of data and biological specimens. This includes subcontracting, purchase of equipment, and other forms of compensation.

8. Assist in the development of protocols and completion of forms as may be required for various committees, such as Institutional Review Boards. Attend such committee meetings if requested by the Contracting Officer Technical Representative (COTR).

B. Development of Study Materials and Procedures

9. Prepare, pretest, and produce data collection forms (e.g., abstract forms, follow-up forms, coding forms, questionnaires and exposure assessment forms, biospecimen collection and processing forms, tracking forms, etc.). Questionnaires may be either paper or computer-assisted.

10. Prepare training programs and materials for abstractors, interviewers and other study personnel. Conduct training for new staff in a timely manner and update training for all staff as needed, but not less than annually.

11. Prepare procedure manuals for nurses, genetic counselors, research assistants, phlebotomists, abstractors, coders, interviewers, tracers, supervisors, data editors, and other personnel as needed.

12. Prepare procedure manuals for the collection of biological specimens, shipment of biological specimens, submission of specimens to repositories, and tracking of specimens and laboratory results.

13. Prepare manuals for obtaining and handling medical records, pathology specimens and reports, submission of pathology specimens for review, and collection of death certificates or cause of death. This includes coordinating systematic reviews and coding of reports or of surgical pathology specimens (i.e., central pathology review) by appropriate nosologists, clinicians or pathologists.

14. Prepare and update manuals of usual operating procedures relative to evaluating, managing and coordinating follow-up of members of high risk families.

15. Prepare nursing assessments and plans for clinical evaluation of individuals at high risk of cancer because of family history or specific exposures.

16. Contribute to preparation of newsletters, brochures, and other large mailings for families participating in ongoing studies.

17. Assist in the preparation of study-specific packages for OMB, IRB, and/or OHSR [the Office of Human Subjects Research, formerly known as OPRR] reviews.

18. Translate data collection instruments or manuals into appropriate languages for foreign studies. This may include, at the request of the COTR, reverse translation of these materials back into English, to insure that the meaning and intent of the original document has been preserved.

19. Coordinate the collection, processing, storage and shipment of biological specimens, tracking of samples sent to collaborating laboratories as well as sample test results. Serve as liaison between the COTR and the staff of various CGB and DCEG support laboratories and biospecimen repository facilities.

20. Arrange for the laboratory analysis of biological materials collected from study participants, preparing subcontracts as necessary to accomplish this goal. Assess the capabilities and quality control procedures of various laboratory facilities, and assist the COTR in selecting high-quality providers of lab services. Monitor quality control of ongoing specimen analyses. Integrate laboratory test results into study data bases.

21. Since many of these activities will be essentially the same form across all disorders and all substudies, systems should be designed in a flexible, modular, generic fashion, so that they may serve as standard "shells" or "templates" which will be readily modified for use in future studies.

C. Subject Identification, Selection, and Tracing

22. Identify study subjects who meet NCI criteria for being included in studies, particularly women, minorities, and children, as appropriate. Plan the method of identification of study subjects and make recommendations on the feasibility of alternative sampling designs. Typical study subjects include:

    a. All members of families in which several members have a particular condition of interest identified by the investigators.
    b. All patients with a newly-diagnosed relevant disorder occurring in a patient or family member with the appropriate genetic disorder.
    c. Patients treated for an initial symptom who are being followed for the occurrence of cancers or other treatment-related outcomes of interest.

23. Trace study subjects and locate them or their next of kin for interview, examination and/or collection of study-specific biological specimens.

24. Maintain current contact information for study participants and their health care providers, updating existing computer records containing contact information in an ongoing fashion, and tracing selected family members who have been lost to follow-up.

D. Interview and Abstracting Data Collection

25. Obtain the necessary permissions/consents and then interview subjects or their family members using mail, telephone, or in person questionnaires. Verify a sample of completed questionnaires. Questionnaire content will be provided by the NCI COTR and will be jointly modified, if necessary.

26. Abstract, photocopy, microfilm or computerize records (clinic or office medical records, hospital charts, vital records, job records, etc.). Maintain quality control over the abstracting or copying process. Verify the accuracy of an appropriately

sized sample of abstracts (determined with the COTR) by independent re-abstracting. Accuracy is to be maintained at a 98% level.

27. Procure death certificates from vital records departments. The Contractor shall be responsible for determining details of and payment for death certificate procurement. The Contractor shall also be responsible for complying with requirements regarding retention of such records in consultation with the COTR.

28. Purchase other data, materials, and/or services as directed by the COTR.

29. Validate exposure or disease histories obtained in interviews by obtaining copies of original records. This includes maintaining a management tracking system for the retrieval of such records.

30. Obtain copies of imaging studies, radiographs, or other clinical tests (e.g. electrocardiograms) and the associated reports as needed for specific studies.

31. Oversee field activities that result in data collection.

32. Implement management tracking systems that monitor the incoming flow of data, the editing of data, changing/modifying data, etc., to permit preparation of descriptive summary reports related to these activities.

E. Clinical Support Activities

33. Provide skilled nursing and genetic counseling support for family studies. This includes obtaining detailed family and personal medical histories, developing and updating pedigrees, educating and counseling patients, triaging inquiries regarding study participation, presenting inquiries and pedigrees at CGB IBMFS meetings for consideration of protocol eligibility, and providing clinical support to the NCI investigators.

34. Arrange admission (both Outpatient and Inpatient) to the NIH Clinical Center for those high-risk individuals and their family members identified by the COTR or NCI investigator. If family members are unable/unwilling to travel to NCI, arrange for family members to be seen by Contractor and/or NCI personnel in local facilities, including obtaining permission to use the facility as necessary.

35. Arrange for and coordinate clinical and research diagnostic studies and laboratory evaluation of NCI outpatients and study participants, both at the Clinical Center and in the patients' home communities, as directed by the COTR or designated NCI investigators, at the patient's convenience. Provide information to the patients about all scheduled procedures and any necessary preparations. Answer clinical questions or direct them to the appropriate NCI investigator.

36. Arrange for collection of biospecimens (including, but not limited to blood, tumor tissue, normal tissue, skin, urine, bone marrow, etc.) either at the Clinical Center or in the patients' home communities.

37. Obtain original pathology slides and blocks with associated pathology reports for review by study pathologist(s). Disperse to the appropriate study pathologist with appropriate clinical history and local pathology report(s). Maintain up-to-date inventory of requested, received, and dispersed slides and tissue blocks. Track results of pathology review, and code data for entry into computerized databases after approval by the NCI investigator(s).

F. Specimen Collection, Processing, and Shipment

38. Provide a person or persons experienced in the arrangement and coordination of all aspects of biological sample collection, handling, transport, storage, distribution, analysis and information processing. Develop subcontracts as necessary to complete these tasks

39. Train phlebotomists and others who will be involved in biospecimen collection. These individuals must be familiar with Universal Precautions required for the safe handling of potentially hazardous biological materials.

40. Collect and safely deliver intact biologic specimens (blood, urine, tumor, etc.) in appropriate shipping containers and under appropriate shipping conditions to designated laboratories or investigators for storage and/or analysis. This includes transport of biologic specimens to and from international sites with necessary custom clearances. Shipping must be done in a manner that will permit rapid and reliable tracking of specimens that go astray. Verify safe arrival of specimens to the destinations.

41. Arrange for specimen storage and/or standard laboratory tests or assays on biologic specimens (in one or several laboratories or repositories), as designated by the COTR or NCI investigator(s).

42. Maintain an onsite repository of selected biological materials and specimens, as requested by the COTR. These might include paraffin blocks, microscope slides, clinical photographs, etc , obtained from study participants. The contents of, and transfers into and out of, this storage facility should be easily accomplished through computerized tracking tools.

43 Perform other support activities involving specimen collection, storage, and/or dispersal to laboratories as requested by the COTR or NCI investigator(s).

44. Report to the appropriate COTR all irregularities, delays, losses, deteriorations, unplanned defrostings, accidents, mishandlings, errors, discrepancies, and

inefficiencies connected with any specimen collection, delivery, storage, or testing activity as soon as it becomes known to the Contractor.

45. Obtain all necessary laboratory reports of results or progress.

46. Interface with, use and program NCI's BSI-II biospecimen repository data base. Monitor the status, and manage the utilization of biological samples collected from CGB study participants and stored in this system. Generate reports as requested by the COTR. This software program and its attendant documentation will be provided by the Government.

47. Interface with, download and store data from the NIH Clinical Center medical information to the extent permitted by the NIH, particularly reports from Clinical Center Laboratories, the Department of Pathology, and the Diagnostic Imaging facility, as well as consultants within the NIH. Details of this activity will be developed when available.

G. Data Preparation

48. Develop or select disease, occupation, industry, demographic, geographic, and exposure coding schemes in consultation with NCI staff.

49. Code all data generated by CGB studies into computer readable form. Verify at least a 10 percent sample of the coding by independent re-coding. Summarize and describe the differences between the two sets of data. Accuracy is to be maintained at 98% level.

50. Develop documentation of codes used and listings of unusual or aberrant responses.

51. Enter coded information into appropriate computer data bases. Verify all or at least a 10% sample (at the discretion of the COTR) by data re-entry (e g , key punch and verification), using a different data entry person. Summarize and describe the differences between the two data sets. Accuracy is to be maintained at 98% level.

H. Computer Programming and Data Processing

52. Use modifiable data management and tracking systems that can be applied across studies. Minimize creation of unique study-specific management and tracking systems. Such systems must be approved by the COTR. Systems should be compatible with the Biospecimen Inventory II, Laboratory Information System of the Core Genotyping Facility, FAIR/FAIRVIEW or others as appropriate and specified by the COTR.

53. Provide capability of creating data sets with up to thousands of study subjects and tens of thousands of variables in SAS, STATA, SPSS, Excel, or other programs as requested by the COTR. All data processing, storage, and transfer must be in compliance with US government standards of privacy and confidentiality.

54. Maintain adequate backup of study data and secure storage of backup media Frequency of backup shall be determined by the Contractor and the COTR.

55. Use the DCEG system FAIR/FAIRVIEW for the maintenance of family studies data. Ensure that nursing personnel and support research assistants all are trained in the use of FAIR/FAIRVIEW and have access to FAIR/FAIRVIEW. Provide pedigrees using PROGENY, CYRILLIC, or other software as designated by the COTR.

Note: FAIR/FAIRVIEW is a proprietary relational database software package developed for use by DCEG, NCI. The government shall provide the FAIR/FAIRVIEW software for its use to the Contractor. The Contractor shall provide the appropriate personal computers and time for training of personnel to use FAIR/FAIRVIEW.

56. Enter coded information onto suitable computer devices. Verify entry by 100 percent re-keying (or a 10% sample at the discretion of the COTR).

57. Prepare edit programs, edit data, and correct computer files where necessary. Describe findings in summary form.

58. Update files with follow-up data, error corrections, etc. as directed by the COTR.

59 Prepare data sets for transfer to personal computers, as specified by the COTR.

60. Respond to priority requests and changes of resource allocations rapidly, by appropriate activities and use of personnel, at the direction of the COTR.

I. Study Monitoring, Quality Control, and Reporting

Quality control of all aspects of data collection and management is a crucial activity. NCI will carefully review studies to ensure that the data are sound. At the beginning of each study, the NCI Investigator who is responsible for the study will approve a plan prepared by the Study Manager for the schedule and contents of reports needed for quality control. Quality controls will require that the Contractor:

61. Document each step in a specific study and maintain, in an orderly arrangement, all relevant material so that any aspect of a study may be reviewed and evaluated by the NCI staff at any point in time. Involved are the following:

    a. Type letters and prepare forms and other documents necessary in the conduct of a study.

b. Duplicate study documents when the original sources cannot be retained.
c. Maintain a filing system of all materials relevant to a particular study, cross referenced in a manner so as to make all of the material easily accessible. These materials shall be maintained under security in accordance with requirements of the Privacy Act as it applies to Contractors. Data for family studies shall be maintained in accordance with requirements of a Certificate of Confidentiality.
d. Maintain a log of decisions made during each study that affect the design, conduct, or analysis. Each entry shall include a brief explanation and date of the problem, the decision made, and the name of the NCI staff member who authorized the change.

62. Develop and use internal record-keeping procedures for assessing the progress and status of data collection, preparation and entry. These record systems may be paper files or computer systems.

63. Monitor and document the performance and progress of any work done under subcontract in the performance of a study.

64. Develop quality control procedures for the handling of biologic specimens specific for the needs of each study.

65. Report verification rates, discrepancy rates, and error rates for data collection, preparation and keying following the schedule agreed upon with the COTR. Any unusual problems shall be brought immediately to the attention of the COTR.

66. Provide monthly, annual and final technical progress reports and monthly budget reports, as specified by the NCI COTR and/or designated representative.

J. Family Medical Record Room and Database Maintenance

67. Store the medical records of more than 1000 families (more than 10,000 individuals). Maintain storage system that makes misfiled records apparent.

68. Provide physical access to patient medical records within thirty (30) minutes by the COTR and designated medical personnel 24 hours a day, 7 days a week.

69 Restrict access to the family medical records to authorized personnel. Any transport/delivery of records outside of the record room must be via secured or locked container. Maintain a tracking log of records that leave the medical record room. Insure that all Contract personnel who have access to these records have been satisfactorily trained with regard to issues of data privacy and confidentiality that are central to appropriately run human subjects research protocols. Systematically follow up records that have been checked out to ensure timely return to the record room.

70. Add new family data to the existing computerized database (FAIR/FAIRVIEW) of records from high-risk families. The Contractor shall establish procedures to ensure that data are entered into FAIR/FAIRVIEW in a timely and accurate manner.

71. Maintain medical records with content and order as directed by the COTR. File reports and other documents in the medical records within one business day of receipt.

72. Maintain pathology slide and paraffin block collection and related databases.

73. Maintain clinical photograph database. These may consist of both paper prints and digital images.

74. Maintain photographic slides and prints in easily retrievable archival quality storage in the Medical Record Room.

75. Maintain referral/consult records as specified by the COTR.

K. Transition

During the first four weeks of the contract, the Contractor shall effect a smooth transition of the management and operations of the existing support provided by the current Contractor to the new Contractor without prolonged interruption of the normal day-to-day provision of support services including:

76. Study initiation, liaison and administrative management;
77. Preparation of study materials and procedures;
78. Identifying and tracking study subjects;
79. Interviewing and abstracting data collection;
80. Clinical support activities;
81. Laboratory aspects involving biologic specimens, tests and laboratory data;
82. Data preparation;
83. Computer programming and data processing;
84. Study monitoring, quality control and reporting;
85. and medical records room and database maintenance

During this period, the Contractor shall establish a working relationship with the new Contractor. In particular, transfer of all current data files shall occur within two weeks of contract award.

Anticipated Period of Performance:

The anticipated period of performance, inclusive of options for this proposed acquisition is January 15, 2011 – January 14, 2016.

Capability Statement/Information Sought:

Small businesses possessing experience and demonstrated capability to accomplish the aforementioned requirements and level of effort are to supply pertinent information in sufficient detail to demonstrate their ability to perform the required services. Information furnished must not exceed 20 pages (12-point font minimum), including all attachments, resumes, charts, etc ; and should include an outline of previous or similar projects performed. All responses must include an indication of current certified small business status, and clearly marked on the first page of the 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 Businesses Sources Sought notice must be submitted electronically (via email) to Michael Welsh, Contract Specialist at welshmi@mail.nih.gov and Annmarie Keane, Contracting Officer at ak155a@nih.gov in either MS Word or Adobe Portable Document Format (PDF) by April 5, 2010, 3:00 PM, EST. All responses must be received by the specified due date and on 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 the information provided by respondents for any purpose deemed necessary and legally appropriate. Any organization responding to this notice should ensure its response is complete and sufficiently detailed to allow the Government to determine the organization's qualifications to perform the work. Respondents are advised the Government is under no obligation to acknowledge receipt of the information received or provide feedbacks 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).