Framingham Heart Study(FHS)

Sources Sought Notice

75N92024R0245

Introduction

This Sources Sought Notice is for interested small businesses. 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 small businesses are classified as HUBZone; service-disabled, veteran-owned; 8(a); veteran-owned; woman-owned; or small disadvantaged; and (3) the 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. The NAICS code for this acquisition is 541715. An organization that is not considered a small business under NAICS code 541715 should not submit a response to this notice.

Background

The National Heart, Lung, and Blood Institute (NHLBI) is conducting a market survey to assess the availability and potential technical capability of qualified sources for a contractor for the program entitled the "Framingham Heart Study (FHS)". The FHS is a long-term multigenerational study that aims to identify genetic and environmental factors influencing the development of cardiovascular and other diseases. Examination of over 5,000 residents of Framingham, Massachusetts was initiated in 1948 (this cohort is hereafter referred to as the "Original" participants). About two decades later, the offspring of the Original participants were recruited into the study (hereafter referred to as "Offspring"). This was followed about three decades later by the third generation of original Framingham participants (hereafter referred to as "Generation 3"). In 2003, the New Offspring Spouse (NOS) Cohort began, which enrolled spouses of the Offspring Cohort if they were also parents of Generation 3 participants, to improve statistical power for family studies. In 2009, two minority cohorts (Omni Groups 1 and 2), which had been initiated by study investigators and funded by NIH grants, were integrated into the FHS contract. The designs and timing of the Omni Groups 1 and 2 examinations match those of the Offspring and Generation 3 cohorts, respectively. Except for the Original cohort, each cohort has recently undergone repeat examinations approximately every 6 years.

Project Requirements

The overall aim of this renewal is to continue the FHS as a scientific resource for the research community to expand knowledge about the determinants of health and disease in heart, lung, blood, and sleep disorders. The overall goals of this acquisition are to (1) enhance statistical power to perform analyses of predictors of clinical events; (2) study the progression of risk factors with aging; and (3) identify new risk factors or interactions between risk factors that inform disease pathophysiology and/or disease progression. The operational goals are to (1) continue retention, annual follow-up, and clinical event ascertainment of all FHS study participants; (2) maintain FHS data and biospecimen repositories and facilitate use of FHS data and biospecimens; and (3) conduct a limited clinical examination of the FHS participants as a platform for investigator-initiated ancillary studies. The funds for a limited clinical

examination will be awarded in this contract at the discretion of NHLBI and will be considered only if there is an ancillary study successfully funded. Should a limited clinical examination be funded, the Contractor shall work closely with ancillary study investigators to coordinate exam components from multiple funding sources.

Throughout the period of performance, the Contractor shall provide appropriate senior personnel with expertise in cardiovascular disease epidemiology, clinical cardiovascular disease, longitudinal studies management, biostatistics, and administrative management. The Contractor shall:

- Develop and maintain a data collection system to conduct event follow-up for morbidity and mortality of Original, Offspring, Generations 3, New Offspring Spouse, Omni 1, and Omni 2 participants. (Task Area A)

- Investigate participants' self-reported clinical events by collecting supporting medical records, death certificates, and other relevant materials; perform abstraction of data from such records required for ascertainment of events; and conduct expert review and classification thereof (the anticipated approximate number of participants expected to be alive in 2025 and thus followed up is approximately 6,000). (Task Area A)

- Establish and maintain study databases, including updating the databases with data from newly ascertained events and ancillary studies both for internal use and external use, including for posting to BioData Catalyst (BDC) and other NIH repositories, such as database of Genotypes and Phenotypes (dbGaP), as appropriate. (Task Area A)

- Establish and maintain the study's biospecimen repository and coordinate approved distribution of biospecimens. (Task Area A)

- Coordinate and participate collaboratively in study committees to provide a transparent committee process, open access to materials, clear policies for access to data and materials, and an approval process for projects (including research proposals and ancillary studies) that is fair and balanced (See Section IV below for details on committee structure). (Task Area A)

- Perform administrative duties to support productive collaboration among study investigators. (Task Area A)

- Arrange for and manage annual meetings of an NHLBI-appointed Observational Studies Monitoring Board (OSMB) as directed by the NHLBI Project Office. (Task Area A)

- Establish and direct appropriate quality assurance and quality control programs. (Task Area A and B)

- Conduct statistical analyses for quality assurance and quality control and, as funding allows, for scientific abstracts, presentations, and publications. (Task Area A)

- Conduct a re-examination of FHS Offspring, Generations 3, New Offspring Spouse, Omni1, and Omni 2 participants. (Task Area B)

- Develop and implement a procedure for reporting genetics results to FHS participants who have been found to have clinically actionable results from contract-supported testing and conduct the appropriate reporting. (Task Area C).

- Perform activities related to study transition or closeout as directed by the NHLBI Project Office. (Task Area D)

- Prepare and submit technical and financial reports. (Task Areas A, B, C, and D)

- Work Cooperatively with all study investigators and staff, including the NHLBI intramural Framingham investigators, the NHLBI Project Office, and nay subcontractors and consultants in all relevant aspects of the study. (Task Areas A, B, C, and D)

Anticipated Period of Performance

The Government intends to negotiate a contract for the potential period of seven years with an approximate award date of February 1, 2025.

Capability Statement – How to submit a response

Small business concerns that believe they possess the capabilities necessary to undertake this work should submit complete documentation of their capabilities to the Contracting Officer. The capabilities statement **must** specifically address **each** project requirement separately. Additionally, the capability statement should include 1) the total number of employees, 2) the professional qualifications of scientists, medical experts, and technical personnel as it relates to the above outlined requirements, 3) a description of general and specific facilities and equipment available, including computer equipment and software, 4) an outline of previous research projects that are similar to the project requirements in which the organization and proposed personnel have participated, and 5) any other information considered relevant to this program. The capability statement must not exceed 15 single sided or 7.5 double sided pages in length and using a 12-point font size minimum.

Interested small business organizations are required to identify their size standards in accordance with the Small Business Administration. The government requests that no proprietary or confidential business data be submitted in a response to this notice. However, responses that indicate the information therein is proprietary will be properly safeguarded for Government use only. Capability statements must include the name and telephone numbers of a point of contact having authority and knowledge to discuss responses with Government representatives. Capability statements in response to this market survey that do not provide sufficient information for evaluation will be considered non-responsive. When submitting this information, please reference the solicitation notice number.

Point of Contact:

Elizabeth Bulger, Contracting Officer, NHLBI, Branch A, Phone (301) 827-7534, elizabeth.bulger@ nih.gov.

Department of Health and Human Services, National Institutes of Health, National Heart, Lung and Blood Institute, Rockledge Dr. Bethesda, MD, Office of Acquisitions 6705 Rockledge Dr. RKL1, Bethesda, MD, 20892-7902, UNITED STATES

Submission Instructions:

Interested parties shall submit capability statements via the FedConnect web portal (www.fedconnect.net) and **reference the FedConnect Sources Sought Number 75N92024R0245**. The due date for receipt of statements is 12:00 pm Eastern Time on January 26, 2024. Vendors can register with FedConnect at https://www.fedconnect.net/FedConnect/default.htm.

Please note that FedConnect is used by multiple federal agencies and therefore FedConnect assistance will be provided by Compusearch Software Systems, not the NHLBI OA. More information about registration requirements can be found by downloading the FedConnect Ready, Set, Go! Guide at https://www.fedconnect.net/fedconnect/Marketing/Documents/FedConnect_Ready_Set_Go.pdf.

For assistance in registering or for other FedConnect technical questions please call the FedConnect Help Desk at (800) 899-6665 or email at support@fedconnect.net. Please use the Contracting Officer contact information provided, should you require a waiver not to use FedConnect for submitting.

All responses must be received by the specified due date and time to be considered.

This notice does not obligate the Government to award a contract or otherwise pay for the information provided in the response. No proprietary, classified, confidential, or sensitive information should be included in your 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 review of the responses received, pre-solicitation and solicitation notices may be published in Federal Business Opportunities. However, responses to this notice will not be considered adequate responses to a solicitation.