

Notice Number: HHS-NIH-NCI-SBSS-ETSB-11002-77

Title: Coordinating Center for Continuation of Follow-up of DES-exposed Cohorts

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-65502 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 the support will be to coordinate the continued follow-up of established DES cohorts (mothers, daughters, sons, and granddaughters) to measure cancer incidence and mortality, especially cancers of the breast and the reproductive system as the offspring enter a period of increasing cancer rates. 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 coordinate the continued follow-up of several cohorts of women and men who were exposed to diethylstilbestrol (DES) in utero. Disease outcomes will be ascertained by means of questionnaires, medical record review, state cancer registries, the

National Death Index, and tissue samples as appropriate.

The work will include but not be limited to, developing study materials and manuals, acting as liaison with NCI and their contractors, and preparing and processing questionnaire, outcome validation, state cancer registry and NDI, and death certificate data. Specific activities to be performed include the following:

a. Liaison

- 1) Establish contact with each of the up to five field centers selected by NCI.
- 2) Establish contact and coordinate activities as needed with NCI's computer programming support services contractor.
- 3) Assist in arranging communications or meetings, as needed, between the NCI Contracting Officer Technical Representative (COTR) and field center staff.
- 4) Attend and report on such meetings, provide background materials as needed and take action on recommendations in consultation with the NCI COTR.
- 5) Respond to queries from NCI COTR. Meet in-person with NCI COTR at least quarterly.

b. Development of Study Materials and Manuals

- 6) Develop mail questionnaires to be sent to daughters and sons, and to other selected subpopulations as needed, in collaboration with the NCI COTR and field center staff.
- 7) Develop and update procedure manuals for the study, in collaboration with the NCI COTR and field center staff. Work with field centers and NCI COTR to establish standardized procedures for each of the sub-studies.
- 8) Develop and update abstract forms as needed, to record the results of clinical exams and abstraction information from medical records and pathology reports.
- 9) Assist field centers in developing cover letters, newsletters, and other materials to be sent to cohort members to enhance participation rates and assist centers in dealing with problems that arise in validating medical outcomes reported on the questionnaire.
- 10) Maintain and update the study web site (<http://www.desfollowupstudy.org/>).

- 11) Organize logistical aspects of pathology slide review for diagnoses of high grade cervical intraepithelial neoplasia, by receiving slides from field centers, and developing a tracking system for sending and receiving the slides to and from the designated central pathologist. The coordinating center will provide storage for the pathology slides returned from the pathologist or will return the slides to the field center in the case that the hospital has requested them back. The coordinating center is not responsible for the pathologist's slide review costs.
- 12) Organize logistical aspects of autoimmune disease abstract review, by receiving abstracts from field centers, and developing a tracking system for sending and receiving the abstract forms to and from the designated rheumatologist. The coordinating center is not responsible for the rheumatologist's abstract review costs. Organize logistical aspects of abstract review for other diseases, as needed.
- 13) Assist in organization of materials for package submitted to NCI Institutional Review Board.

c. Data Preparation and Processing

- 14) Receive mail questionnaires and abstract forms from field centers for data entry.
- 15) Coordinate and conduct National Death Index searches to determine vital status. Assist in reconciliation of vital status using available sources. Assist study sites in coordination and conduct of state cancer registries searches.
- 16) Code specific diseases reported on questionnaires, pathology reports and death certificates using standard ICD coding procedures.
- 17) Scan mailed questionnaires. Enter data from questionnaires and abstract forms as needed.
- 18) Edit and correct computer files as needed.
- 19) Maintain a master study file with vital status and response to 1994, 1997, 2001, 2006 and next follow-up questionnaires and respond to requests by NCI COTR.
- 20) Transmit computerized data files containing edited, corrected data to the NCI COTR or representative at the completion of each wave of follow-up, or as appropriate.

d. Monitoring, Information Management, Reporting and Documentation

- 21) Utilize a computerized information system to monitor the progress of data collection.
- 22) Initiate regular monthly telephone calls to the field centers to monitor progress and address problems during the data collection phase of the study.
- 23) During the data collection phase of the study, receive monthly reports from the field centers and provide them to the NCI COIR for review. On a quarterly basis, create a combined report from all the field centers to monitor the overall progress of the study.
- 24) Document all of the individual steps in the study and maintain orderly files of all relevant materials, so that any aspect of the study can be reviewed and evaluated by NCI staff at any time during the course of the study.

Included are the following:

- i. Type letters, forms and other documents necessary to conduct the study.
- ii. Maintain a filing system of all relevant materials, cross-referenced to permit easy access. These materials shall be stored in accordance with requirements of the Privacy Act
- iii. Maintain a log of all decisions made during the study that pertain to study design, conduct, and analysis. Examples of such decisions are criteria for selecting individual cohort members for participation in sub-studies, and coding decisions for questionnaires and medical records.

Anticipated Period of Performance:

The anticipated period of performance, inclusive of options for this proposed acquisition is April 30, 2011 – April 29, 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 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).