

* ALS Bioregistry Announcement: ATSDR Sources Sought

Solicitation Number:

2011-N-13395

Notice Type:

Sources Sought

Synopsis:

Added: Apr 04, 2011 1:25 pm

Introduction: This is a Sources Sought notice. This is NOT a solicitation for proposals, proposal abstracts, or quotations. The purpose of this notice is to obtain information regarding the availability and capability of all qualified sources to perform a potential requirement.

Background: The ALS Registry Act (H.R. 2295) was passed on October 16, 2008. The ALS Registry Act amends the Public Health Service Act to require the Secretary of DHHS, acting through the Director of CDC, to (1) develop a system to collect data on amyotrophic lateral sclerosis (ALS); and (2) establish a national registry for the collection and storage of ALS data.

In October, 2010, ATSDR officially launched the National ALS Registry (www.cdc.gov/als). The purpose of the ALS Registry is to better describe the incidence and prevalence of ALS in the United States; examine factors, such as environmental and occupational, that might be associated with the disease; better outline key demographic factors (such as age, race or ethnicity, gender, and family history of individuals who are diagnosed with the disease) associated with the disease; and facilitate examination of the connection between ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS.

As the National ALS Registry is currently operational, ATSDR is now engaging in a series of activities to further enhance the National ALS Registry. Examples already underway include creating new survey modules to help identify potential risk factors for ALS and developing comprehensive surveillance activities in select states and large metropolitan areas to help test the completeness of the Registry.

Because little is known about the role genetics plays in ALS, ATSDR is interested in establishing a proposed biorepository to collect human specimens from ALS patients who enroll in the National ALS Registry. Such a biorepository will make this a more comprehensive Registry and potentially help scientists and researchers to better understand the genetic causes of ALS.

Purpose and Objectives: The purpose of this proposed acquisition is to establish a protocol for the creation of a biorepository of specimens from persons with ALS enrolled in the National ALS Registry. A subsequent pilot effort will be conducted based upon the protocol developed.

Because the genetic causes of ALS are largely unknown, ATSDR is seeking expert guidance on establishing a biorepository of samples that are linked with ALS patients enrolled in the National ALS Registry. ATSDR is particularly interested in blood and tissue samples. While there are other biorepositories currently in existence that contain specimens from persons with ALS, these biorepositories are often limited and target select groups (e.g., military veterans with ALS).

Submission of specimens for this biorepository would be open to all U.S. citizens and Legal Residents of the U.S with ALS enrolled in the congressionally mandated National ALS Registry. The ability to connect the biological material to information about risk factors and data about medical treatment will make the biorepository especially valuable to ALS researchers.

This acquisition will require the preparation of a protocol for the creation of a biorepository of specimens from persons with ALS enrolled in the National ALS Registry. This acquisition will also require a small, subsequent pilot to collect biological samples from Registry enrollees.

The NAICS code for this notice is 541990 and the project requirements of the acquisition will include the following scope of services:

Although biorepositories vary in scope and size, it is anticipated that the successful contractor will create a protocol that can be used to develop a biorepository of ALS human samples to complement the National ALS Registry. Before the protocol is developed, the Contractor should convene a group of experts in registries, surveillance, and/or neurological diseases to determine the best practices for establishing a biorepository as described. The Contractor will test and finalize the approved protocol by conducting a pilot to collect biological samples from at least 100 Registry enrollees.

The contractor would be responsible for the following:

1. The Contractor will determine the overall viability of a biorepository linked to persons with ALS who are enrolled in the National ALS Registry.
2. The Contractor will determine the most efficient sample collection strategies (e.g., blood spots, buccal swabs, blood draws) for patients with ALS.
3. The Contractor will give all specimens collected during the pilot to the Government at the end of the pilot.
4. The Contractor will guarantee the security of personal identifying information (PII) during the custody chain. The Contractor will transfer all PII to the Government at the end of the pilot.
5. The Contractor will work closely with the Veterans Administration (VA) to determine how Registry enrollees with military experience can become part of the VA's Brain Banking program.
6. The Contractor will provide guidance on the type of molecular analyses that can be conducted.

7. The Contractor will make recommendations about the most appropriate location(s) to house the repository specimens.
8. The Contractor will be responsible for complying with ATSDR's requirement for external peer-review of the protocol and for addressing the comments of the external reviewers.
9. The Contractor will provide ATSDR with quality assessment/quality control procedures for sample collection.
10. The Contractor will produce a final protocol which incorporates all changes needed to respond to comments from the IRB and ATSDR required review.
11. The Contractor will be responsible for executing all aspects of the pilot.
12. The Contractor will be responsible for summarizing all of the findings of the pilot effort in a report.
13. The Contractor will devise a plan for releasing specimens to qualified scientists/researchers.
14. Should scientific publications be developed based on this work, the contractor will comply with ATSDR and CDC requirements for pre-submission review and clearance of scientific documents.
15. Contractor will be required to provide their own off-site work space and equipment.

Anticipated period of performance: It is estimated that this requirement will be conducted over a 48 month period of performance or less.

Other important considerations: It is expected that a successful awardee for this requirement would possess the following qualifications and experience:

1. Substantial experience in conducting studies, program evaluation, program analysis, program management on establishing a biorepository of samples that are linked with patients.
2. Experience in management planning and describing approaches for managing work for specific projects to be performed in public health.
3. Substantial experience developing and utilizing a variety of design and implementation strategies, such as experience in the creation, operation, and intimate-working knowledge of biorepositories and how this experience specifically relates to disease/health registries.
4. Substantial relevant experience collecting samples of human specimens (e.g., blood) and intimate knowledge of requirements to handle them prior to being placed into a biorepository.

5. Capability to acquire staff for specific projects and have access to recognized practicing consultants in environmental public health.

6. Experience developing packages for IRB and OMB PRA submissions.

Capability statement /information sought: In response to this notice, interested parties should provide a capability statement that contains enough detail and information to indicate it has the experience, knowledge and ability to perform the work requirements described herein.

Interested parties having the capabilities necessary to perform the stated requirements may submit capability statements via email to Patrick Gourley Contracting Officer at pgourley@cdc.gov no later than 5:00 PM EDT, April 18, 2011.

Capability Statements shall be limited to 25 pages and must include the following information:

Business Information --

- a. DUNS:
- b. Company Name
- c. Company Address
- d. Current GSA Schedules appropriate to this Sources Sought
- e. Do you have a Government approved accounting system? If so, please identify the agency that approved the system.
- f. Type of Company (i.e., small business, 8(a), woman owned, veteran owned, etc.) as validated via the Central Contractor Registration (CCR). All offerors must register on the CCR located at <http://www.ccr.gov/index.asp> .
- g. Business/Administrative Company Point of Contact, Phone and Email address
- h. Technical Point of Contact, Phone and Email address of individual(s) who can further explain or verify the capability information provided in the response

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).

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.

Capability statements will not be returned and will not be accepted after the due date.

Added: Apr 13, 2011 9:40 am

This sources sought notice is being revised to:

1. extend the due date for responses
2. add one administrative element to the capability statement

The due date for responses is extended to 5:00 PM EDT April 25, 2011.

As an addition to the capability statement, interested parties are requested to indicate their organization's contracting ability to perform this work under a firm fixed price contract. The capability statement should indicate whether the organization has the ability to develop a cost/price proposal on a firm fixed price basis and would be able to accept a contract award on a firm fixed price basis. An ability to perform this work under a firm fixed price contract is not considered to be a mandatory requirement. Technical capability is paramount but the contracting officer will use the information collected from this sources sought notice to determine the most appropriate contract type and to develop a solicitation that reflects the best interest of the Government.

Contracting Office Address:

2920 Brandywine Road, Room 3000

Atlanta, Georgia 30341-4146

Place of Performance:

Contractor facilities

* Note: This announcement was closed on July 1, 2011.