Sources Sought Notice No.: HHS-NIH-NCI- SS-ETSB-01007-74

Title: Resource for the Collection and Evaluation of Human Tissues and Cells from Donors with and Epidemiology Profile

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 concerns; (2) whether there are small businesses HUBZone small business, service-disabled, veteran-owned business or small disadvantaged business; 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 622110
The small business size standard is $34.5 million in annual receipts.

Background

This project is a projected recompetition of an existing contract which provides human specimens from donors with histopathology and epidemiology data linked to tissues from subjects with cancer, pre-cancerous conditions, non-cancer donors and hospitalized and non-hospitalized control volunteers.

This work is currently being conducted under contract HHSN261200577000C held by the University of Maryland, Baltimore.

Purpose and Objectives

The purpose of this procurement is to collect malignant tissues and adjacent and uninvolved target-organ tissues plus blood, blood components and urine from cancer patients at the time of surgery and blood, blood components, urine and other fluid substances such as sputum from normal non-hospitalized matched controls, accompanied by completed questionnaires containing occupation, health and social histories of each volunteer.

As part of the work under this potential contract semiannual, annual and a final technical report are expected.

Project Requirements

Major tasks required of the Contractor include the following:

A. <u>Recruitment of and Specimen Collection from Case-Control Participants:</u>

1) Document the relevant patient populations enrolling annually in the medical

institutions in Baltimore, Maryland and surrounding counties in the metropolitan vicinity that will be targeted as potential participants in the patient accrual and specimen collection efforts for case-control studies of cancers of the lung, prostate, liver and the pancreas Obtain the necessary approvals and written agreements (i e , Study protocol; consent forms, etc,) for the study activities from Internal Review Boards, Chairpersons, Division Heads and key personnel (surgeons, pathologists, etc) to insure the cooperation of essential Units and Departments (e g , Admissions, Pulmonary Care, Radiotherapy, Surgery, Pathology, Histology, etc) and personnel (where necessary)

2) Continue (via informed consents) the accrual of a minimum of 2000 (500 each) of **lung cancer** cases before or ASAP after diagnosis and prior to the beginning of therapy from male and female, Caucasian and African-American patients and population-based non cancer controls matched by age, gender, race, and locality: specifically: Baltimore, Maryland and surrounding counties in the metropolitan vicinity Collect malignant tissue specimens and adjacent, uninvolved normal tissues; whole blood, plasma, serum, bully coats, and urine from each enrolled patient that goes to surgery and provide a completed questionnaire administered to each cooperative enrollee including all relevant information available in the individual medical records.

3) Complete the accrual of a minimum of 600 cases (120/year) of **prostate cancer** and 600 population-based non cancer controls (120/year) frequency-matched to cases by gender, age and race. Collect malignant tissue specimens and adjacent, uninvolved normal tissues from each enrolled patient that goes to surgery. The subjects should be of Caucasian and Afro-American origin and from the same general locality (specifically, Baltimore, Maryland and surrounding counties in the metropolitan vicinity). Controls recruited for this study and the liver and pancreatic cancer studies are shared with the lung cancer study and are included in the targeted number for population-based controls in the lung study.

4) Continue the accrual of a minimum of 500 of primary **hepatocellular liver carcinomas** (HCC), (100/year), 1000 patients with chronic liver disease (CLD) (200/year), and 1000 population controls (200/year) via the common eligibility for the lung, prostate, liver and pancreatic cancer case control studies from Caucasian, African-American and Asian-American patients and population-based non cancer controls frequency matched by gender, race, and locality. The HCC cases and chronic liver disease cases will require a custom designed liver questionnaire (See attached) while the population controls will receive the current questionnaire for the lung/prostate studies, Collect blood (including plasma, serum, and buTTY coats) /urine and cheek swabs from all subjects and cancer associated tissue from approximately 20% of HCC patients undergoing surgery

5)Following the receipt of written approval from NCI-IRB and your local IRB, initiate the accrual of a minimum of 500 primary **pancreatic cancer** cases (100/year) of Caucasian and African-American origin, 250 cases of chronic pancreatitis and 500 population-based controls matched by age, gender, and race.

6) Collect from all participants completed NIH designed epidemiology questionnaires, administered via informed consent and computerize in a second NIH designed and provided patient information data base. Maintain and frequently update the epidemiology database to provide periodic reports as requested by the Project Officer

7) Collect whole blood from all participants and prepare blood components, i.e., red blood cells, white blood cells, serum and/or plasma as requested by the Project Officer. Also provide urine from lung, prostate, liver and pancreatic cancer cases and controls at the time of entry into the study, and when surgically available, specimens of tumor and uninvolved, normal appearing adjacent tissues at the time of surgery, from all case-control cancer patients. **Package these specimens for immediate or specified delivery intervals to NIH (As described in Deliverables).**

8) Receive, prepare and submit lists of cases selected and provided by the Project officer from the accumulated cases in the study databases for survival searches via the Veteran's Administration Patient Database, Social Security Database, and/or the CDC National Death Index systems

9) Obtain as frequently as needed from the State of Maryland DMV records of licensed drivers to be used to identify and locate potential volunteers as population controls. Maintain these records as reasonably and efficiently functional up to-date databases (renewed with a frequency to reflect the current populations) in the specific municipalities from which the subjects are being recruited for the case-control studies.

B. <u>Multi-Organ Patient Accrual and Tissue Collections:</u>

In the previous years of this project Multi-Organ tissue collections from all cooperating cases going to surgery and autopsies of non cancer patients represented the primary focus of the collection activity. With the establishment of case-control studies in 1996, this aspect began to be de-emphasized. Then in 2005 it was reduced to the secondary status of collections from mostly those cases that do not qualify for specified case-control cancer types or specified, limited collections of non active case-control cancer types (esophagus, colon, breast, etc.) using the original questionnaires that are now inactive.

(a) In the current contract, the questionnaires for the two collection categories have been merged. Whenever specified cancer types targeted for case control studies agree to participate but are excluded due to criteria failure, collect the specimens of lung, prostate, liver, and pancreas tissues and fluids (e.g., whole blood and blood (including plasma, serum, and buffy coats), urine, and pleural fluids, or a combination of these to a minimum of 50 donors per annum at the time of either pre-surgical diagnosis or surgery, from patients with these cancers but classified as "ineligible for case-control".

(b) Prior to the approval of a Case-Control study of pancreatic cancer, collect a minimum of 100 (per year) of primary pancreatic cases, and the adjacent (surrounding?) non cancerous, uninvolved tissue samples; also 100 cases of chronic pancreatitis tissues (including inflamed and non-inflamed areas) and blood for both plasma and serum preparations from each donor

C. Epidemiological Data:

(a) In accordance with NIH and OMB regulations, provide isolation and secure storage of completed hard copy questionnaire forms in the Contractor's facility. Provide hard and/or computerized copies of data, coded but without personal identifiers in the physical systems that house the contract data specified for use of the project when requested by the Project Officer.

(b) Provide (from each cooperative donor) an epidemiology profile from extracts of medical records and/or the personal information in completed, NCI-developed, epidemiology questionnaires administered (via informed consent) by trained and experienced interviewers;

(c) Store and maintain the computerized profiles (without personal identifiers) in an NIH designed, tissue-donor epidemiology database in an "Access" environment, secured according to the Privacy Act requirements

(d) Conduct interviews with case and control subjects in the field using computer tablets loaded with NIH-programmed software systems for keying in and electronic transfers to compile the data initially on desk-top servers during or after "field" applications and acquisitions.

(e) As required by the LHC investigators and requested via the Project Officer and Prepare and submit lists of select cases in the study for survival searches via the Veteran's Administration Patient Database, the Social Security Database, and the National Death Index.

(f) Provide annually updated approvals for the accrual of subjects and operation of the project in accordance with your local IRB, Privacy Act, and HIPPA regulations.

D. Solid Tissue Collections:

(a) Collect a minimum of 50 specimens from lung (1 cm^2 epithelial surface area of each specimen), liver (50cm^2 surface area of each specimen), and from prostate (lcm^2 area of each specimen), using H&E analyses to assure malignant tissue in the paraffin-embedded and the fresh-frozen tissues, and pancreas (200mg to 500mg per specimen) from patients with cancer or chronic pancreatitis by race and gender as specified by the project officer.,

(b) Provide analytical reports of collection data according to guide-lines provided by the Project Officer

(c) Classify histo-pathologically both neoplastic and non-neoplastic tissues provided to the NCI by routine light microscopy, high resolution light microscopy (1 micron sections), cytochemistry and immunochemistry as specified by the Project Officer

(d) Perform cytochemical and immunohisto-chemical assays for viruses, e.g., HIV and hepatitis B, p53 or cellular or viral proteins, e.g., hepatitis B viral X protein and surface antigen, NOS2, COX2, HPR estrogen receptors, keratin, mucus and other such

materials on collected and cultured tissues where indicated or as requested by the Project Officer.

E **Histopathological Analyses:**

Characterize and classify, histopathologically, both cancerous and non-cancer tissues delivered to the NCI:

a) Provide the diagnosis(ses), the stage, the grade and the INM status from the routine pathology reports generated and compiled by the physician and the pathologist of record for individual cases

b) Using routine light microscopy, high resolution light microscopy (1 micron sections), cytochemistry and immunochemistry perform assays to detect infectious viruses (e.g., HIV and hepatitis B), p53 or cellular or viral proteins, (e.g., hepatitis **B),** viral X protein and surface antigens, NOS2, COX2, GRPR, estrogen receptors, keratin, mucus and other such materials on collected and cultured tissues where indicated or as specified by the Project Officer;

c) When requested and in accordance with SOP's provided by the Project Officer, obtain (from histology repositories of participating hospitals, and repositories within the research project), section and leave unstained or stain (routine HE or special immunological stains as requested) paraffin embedded tissues from new cases and/or cases previously processed for the project (as specified by investigators via the Project Officer).

F. Software maintenance and modification:

All electronic or information technology used in this project will be "as is" or slightly modified from modules of the LHC laboratory management system, referred to as LAB MANAGER (aka, LABMGR; LabMgr), the name of an internallexternal, LHC alpha developed, menu driven, password protected, customized system of multiple, networked, and complementary software programs designed and operated to store experimental laboratory research data, including associated laboratory support, maintenance and resource data, for results, analyses and reports management in the research programs in LHC There are a total of 12 software programs that have been developed, of which 8 systems are complete and functioning; all have assigned or proposed LHC supervisory/ systems accommodating the products produce by the tissue collection contract The systems or programs that are internal to the contract require the following services:

a) Provide a professionally trained and experienced software developer to redesign, expand,upgrade, train relevant personnel, and maintain in your facilities the three NIH contractor-designed databases (1.Personal profiles and questionnaires database; 2. Tissue collection and transport preparation database; 3. Histology service request and monitoring database, referenced in 1,e and 2 ,c above) in PC's with Windows 95, 98, and NT 2000 operating systems environments, using Dbase III and IV, Visual Dbase and Access 92 languages to provide storage, retrieval, and analytical report capabilities via the services of a professional software developer with relevant training and experience, preferably one with experience relevant to the current status of the existing software;

b) Provide systems upgrades for commercial packages and modifications of the existing systems designed previously by the NIH, the contractor and the professional consultant when required by the NIH or the contractor in response to the demands and evolving project and devoted to specific requirements of the project.

c) When requested by the Project Officer, provide redesigned versions either of the desktop questionnaire software used for permanent data storage (tissue collection or subject profile data or denovo, original "alpha" designs for the newly introduced "Tablet" questionnaire software used "in the field" by interviewers to complete subject questionnaires.

Anticipated Period of Performance

The anticipated period of performance for this requirement is one year, with four one year options

Other Important Considerations

There is a high risk probability for microbial contamination and damage by autolytic enzymes released following death and present during tissue collection, histopathology sampling and during transportation for delivery to NIH. In order to reduce these negatives, the tissues must be expeditiously placed in contravening conditions and delivered with the most reasonable and safest speed. Therefore, offerors must demonstrate their ability to facilitate delivery of non-frozen viable tissues to NIH within two (2) hours of receiving them from the pathologist, at all time of the day.

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) resented 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 concerns's name, point of contact, address and DUNS number

Information Submission Instructions

All capability statements sent in response to this Sources Sought notice must be submitted electronically (via email) to Odessa S. Henderson, Contracting Officer at oh4o@nih.gov in MS Word, WordPerfect or Adobe Portable Document Format (PDF) by January 29, 3:30 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 view 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).