HHS-NIH-NCI-ETSB-71003-72
NOTICE INFORMATION

Agency/Office: National Institutes of Health

Location: National Cancer Institute, Office of Acquisitions

Title: Measurements of Estrogen and Estrogen Metabolites in Epidemiology Studies

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 sources; (2) whether they are small businesses; HUBZone small businesses; service-disabled, veteran-owned small businesses; 8(a) small businesses; veteran-owned small businesses; woman-owned small businesses; or small disadvantaged businesses; 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. This requirement is assigned a NAICS code of 541380 and the small business size standard for such requirements is $15 Million per annum. Statements should also include an indication of current certified business status; this indication should be clearly marked on the first page of your capability statement (preferably placed under the eligible small business concern's name and address) as well as the eligible business concern's name, point of contact, address, and DUNS number.

The Division of Cancer Epidemiology and Genetics (DCEG), National Cancer Institute (NCI) is seeking capability statements from all eligible Small Businesses as stated above.

THERE IS NO SOLICITATION AVAILABLE. THIS IS STRICTLY FOR MARKET RESEARCH.

Background:

The mission of the Division of Cancer Epidemiology and Genetics (DCEG), National Cancer Institute (NCI) is to conduct population and multidisciplinary research to discover the genetic and environmental determinants of cancer and new approaches to cancer prevention. Estrogens have been shown to play important roles in the pathophysiology of breast tumors and are recognized causal factors in the etiology of breast cancer. Endogenous estrogens may also play causal roles in endometrial and ovarian cancers and could also be important in male reproductive cancers, such as male breast cancer, testicular cancer, and prostate cancer. Substantial inter-individual variability has been observed in levels of circulating and excreted estrogens and estrogen metabolites among men, postmenopausal women, and pre-menopausal women. Because estrogens and estrogen metabolites vary with respect to bioavailability, affinity to estrogen receptors, and mutagenic potential, it has been hypothesized that variations in estrogen/estrogen metabolite profiles may account for inter-individual differences in cancer risks. Recent development of a liquid chromatography-tandem mass spectrometry method for measurement of estrogens and estrogen

metabolites in urine and serum represents an important methodologic development because it provides an assay with characteristics that make it feasible for use in epidemiologic studies: high sensitivity, specificity, reliability, and scalability for high-throughput work.

Purpose and Objectives:

The scope of this contract will be to measure estrogens and estrogen metabolites, in both unconjugated and total (sulfated + glucuronidated + unconjugated) forms, in human serum, heparin-plasma, and urine using stable isotope dilution liquid chromatography/tandem mass spectrometry (LC-MS/MS).

Project Requirements:

The Contractor shall furnish services, qualified personnel, material, equipment, including secure computers, and facilities, to measure estrogens and estrogen metabolites, in both unconjugated and total (sulfated + glucuronidated + unconjugated) forms, in human serum, heparin-plasma, and urine using stable isotope dilution liquid chromatography/tandem mass spectrometry (LC-MS/MS).

Tasks:

The Contractor shall:

1) Measure estrogens and estrogen metabolites in both unconjugated and total (sulfated + glucuronidated + unconjugated) forms, in ≤ 0.5 mL of human serum, heparin-plasma, and urine using a stable isotope dilution liquid chromatography/tandem mass spectrometry (LC-MS/MS) method that exhibits high sensitivity, validity and reproducibility according to the general approach described by Xu X. et al. (2005, 2007). The specific estrogens and estrogen metabolites to be measured include the parent estrogens (estrone and estradiol); metabolites in the 2-hydroxylation pathway (2-hydroxyestrone, 2-methoxyestrone, 2-hydroxyestradiol, 2-methoxyestradiol, and 2-hydroxyestrone-3-methyl ether); metabolites in the 4-hydroxylation pathway (4-hydroxyestrone, 4-methoxyestrone, and 4-methoxyestradiol); and metabolites in the 16-hydroxylation pathway (16a-hydroxyestrone, estriol, 17-epiestriol, 16-ketoestradiol, and 16-epiestriol).

   For serum, plasma, and urine, the sensitivity shall be adequate to measure quantitatively estrogens and estrogen metabolites in samples from postmenopausal women not currently or recently using exogenous hormones. The more abundant estrogens and estrogen metabolites shall be quantifiable in nearly all samples from postmenopausal and premenopausal women and men. The least abundant estrogens and estrogen metabolites may not be quantifiable in all postmenopausal women. For reproducibility, total laboratory coefficients of variation, including all steps of the assay procedure and both within- and between-batch variation, shall be less than 10% for most of the 15 estrogens and estrogen metabolites in premenopausal women, postmenopausal women, and men, and less than 15% for all of them. For validity, the percent recovery of a known amount of each of the 15 estrogens and estrogen metabolites added to charcoal-stripped serum or plasma samples shall range from 90% to 110% for most of the 15 estrogens and estrogen metabolites. Absolute recovery shall be at least 50% for each estrogen/estrogen metabolite. Measurement of unconjugated estradiol in serum shall meet the

requirements of the Centers for Disease Control and Prevention Hormone Standardization Program (HoST).

References:

Xia, X., Roman, J., Issaq, H., Keefer, L., Veenstra, T., and Ziegler, R. Quantitative measurement of endogenous estrogens and estrogen metabolites in human serum by liquid chromatography-tandem mass spectrometry. Anal. Chem. 2007; 79: 7813-21.

Xia, X, Veenstra, T., Fox, S., Roman, J., Issaq, H., Falk, R., Saavedra, J., Keefer, L. and Ziegler, R. Measuring fifteen endogenous estrogens simultaneously in human urine by high-performance liquid chromatography-mass spectrometry. Anal. Chem. 2005; 77:6646-54.

Anticipated Period of Performance:

It is anticipated the services will be acquired through full and open competitive procedures. It is anticipated that one Indefinite Delivery Indefinite Quantity (IDIQ) contract will be awarded with a five (5) year period of performance beginning on or about February 7, 2017.

Information Sought:

To be deemed capable of providing services that meet the DCEG requirements, please submit a written capability statement demonstrating your ability and experience.

Submission Information:

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) presented 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 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 Juana A. Diaz, Contracting Officer, at diazj@mail.nih.gov in MS Word or Adobe Portable Document Format (PDF) by April 29, 2016 10:00 AM, EST. All responses must be received by the specified due date and time in order to be considered. CAPABILITY STATEMENTS RECEIVED AFTER THIS DATE AND TIME WILL NOT BE CONSIDERED. No collect calls or facsimile transmissions will be accepted.

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.