

## SOURCES SOUGHT NOTICE

**HHS-NIH-NCI-SBSS-ETSB-0872-72**

**Agency/Office:** National Institutes of Health

**Location:** National Cancer Institute, Office of Acquisitions

**Title:** Collection of Discarded Cervical Cancer Screening Specimens

**Type of Notice:** This is a Small Business Sources Sought (SBSS) 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 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.

### **Background:**

Despite HPV vaccines, screening will remain central for decades to control cervical cancer. Recently, HPV testing alone or with cytology was introduced in the US as an alternative to cytology screening. However, most HPV infections are harmless and additional tests are required to identify women at highest cancer risk. With three (3) options for primary screening, and without clear strategies for triage of screen-positive women, there is great confusion about the best approach. Also, increasing HPV vaccination coverage will lead to lower disease prevalence, and force new screening approaches. Therefore, NCI plans to evaluate performance of several promising biomarkers head-to-head in a screening population. Integral to these studies are cervical specimens and clinical data among women screened.

**This Small Business Sources Sought Notice is amended to add the following:**

**The incumbent, Kaiser Permanente Northern California (KPNC), has collected HPV and cytology specimens for 55,000 women screening HPV-positive and shipped them to the NCI biorepository under its subcontract to Westat Contract HHSN261200800029C. KPNC is in the process of collecting specimens from 23,000 women under its subcontract to Westat Contract HHSN261201300016C.**

### **Purpose and Objectives:**

The NCI will obtain and store “discard” HPV and cytology specimens as well as collect the risk factor and clinical outcome data for a population-based sample of women in the cohort. These specimens are termed “discard” because they are routinely discarded soon after processing in the

laboratory that runs the cervical cancer screening tests. Instead of discarding the specimens, the NCI seeks to collect them before they are destroyed. After transferring the specimen into storage tubes, they shall be shipped to the NCI Biorepository and stored for later testing by NCI.

### **Project Requirements:**

1. As specified by the NCI protocol, the Contractor will sequentially identify within their routine laboratory practices samples from 20,000 women age 25 and older undergoing cervical cancer screening. For this collection, the Contractor will pull the specimens from short-term storage prior to the planned discard of HPV and cytology specimens for these women.
2. As specified by the NCI protocol, the Contractor will sequentially identify within their routine laboratory practices 27,000 women age 25 and older who test HPV-positive in cervical cancer screening. For this collection, the Contractor will pull the specimens from short-term storage prior to the planned discard of HPV and cytology specimens for these women.
3. As specified by the NCI protocol, the Contractor will create and update monthly a SAS database of specimens that protects against release of identifying information and includes study ID and linkage of specimens to women and their clinical characteristics/cervical outcomes, prior to and after enrollment.
4. As specified by the NCI protocol, the Contractor will transfer HPV and cytology specimens to storage tubes. The Contractor will process HPV specimens under conditions specified by the NCI that ensure no cross-contamination of specimens and store them frozen in a new transport tube before shipping. Cytology specimens will be processed and aliquoted as needed into new transport tubes and stored either frozen or at ambient temperature. Specimens will be appropriately labeled using a randomized non-identifiable study ID.
5. Within one (1) month of collection the Contractor will send all specimen aliquots to either the NCI Biorepository or another recipient designated by the NCI Contracting Officer's Representative (COR). The Contractor will ship specimens at appropriate temperatures (ambient or frozen) as specified by the NCI protocol.
6. As specified by the NCI protocol, the Contractor will send all women selected for the study an opt-out letter and track responses.
7. The Contractor will use existing laboratory and clinical datasets within the integrated health services delivery system to deliver the following data to NCI: date of birth, STD information (chlamydia, HIV, gonorrhea), hormonal contraception use, smoking status, BMI, and entire history of HPV, Pap results, and all coded cervix histology results (from biopsy, excisional procedures or hysterectomy), previous and future enrollment status. Cervix histology results not previously coded will be coded for the purposes of this study.

### **Anticipated Period of Performance:**

The anticipated period of performance for this requirement is a one-year base period and three 12-month options.

### **Capability Statement/Information Sought:**

We encourage small businesses to submit a capability statement which will be considered by the agency. 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 5 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 sent electronically (via email) to Jame Chang, Contracting Officer at [jame.chang@nih.gov](mailto:jame.chang@nih.gov) and Jill Johnson, Contracting Officer at [jill.johnson2@nih.gov](mailto:jill.johnson2@nih.gov) in either MS Word or Adobe Portable Document Format (PDF) by March 14, 2016, 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 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.