

## DEPARTMENT OF VETERANS AFFAIRS

### Justification and Approval For Other Than Full and Open Competition

#### 1. Contracting Activity

The contracting activity is The Department of Veterans Affairs (VA), Veterans Health Administration (VHA), SAO West/NCO 18 Contracting Office/Big Spring, TX.

The VA proposes to award this follow-on procurement on the basis of other than full and open competition, in support of the Cooperative Studies Program Clinical Research Pharmacy Coordinating Center (CSPCRPCC), Albuquerque, NM. The Purchase Request Numbers are 501-15-2-283-0023 thru 0025. The VISN 18 Network Contracting Office (NCO) requests approval of this ***Class J&A***, to solicit and award a firm-fixed-price Multiple-Award Indefinite Delivery, Indefinite Quantity (IDIQ) contract, using Other Than Full and Open Competition (limited to the former incumbent SB contractors on the previous set of IDIQ contracts that will expire on 12/31/2014).

#### 2. Nature and/or Description of the Action Being Processed:

The aforementioned services are for Monitoring and Auditing Good Clinical Practice (GCP) Clinical Research Quality Associate (CRQA). Below is a sampling of the various tasks conducted by these monitors:

- Conduct site initiation visits as defined by the CRQA Plan, with the support of a Lead CRQA from the SMART. These visits include –
  - Protocol procedures including inclusion/exclusion criteria
  - Subject informed consent process
  - Screening procedure
  - Randomization procedure
  - Investigational Product Accountability
  - Unanticipated Adverse Event reporting and Serious Adverse Event Reports
  - Source document requirements and availability
  - Case Report Form (CRF) completion, correction, QA procedures
  - Institutional Review Board (IRB) policies and procedures
  - Regulatory and other study document completion and maintenance
  - Site correspondence with sponsor, CRQA and maintenance
  - Un-blinding procedures of a blinded study
- Conduct routine CRQA visits as defined by the CRQA Plan with the support of a Lead CRQA from the SMART. These visits include –
  - Check for protocol compliance
  - Review Essential Document Binder
  - Conduct subject data review
  - Verify CRF data against Source Documents

- Review Source Documents for Adverse Events (AE)/Serious Adverse Events (SAE)
- Review CRFs for accuracy and legibility
- Check for CRF submission to Data Coordinating Center
- Perform investigational product accountability
- Determine follow-up actions to be taken
- Provide relevant GCP Training
- Hold exit interview with study team to discuss site status
- Conduct study closeout visits as defined by the CRQA Plan with the support of a Lead CRQA from the SMART. These visits include –
  - Discuss site close-out procedures with staff
  - Assure submission of data
  - Review Essential Document Binder for completeness
  - Check for final disposition of investigational product
  - Retrieve documents for Sponsor files
  - Discuss record retention with investigator

The proposed contractors are the former incumbents on the previous set of IDIQ contracts. They are:

- B&B Monitoring Services (AKA Allison Shontz);
- South Shore Clinical Consulting Inc.;
- Granite Clinical Research Consulting LLC.

The anticipated award date is 1 January 2015, with a performance period of 1 January to 30 June 2015. This is intended to be an interim (bridge) contract vehicle to provide uninterrupted service for ongoing clinical research studies, pending approval of the current multi-year, multiple-award IDIQ, presently in CRT review. The estimated value of all task orders planned during this period is [REDACTED] This is the estimated aggregate value of task orders against all 3 contracts, based on planned clinical research study support during this period). After the award, a notice of award will be posted to FBO with this justification attached, in order to properly announce the award and post this justification. The Class J&A approval supports the need to issue up to three (3) separate contracts under this IDIQ, for support of the VA's Cooperative Studies Program.

### **3. Description of Supplies/Services Required to Meet the Agency's Needs:**

The VA Cooperative Studies Program (CSP), Albuquerque, NM, has a requirement for the services of a contractor or contractors to conduct the monitoring and auditing of its clinical trials. The CSP is the division of VA Research and Development that is responsible for the planning and conduct of large, multicenter clinical trials and epidemiological studies for the Department of Veterans Affairs. Within the CSP is the Clinical Research Pharmacy Coordinating Center (CSPCRPCC).

The CSPCRPCC provides Good Clinical Practice Clinical Research Quality Assurance (GCP CRQA) services for clinical trials that have been conducted by the CSP. These trials are

conducted at 300-400 VA facilities and associated non-VA facilities throughout the United States. The scope and magnitude of these studies, along with the geographic complexities of dealing in such a diverse area of operation, makes the execution of these GCP CRQA services unattainable if conducted solely by VA personnel. Therefore, the VA acquires the services of experienced contractors to provide these services to the CSP through a division of the CSPCRPCC called the Site Monitoring, Auditing and Resource Team (SMART), also located in Albuquerque, New Mexico. SMART is responsible for assuring that VA and Non-VA personnel conducting or supporting clinical trials are trained in GCP and that any compliance problems at participating research sites are identified and resolved through a program of site CRQA visits.

The forthcoming multi-year multiple award IDIQ contracts addressed in Paragraph 2 above will not be ready for award in time to continue these services without interruption due to two significant issues: 1) the contracting officer, with concurrence from the CSP Project Manager, elected to revise the statements of work to separate the performance requirements into 3 separate levels of effort (monitoring, auditing and project management), thereby allowing for a larger competitive pool from which to select research monitoring and auditing service providers; 2) the magnitude, complexity and type of service required (these are Advisory and Assistance services) requires they be subject to a CRT review. The time required for drafting the new SOWs and preparing the solicitations, coupled with the timelines for CRT approval to solicit and award far exceeds the remaining period of performance on the current contracts. Therefore, this request is being submitted for approval to provide the CSP with a class of contract vehicles for continuing these studies.

The solicitation would be issued to the incumbent contractors, all of whom are small businesses, for performance from 1 January through 30 June 2015. This should provide sufficient time for solicitation and award of the multi-year IDIQs, as well as a transition training period for newly awarded contractors untrained in the specific and extensive monitoring protocols required for the new contracts. It must be noted, there is an advantage in staying within the former group of contractors: there is an already developed familiarity with VA/CSP Standard Operating Procedures and policies; the contractors' expertise with the specific research protocols assigned; and the rapport developed with investigators and staff at the assigned research sites. More importantly, these ongoing trials, which have been observed and monitored by the current contractors since their commencement, require, in addition to continuity of service, strict compliance with the standards and measures under which the trials began.

Below are the estimated min-max amounts for the proposed contracts. These amounts take into account historical data on the number of visits required for each study, as well as forecasted studies during this 6-month period.

MINIMUM AND MAXIMUM											
Site Monitoring Auditing and Resource Team											
Auditing and Monitoring											
			Minimum					Maximum			
			# of Studies	# of Visits	Hours			# of Studies	# of Visits	Study Hrs	
1	QAS - Monitoring										
	Visits		5	22	0		10	44	0		
	Study Hrs				60				120		
	Travel Expenses		5	22	0		10	44	0		
2	QAS - Auditing										
	Visit		1	5	0		2	11	0		
	Study Hrs				360				720		
	Travel Expenses		1	5	0		2	11	0		
AUDITING/MONITORING TOTALS											

4. **Statutory Authority Permitting Other than Full and Open Competition:** 41 USC §253(c) (1), as implemented by FAR 6.302.1:

- ( ) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
- ( ) (2) Unusual and Compelling Urgency per FAR 6.302-2;
- (X) (3) **Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3; [specifically 6.302-3(b)(2)(iii)]**
- ( ) (4) International Agreement per FAR 6.302-4
- ( ) (5) Authorized or Required by Statute FAR 6.302-5;
- ( ) (6) National Security per FAR 6.302-6;
- ( ) (7) Public Interest per FAR 6.302-7;

5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):**

On 1 September 2013, six interim contracts were awarded for the subject monitoring and auditing services - VA258-13-D-0073 thru 0078. The intent was to have the new multi-year contracts in place at the expiration of these contracts. However, manpower constraints and workload distribution to offset these personnel shortages necessitated deferring the start of the new solicitation for several months.

In preparation for the new solicitations, the CO issued a Sources Sought Notice as part of ongoing market research. The notice discussed monitoring and auditing services as one SOW. Feedback from several respondents advanced the idea of splitting the requirement into separate services in order to promote increased competition, as many contractors were qualified to provide one or the other of these services, but not both. New SOWs and government estimates were developed and 3 separate solicitations were drafted for multi-year IDIQs. However, as mentioned previously the current contracts are due to expire on 12/31. Some of the studies initiated under these contracts are ongoing as part of a

continuing series of related studies, and there is insufficient time to make an award from the current solicitations.

These trials are under FDA review and have established schedules for monitoring visits, which require strict adherence. Interruption of services will jeopardize both the safety of veteran study participants and the scientific integrity of these trials. Therefore, continuity of service, which is always important in providing clinical QAS, is especially important in this instance. Having been fully trained and fully immersed in this environment for the past four years, the incumbent contractors have already obtained the required skills necessary to continue their monitoring and auditing support to CSP necessary during the period in question. It should be noted, only 3 of the expiring contracts are currently linked to ongoing and planned studies; therefore, all 6 contractors do not require the issuance of emergency contracts. The nature of these ongoing studies does not permit a postponement pending synopsis and award of a contract under the Full and Open Competition process. If these clinical trials and associated monitoring services are to be successful, any additional delays in the award and implementation of a new contract are unacceptable.

This request is not for approval to solicit a sole source for the aforementioned new set of multi-year, multiple award IDIQ contracts, but rather to solicit the incumbents noted above, who have the highly specialized qualifications and prerequisite skills to provide these services. Accordingly, these three contractors (see 1<sup>st</sup> paragraph above for details) are currently uniquely capable of providing the subject monitoring and auditing services. They represent the limited responsible sources capable of supplying the services described in Section 3 above, without the Veterans Health Administration experiencing unacceptable delays in fulfilling its requirements.

**6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:**

A large pool of qualified contractors exists in the field for this service, as evidenced by the responses to the recent Sources Sought Notice. However, expiration of the current contracts, the VA-required lengthy training process, and associated learning curve after award (in order to attain a qualified level of proficiency) precludes seeking outside competition at this time. The aforementioned IDIQ awards will provide these services in a competitive, multi-year, multiple award setting.

**7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:**

The government estimate is based on the use of the negotiated labor rates in the current set of contracts, in combination with the estimated number of remaining or new visits and/or hours for the various trial monitoring services, both ongoing and planned. Elements of the cost estimate include all monitoring and auditing functions during the trials, reimbursable travel to-and-from the various trial sites and administrative efforts in compiling the data (and associated reports) developed in support of CSP. The total estimated amount is [REDACTED] for a 6-month period of performance, assuming the entire 6-

month period of performance is required. Award of the IDIQ contracts (estimated as April 2015) will cancel these emergency contracts. Based on the use of the aforementioned negotiated rates in the current period, the contracting officer has determined that the cost will be considered fair and reasonable.

**8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:**

Market research was conducted by way of a Sources Sought Notice VA258-14-I-0774, published on 7/23/2014, and an eBuy RFI on 8/8/2014. The notices garnered considerable interest and were the basis for a change in processes for developing the statement of work for the formal solicitation (ref. Sections 3 & 5 for details). The research also supported the CO's decision to issue the solicitation as a 100% small business set-aside, based on the excellent showing of interest by small businesses.

**9. Any Other Facts Supporting the Use of Other than Full and Open Competition:**

A review of FAR 8.002, *Priorities for Use of Government Supply Sources*, has determined these services presently are not available from the #1 priority, Ability One/ NIB-NISH.

**10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:**

The acquisition has not been advertised; therefore, outside sources are not available to express an interest in this acquisition. However, the aforementioned Source Sought notice did generate considerable interest, which will be utilized in the forthcoming multi-year multiple award IDIQ acquisition.

**11. A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:**

As stated above, the forthcoming acquisition will contain updated key documents and revised scopes, thus enabling larger participation by the advisory and assistance community.

**12. Requirements Certification:** I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

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Michael R. Sather, PhD  
Director, VA Cooperative Studies Program  
Clinical Research Pharmacy Coordinating Center

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Date

13. Approvals in accordance with FAR 6.304

- a. **Contracting Officer's Certification: (required)** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Enrique J. Rivera  
203707

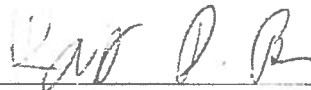
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12/10/2014

Date


Enrique J. Rivera  
Contracting Officer  
SAO-W/NCO 18, Big Spring

- b. **DOC:** I certify the justification meets requirements for other than full and open competition.

*for*   
Sabrina J. Smith  
Director of Contracting  
Network Contract Office 18

12/11/14  
Date

- c. **SAO:** I certify the justification meets requirements for other than full and open competition.

*for*   
Delia A. Adams, CPCM  
Director, SAO West

12/12/14  
Date