

Notice Number: HHS-NIH-SBSS-01011-77

Title: 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 contracts N01-CP-55507 with Trustees of Boston University, N01-CP-55508 with New England Medical Center Hospital, N01-CP-55509 with the University of Chicago, N01-CP-55510 with the Methodist Hospital Research Institute, and N01-CP-55511 with Trustees of Dartmouth College, which were 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 continue 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 continue follow-up of surviving members of an existing cohort of at least 500 women, men and their grandchildren who were exposed to diethylstilbestrol (DES) in utero. Disease outcomes will be ascertained by means of questionnaires, medical record review, and tissue samples as appropriate.

The work will include but not be limited to, mailing questionnaires to cohort members, conducting telephone interviews with study participants who did not respond to the questionnaire, validating outcomes reported on the questionnaire, analysis of resulting data, and development of a questionnaire for follow-up beyond the contract period. In addition, the work will include conducting searches of the NDI (or providing death certificates) and relevant state cancer registries. Tracing efforts and keeping addresses up to date will occur throughout the contract period. Specific activities to be performed include the following:

- 1) Conduct one questionnaire follow-up during the first year of the five-year period to ascertain disease outcome and risk factor information. [The questionnaire will be largely developed in an existing contract.] Distribute/mail questionnaires to all surviving daughters and sons. Continued follow-up of DES-granddaughters shall be undertaken by means of one mailed questionnaire to those who have reached 18 years of age and whose mothers have consented to allow contact with them. Conduct telephone interviews with subjects who did not respond to the questionnaire.
- 2) Continue tracing efforts for cohort members who have been lost to follow-up through the use of, but not limited to, credit bureaus, motor vehicle bureaus, town listings, previously known contact persons, and searches of the National Death Index. Keep addresses up-to-date, within one year, for recently contacted cohort members. Mail two newsletters or letters to cohort members during the five-year period.
- 3) Pursue plans, if proposed and approved, for the identification of individuals with documented DES exposure who have not been previously studied for inclusion in the cohort study.
- 4) Collect medical records, pathology reports, and tissue samples for disease outcomes of interest, as specified by the study Steering Committee. The Steering Committee will consist of one (1) member from each Center, a representative from the Division of Cancer Epidemiology and Genetics (DCEG) and any consumer advocates and external advisors that provide general oversight to the study.
- 5) Provide data from completed questionnaires and medical record validation to a contractor designated by NCI. Quarterly reports on data collection

progress shall be sent to NCI by email or in paper format. [It is anticipated that questionnaires will be coded and entered centrally by a contractor to ensure standardization of data items. It is also anticipated that medical records and pathology reports will be centrally abstracted, coded, and entered.]

- 6) Determine causes of death for cohort members, including mothers, who have died.
- 7) Establish and maintain quality control procedures to ensure standardization and high quality of data collection, including:
 - a) Maintain a written log or record book of decisions that affect study design, conduct or analysis.
 - b) Verify the completeness and accuracy of data
 - c) Train study personnel to follow study procedures.
 - d) Monitor the performance of field activities, by tracking response rates, workload, and completeness and accuracy of data collection.
- 8) Agree to the pooling of nonidentified data with other participants in this effort and to be involved in analyses approved by the Steering Committee. Meet one to two times per year with the Project Officers, other collaborators, and members of the Steering Committee to discuss analysis of pooled data and to decide upon procedures for dissemination of data after the completion of the manuscripts prepared from the pooled data. Participate in conference calls to discuss progress on the study as needed.
- 9) Review and comment upon the analysis. Collaborate in the preparation of manuscripts from the pooled data.
- 10) Review and comment upon the questionnaires and newsletters.

Anticipated Period of Performance:

The anticipated period of performance, inclusive of options for this proposed acquisition is September 30, 2010 – September 29, 2015.

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 in either MS Word or Adobe Portable Document Format (PDF) by December 1, 2009, 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).