

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

1. **Contracting Activity:** The Department of Veterans Affairs Research Service (151/GRECC 182B) has a requirement for research and development leading to biomarker assays of plasma and/or other peripheral fluids or tissue used in conjunction with near-infrared optical spectroscopy for detection of human neurologic disorders in vivo for Edith Nourse Rogers Memorial Veterans Hospital, Research 151, 200 Springs Road, Bedford, MA, as described in requisition number 518-12-1-108-0001.
2. **Nature and/or Description of the Action Being Processed:** The proposed action is to award a new, sole-source, indefinite-delivery contract (IDC) with firm fixed price (FFP) line items to Weiming Xia, a sole-proprietor, Boston, Massachusetts (DUNS: 806952458). A five year contract is under consideration. The initial task order shall comprise the minimum order guarantee and shall be issued concurrently with the basic award. The estimated ceiling price is \$425,000. The contract is to identify and develop assays for prognostic biomarkers of Alzheimer disease (AD) dementia and related disorders due to disease or injury. In conjunction with near-infrared spectroscopy, these biomarker assays will enable minimally invasive and/or non-invasive assessment of neurological disorders due to injury or disease, such as mild traumatic brain injury or Alzheimer disease and related neurodegenerative diseases.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The Contractor shall identify biological markers of disease and design, develop, implement, test and provide assays for said biomarkers, to be used in conjunction with near-infrared optical spectroscopy for the minimally invasive detection, diagnostic evaluation and monitoring of neurological disorders such as Alzheimer disease (AD) and related neurodegenerative disorders, including mild traumatic brain injury (mTBI). It is expected that this work will be an implementation of the concepts outlined in Xia, et al. *Arch Neurol.* 2009; 66(2):190-199. Performance shall be provided in close collaboration with Edith Nourse Rogers Memorial Veterans Hospital, Bedford, MA (Bedford VAMC) and according to specifications developed jointly by Bedford VAMC and Contractor. The data, assays and services provided shall be comprised of:
  - 1) Specific enzyme-linked immunosorbent assays to examine in vivo levels of  $\beta$ -amyloid ( $A\beta$ ) oligomers, monomeric  $A\beta$  of various peptide lengths and other putative biomarkers for AD and related disorders in plasma, cerebrospinal fluid (CSF) and brain tissue of patients with sporadic AD at various stages, including very early or pre-symptomatic AD.
  - 2) Acquisition and delivery of data and demonstration of the correlation of assayed biomarkers in vivo with "pre-symptomatic" AD and the prognostic value of such biomarkers for predicting progression to overt clinical dementia.
  - 3) Correlation of peripheral fluid and/or tissue assays with more clinically validated biomarkers, such as CSF  $A\beta$ /tau ratio, PIB-PET imaging, and anatomic or functional MRI imaging data.
  - 4) Correlation of biological markers predictive for progression to dementia with near-infrared spectroscopy.
  - 5) Longitudinal studies demonstrating utility of peripheral biological markers of AD, near-infrared spectroscopy and both together for monitoring progression of AD.5) A diagnostic algorithm incorporating demonstrated prognostic value of near-infrared optical spectroscopy plus plasma AD biomarkers for predicting progression of "pre-symptomatic" individuals to overt clinical AD.

4. **Statutory Authority Permitting Other than Full and Open Competition:** Contracting without providing for full and open competition is authorized by 41 USC §253(c), as implemented by FAR 6.302-1: Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements.
5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** The contractor is uniquely qualified to provide the above data and services. Previous unique investigations by the contractor into the biology of the gamma secretase complex, which is the enzyme responsible for generation of A-beta peptides found in Alzheimer's disease cerebral cortex, have produced unique capability to analyze the products of gamma secretase enzyme activity. The contractor offers unique expertise and capabilities in measurements of A $\beta$  and tau species by multiple methodologies, including immunoassays, ELISA, bioassays, and mass spectroscopy. Capability to perform these measurements on multiple A-beta species from the cerebral cortex of human post mortem tissue and animal models of disease is essential to the success of this program. The contractor is the only vendor that offers the scientific and technical expertise required to provide all the above specified goods and services, which are required to maintain the VA funded research and development capability established at the Bedford VAMC under the direction the VA.
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** This requirement will be advertised as an intent to solicit and negotiate with only one source under the authority of 6.302, as required by FAR 5.203.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** An Independent Government Estimate (IGE) was produced. The noted price is reasonable compared to the IGE. The price is also reasonable compared to market prices for the expertise required for assay and algorithm development and hours anticipated.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** [ ] The above requirement was reviewed by senior medical, administrative and scientific research staff at Edith Nourse Rogers Memorial Veterans Hospital. The undersigned Health Research Scientist and the GRECC Director, continue to monitor developments in this field and the scientific labor market.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** To their expert knowledge of the field, neither Dr. Hanlon nor senior colleagues in biochemistry and molecular biology at Edith Nourse Rogers Memorial Veterans Hospital know of any other contractor who can provide the specified requirements. In addition, the specific knowledge, expertise and technology that the contractor can provide is required so that the data to be obtained will be compatible with already existing data and results in this research program.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** No sources have expressed an interest in this acquisition. However, an FBO announcement announcing the VA intent to negotiate a sole source procurement will be publicized. Responses will be forwarded to the Program Office.
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:** See paragraphs 8 and 10 above. The requirement will be synopsisized to FBO, responses will be forwarded to the Program Office. The undersigned Health Research Scientist and the GRECC Director, continue to monitor developments in this field and the scientific labor market.

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.

Eugene B.  
Hanlon, Ph.D.

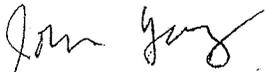
Digitally signed by Eugene B. Hanlon,  
Ph.D.  
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o=VHA, ou=Research,  
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Eugene B. Hanlon  
Research Health Scientist  
VISN1/518

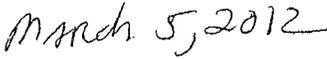
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13. **Approvals in accordance with FAR 6.304**

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



John Young  
Contracting Officer  
NCO 1/650/90C



\_\_\_\_\_  
Date

**b One Level above Contracting Officer:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

**Kristine Clark**

Kristine Clark

Supervisory Contract Specialist  
NCO 1/650/90C

Digitally signed by Kristine Clark  
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of Veterans Affairs, ou=Internal Staff,  
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**c.** NCO 1 - Quality Assurance

**Gary W. Dilk**

Mary Connors  
Quality Assurance  
NCO 1

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