

SIMPLIFIED ACQUISITION SOLE SOURCE JUSTIFICATION

1. Contracting Activity:

Department of Veterans Affairs
Office of Acquisition Operations
Strategic Acquisition Center
321 Ballenger Center Drive, Suite 125
Frederick, MD 21703

2. Description of Action:

The proposed sole source action with Craig Hospital is for Traumatic Brain Injury (TBI) Veterans Health Registry and the Polytrauma Rehabilitation Center (PRC)/Traumatic Brain Injury Model Systems (TBIMS) longitudinal research database. Services were previously procured under an Interagency Agreement between VA and the Department of Education, which ended 9/30/2015. The estimated value of the acquisition over the base year and four option years is \$1,965,043.

3. Description of Supplies or Services:

At the direction of Congress, the Department of Veterans Affairs (VA) maintains the VA TBI Veterans Health Registry that includes information about Veterans who served in Operation Enduring Freedom (OEF), Operation Iraqi Freedom (OIF), or Operation New Dawn (OND), who exhibit symptoms associated with TBI and seek care or benefits from the VA. From October 2001 through September 2014, a total of 261,152 Veterans have entered the VA TBI Veterans Health Registry.

In addition to the Registry, this contract supports VA's collaboration with the National Institute on Disability, Independent Living and Rehabilitation Research (NIDILRR) funded TBIMS through the development and support of the VA PRC/TBIMS longitudinal research database. The Department of Health and Human Services (DHHS) funds a Center of Excellence (COE) through a grant to perform research and maintain data on TBI across a system of 16 academic centers across the US specializing in TBI care. VA is required by Public Law 110-181—JAN 28, 2008 122 STAT. 491 to collaborate with facilities that conduct research on rehabilitation for individuals with TBI. Previously, the VA has collaborated with the TBIMS through an interagency agreement (IAA) with the Department of Education (DOE), from 2008 through 9/30/2015. NIDILRR was realigned under DHHS, which requires VA to establish a new method of acquisition to meet the public law requirement. DHHS will no longer accept the IAA from VA..

4. Statutory Authority:

The statutory authority permitting sole source acquisitions is FAR 13.501(a), sole source acquisitions.

5. Rationale Supporting Use of Authority Cited Above:

VA is required to maintain the PRC/TBIMS national longitudinal database for data submitted by each of the TBI Model System Centers. This National Data and Statistical Center must also ensure collection of high quality data and support rigorous research by the Model System Centers by monitoring data quality, providing training in collecting TBI Model System Centers data, and providing methodological consultation to these centers. Public Law requires VA to collaborate with facilities that receive NIDILRR grants. Craig Hospital has developed extensive expertise in the area over a ten year period of research with a network of Polytrauma Rehabilitation Centers across the United States. Craig Hospital is uniquely qualified to provide high quality research data, expert consultative services regarding research data variables, knowledge translation, committee participation, and preparation and presentation of brochures, presentations and reports.

The TBIMS NDSC at Craig Hospital is the only NIDILRR grantee and the only institution that brings the following critical elements to the collaboration between VA and NIDILRR, required to fulfill the VA TBI Registry and the VA PRC TBI Database as stated in the PL since 2008. Craig Hospital represents:

- The only NIDILRR grantee charged with responsibility for managing the TBIMS National Database;
- The only NIDILRR grantee charged with responsibility for collaborating with the VA on the VA Health Registry and the VA PRC TBI Database;
- The only NIDILRR grantee to have access to and analysis of large TBI datasets, bringing to bear extensive statistical and methodological expertise; utilizing state-of-the-art analytic approaches; and applying their extensive TBI expertise to guide the research process and to interpret the findings.; and,
- Staff that are the national leaders in the International TBI Common Data Elements (CDE) initiative. Craig Hospital's Project Director (for the TBIMS NDSC) and Craig Hospital colleagues have been key figures in all phases of the CDE development effort.
- In addition, there is a Presidential Executive Order (Improving Access to Mental Health Services for Veterans, Service Members, and Military Families) signed August 31, 2012 directing the Departments of Defense (DoD), VA, DHHS, and DOE to develop a National Research Action Plan (NRAP [August 2013]) on posttraumatic stress disorder (PTSD), other mental health conditions, and TBI "to improve the coordination of agency research into these conditions and reduce the number of affected men and women through better prevention, diagnosis, and treatment."

The TBI Veterans Health Registry and the VA PRC/TBIMS longitudinal research database demonstrate VA's compliance with the National Defense Authorization Act of Fiscal Year 2008. The public law reads as follows:

PL 110-181, Section 1704

RESEARCH, EDUCATION, AND CLINICAL CARE PROGRAM ON TRAUMATIC BRAIN INJURY.

(a) **IN GENERAL.**—To improve the provision of health care by the Department of Veterans Affairs to veterans with traumatic brain injuries, the Secretary of Veterans Affairs shall—

(1) conduct research, including—

(A) research on the sequelae of mild to severe forms of traumatic brain injury;

(B) research on visually-related neurological conditions;

(C) research on seizure disorders;

(D) research on means of improving the diagnosis, rehabilitative treatment, and prevention of such sequelae;

(E) research to determine the most effective cognitive and physical therapies for such sequelae;

(F) research on dual diagnosis of post-traumatic stress disorder and traumatic brain injury;

(G) research on improving facilities of the Department concentrating on traumatic brain injury care; and

(H) research on improving the delivery of traumatic brain injury care by the Department;

(2) educate and train health care personnel of the Department in recognizing and treating traumatic brain injury; and

(3) develop improved models and systems for the furnishing of traumatic brain injury care by the Department.

(b) **COLLABORATION.**—In carrying out research under subsection (a), the Secretary of Veterans Affairs shall collaborate with—

(1) facilities that conduct research on rehabilitation for individuals with traumatic brain injury;

(2) facilities that receive grants for such research from the National Institute on Disability and Rehabilitation Research of the Department of Education; and

(3) the Defense and Veterans Brain Injury Center of the Department of Defense and other relevant programs of the Federal Government (including Centers of Excellence).

(c) **DISSEMINATION OF USEFUL INFORMATION.**—The Under Secretary of Veterans Affairs for Health shall ensure that information produced by the research, education and training, and clinical activities conducted under this section that may be useful for other activities of the Veterans Health Administration is disseminated throughout the Veterans Health Administration.

(d) **TRAUMATIC BRAIN INJURY REGISTRY.**—

(1) **IN GENERAL.**—The Secretary of Veterans Affairs shall establish and maintain a registry to be known as the “Traumatic Brain Injury Veterans Health Registry” (in this section referred to as the “Registry”) Establishment.

- (2) DESCRIPTION.—The Registry shall include the following information:
- (A) A list containing the name of each individual who served as a member of the Armed Forces in Operation Enduring Freedom or Operation Iraqi Freedom who exhibits symptoms associated with traumatic brain injury, as determined by the Secretary of Veterans Affairs, and who—
- (i) applies for care and services furnished by the Department of Veterans Affairs under chapter 17 of title 38, United States Code; or
 - (ii) files a claim for compensation under chapter 11 of such title on the basis of any disability which may be associated with such service.
- (B) Any relevant medical data relating to the health status of an individual described in subparagraph (A) and any other information the Secretary considers relevant and appropriate with respect to such an individual if the individual—
- (i) grants permission to the Secretary to include such information in the Registry; or
 - (ii) is deceased at the time such individual is listed in the Registry.
- (3) NOTIFICATION.—When possible, the Secretary shall notify each individual listed in the Registry of significant developments in research on the health consequences of military service in the Operation Enduring Freedom and Operation Iraqi Freedom theaters of operations.

In summary, Public Law requires the Secretary of VA to maintain a registry and collaborate with facilities that receive grants from NIDLIRR. NIDRR has transferred from the Department of Education to DHHS effectively completed in 2015. Craig Hospital is the grantee for the NDSC grant, which will begin October 1, 2016. The VA PRC/TBIMS database supports longitudinal research that mirrors data elements collected through the NIDLIRR funded TBIMS project.

The grant provides funding to support the TBIMS database. TBIMS is the world's leading longitudinal database of TBI outcomes with more than 13,000 enrollees followed for up to 25 years, which assesses the rehabilitation and functional outcomes of individuals at 16 academic centers across the US specializing in TBI care. In addition to the VHA Registry, this contract supports VA's collaboration with the NIDLIRR funded TBIMS through the development and support of the VA PRC/TBIMS longitudinal research database. The TBI Veterans Health Registry includes processing of VA Data on OEF/OIF/OND Veterans and issuing brief quarterly reports, more comprehensive internal administrative documents on a quarterly basis, and special reports to VA leadership as needed. Through VA's involvement in the TBIMS project; 1) a parallel database of Veterans with TBI at the PRCs has been established, 2) the VA is able to benchmark its clinical outcomes with the nation's leading centers of excellence, and 3) the PRCs are able to collaborate in evidence-based research on TBI rehabilitation interventions.

6. Efforts to Obtain Competition:

The TBI Model Systems National Data and Statistical Center is a grant, awarded every five years through the competitive grant application process of our federal agency. DHHS evaluated two competing applications for the grant, announcement number HHS-2016-ACL-NIDILRR-DP-0145, National Data and Statistical Center required to maintain the national longitudinal database for data submitted by each of the TBI Model System Centers. Craig Hospital has received this grant for two consecutive cycles. Their current 5 year grant will expire on September 30, 2016. Craig Hospital has recently been awarded the grant for the next 5 year grant cycle which will begin on October 1, 2016.

7. Market Research:

Market Research was not conducted because PL law specifically directs VA to collaborate with HHS NIDILRR grant holders; facilities that conduct research on rehabilitation for individuals with TBI; and, DOD and other relevant programs of the Federal Government.

8. Other Facts and sources:

There are no other facts surrounding this action nor have any other sources expressed interest in this requirement.

10. Technical and Requirements Certification: I certify that the supporting data under my cognizance, which are included in this justification, are accurate and complete to the best of my knowledge and belief.

Erick Ishii

Date: 31 August 2016

Health Science Specialist

Signature: Erick B. Ishii

11. Fair and Reasonable Cost Determination: I hereby determine that the anticipated price to the Government for this contract action will be fair and reasonable based on an analysis of the contractor's price to fulfil these services. The contractors priced labor hour rates will be verified to confirm that they do not exceed a reasonable rate. The level of effort and the mix of labor proposed will be evaluated to determinate that the total price is reasonable for the effort.

Carey M. Kauzlarich

Date: _____

Procuring Contracting Officer

Signature: _____

12. Procuring Contracting Officer Certification: I certify that this justification is accurate and complete to the best of my knowledge and belief. As this contract exceeds \$700,000, the certification below required by FAR 13.501 serves as approval.

Carey M. Kauzlarich

Date: _____

Contracting Officer

Signature: _____

13. Approval: In my role as Contracting Activity Competition Advocate, based on the foregoing justification, I hereby approve the acquisition of Traumatic Brain Injury (TBI) Veterans Health Registry and the Polytrauma Rehabilitation Center (PRC)/Traumatic Brain Injury Model Systems (TBIMS) longitudinal research database, on an other than full and open competition basis pursuant to the statutory authority cited in paragraph 4 above, subject to availability of funds, and provided that the property and services herein described have otherwise been authorized for acquisition.

Clint Druk

Date: _____

Deputy Director – SAC-F

Signature: _____