

## DEPARTMENT OF VETERANS AFFAIRS

### Justification and Approval

#### For

#### Other Than Full and Open Competition

1. **Contracting Activity:** Network 23 Contracting Office (NCO 23) – Sioux Falls, 2501 W. 22nd Street, Sioux Falls SD 57105; 636-14-1-4602-0221.
2. **Nature and/or Description of the Action Being Processed:** This will be a fixed price contract with the University of Iowa who will provide necessary labor in support of the research for VACO reviewed project #INFA-008-12F, “The effects of Hepatitis C Virus (HCV) E2 protein on host immunomodulation,” Jack Stapleton, MD.
3. **Description of Supplies/Services Required to Meet the Agency’s Needs:**  
The University of Iowa will provide expertise in conducting experiments to characterize the HCV envelope glycoprotein E2 effects on TCR signaling. There is no government furnished property. Estimated Cost: \$149,900. Anticipated period of performance. Date of Award – 12/31/2014.
4. **Statutory Authority Permitting Other than Full and Open Competition:** 41 USC §253(c)(1), as implemented by FAR 6.302-1.  
  
(X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
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 University of Iowa has the specific expertise needed to conduct experiments to characterize the constituents of HCV envelope glycoprotein E2 containing exosomes, and in exosomes present in the plasma of HCV-infected subjects. The work cannot be conducted without utilizing the University of Iowa. The University of Iowa is providing consultation services in support of Dr. Stapleton’s VA funded research project. The University of Iowa has the unique capabilities and expertise combined with the required knowledge to consult on the research questions proposed in this project. These are very specialized procedures that only the University of Iowa has the knowledge to complete. Going outside the University of Iowa would severely hamper the progress of research and impact the timeliness of research results.
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Market research was conducted as part of the review process by the Principal Investigator. No other vendor was identified in the process as meeting the specific requirements.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The anticipated cost to the Government is based upon a comparison of previously proposed prices and previous Government and commercial contract prices with current proposed prices for similar services and comparison of proposed prices with prices obtained through market research for the same or similar items. According to the U.S. Department of Health & Human Services, National Institutes of Health (NIH), National Center for Biotechnology Information (NCBI) and the Journal of the American Medical Association (JAMA), the median calculated cost of conducting 243 studies was \$24,471.00 (interquartile range [IQR], \$11,531.00 - \$63,808.00). The median authors' estimate of study cost was \$10,000.00 (IQR, \$4,000.00 - \$25,000.00). Some funding was obtained for 72 (29.6%) of the studies. Of studies that were funded, the median amount of funding was \$15,000.00 (IQR, \$5,000.00 - \$66,500.00). The median calculated cost of funded studies

was \$37,315.00 (IQR, \$18,731.00 - \$82,393.00). Article located at <http://jama.jamanetwork.com/article.aspx?articleid=201474>

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 as part of the review process by the Principal Investigator. No other vendor was identified in the process as meeting the specific requirements.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** None.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** See Section VI above. The University of Iowa, Department of Internal Medicine, 616 MRC, Iowa City, IA 52242
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:** We will be open to other sources in the future when making a new project application. The projects are funded through VA Central Office after leadership review and a review of the budget and investigators listed for their expertise.
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.

kari.steinkamp2@va.gov  
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Kari Steinkamp  
AO for Research  
Iowa City VA Health Care System

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.

john.becker3@va.gov  
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John Becker  
Contracting Officer, NCO 23 Sioux Falls

Date

- b. **FCM(Required \$3K and above):** I certify the justification meets requirements for other than full and open competition and I approve for other than full and open competition.

Lori Fischer

Lori Fischer

Facility Contract Manager, NCO 23 Sioux Falls

12-4-13

Date