

**DEPARTMENT OF VETERANS AFFAIRS**

**Justification and Approval (J&A)  
For  
Other Than Full and Open Competition (>SAT)**

**Acquisition Plan Action ID:** 36C260-19-AP-3930

- 1. Contracting Activity:** Department of Veterans Affairs, Veterans Health Administration, Regional Procurement Office West, Network Contracting Office 20 on behalf of VISN 20, VA Puget Sound Healthcare System (VAPSHCS). [REDACTED].
- 2. Nature and/or Description of the Action Being Processed:** Brand Name Justification and Approval of the items listed below. This action will be awarded as a new firm-fixed-price contract with an estimated value of \$ [REDACTED]. The requested items enable biomedical research capabilities.

One (1) each of the following Leica brand items:

1. Leica 45.0005 Peloris III \$ [REDACTED]
2. Leica S45.4503A spaced basket kit \$ [REDACTED]
3. Leica 1491200 VT1200S config \$ [REDACTED]
4. Leica 14048142075 Vibrocheck \$ [REDACTED]
5. Leica 14041157009 power cord various NEMA5-15C13 \$ [REDACTED]
6. Leica 149003050S01 CM3050S Configured \$ [REDACTED]
7. Leica 14041149613 Power Cord Various NEMA5-20 C19 \$ [REDACTED]
8. Leica 149Auto00C1 Histocore Auto Config \$ [REDACTED]
9. Leica 14051756261 Tray \$ [REDACTED]
10. Leica 1405023 foot switch RM22 \$ [REDACTED]
11. Leica 14041157009 Power cord various NAMA5-15 C13 \$ [REDACTED]
12. Leica 14052056572 Histocore nanocut-fully motorized microtome \$ [REDACTED]
13. Leica 14050237717 fixture orienting silver \$ [REDACTED]
14. Leica 14050237718 quick clamping system assembly \$ [REDACTED]
15. Leica 14050237999 UCC w/adpt RM2125 silver \$ [REDACTED]
16. Leica 14050255546 blade holder base \$ [REDACTED]
17. Leica 14050254497 2-in-1 blade holder E \$ [REDACTED]
18. Leica 14051756261 tray \$ [REDACTED]
19. Leica 14050238257 foot switch RM22 \$ [REDACTED]
20. Leica 14041157009 power cord various NEMA5-15 C13 \$ [REDACTED]
21. Leica 14039357258 Arcadia H embedding unit \$ [REDACTED]
22. Leica 14039357261 Arcadia C embedding unit \$ [REDACTED]
23. Leica 14041157009 Power cord various NEMA5-15 C1 \$ [REDACTED]

- 3. Description of Supplies/Services Required to Meet the Agency's Needs:** The VISN 20 VAPSHCS MIRECC requires the above listed pieces of equipment that are crucial for research and development's need for consistency, data integrity, and interfacing with existing equipment. These Leica Biosystems models have been used and validated for protocol compliance. Rigorous protocol compliance and its associated instrumentation, equipment characteristics and dimensions are

required to establish an essential research capacity that, in part, fulfills the VAPSHCS VISN20 MIRECC's Congressionally-mandated investigation of posttraumatic stress disorder (PTSD) and its comorbidities which includes, but is not limited to, traumatic brain injury (TBI).

4. **Statutory Authority Permitting Other than Full and Open Competition:** 41 USC §3304(a)(1), as implemented by FAR 6.302-1 Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1(c) Application for brand name description.
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 Government must establish or maintain an essential capability for theoretical analyses, exploratory studies, and experiments in research of PTSD and or TBI at the VISN20 MIRECC, as mandated by Congress. This capacity must be consistent with the department's existing research development of various clinical, preclinical and molecular biological research protocols while leveraging equipment modernization. This request is for "Brand-name" procurement. Only the items listed above satisfy the Government's requirements as listed in Section 3 above, meet the performance history and standards of the research unit and are consistent with brands used to establish the research program.

The VA Northwest Network (VISN-20) Mental Illness Research, Education, and Clinical Center (MIRECC). The MIRECC is a neuroscience research facility with a Congressionally-mandated focus in military posttraumatic stress disorder (PTSD) and its complex comorbidities. Among the comorbidities included are repetitive blast concussion mild traumatic brain injury (the "signature injury" of the wars in Afghanistan and Iraq), alcohol misuse, and chronic post concussive symptoms. The Seattle MIRECC has particular strength in blast concussion mTBI and its sequelae – both in the short term (e.g., chronic post concussive migraines, irritability and anger dyscontrol) and long-term (potential neurodegeneration and dementia). This research program comprises 24 VAPSHCS Investigators, 30 funded research projects (3 of which are DoD grants), and is intimately partnered with local and national DoD, VA, and academic affiliates. In conjunction with the VA GRECC here at VA Puget Sound and with the Neuropathology Division of the Dept. of Pathology at the University of Washington (among a number of UW departments), we have a very robust research program in living Veterans with mild TBI, a corresponding clinically-relevant translational animal research program, and an innovative and successful program to obtain autopsy brain tissue from active duty service members and Veterans with TBI. These research foci are of high value to VHA (as well as DoD).

The Northwest MIRECC applies modern genetic, neurobiological and clinical trial methodology to the discovery and development of new and more effective treatments for major and often treatment resistant mental disorders afflicting Veterans and the active duty combat personnel who will become Veterans. Pertinent to this request, these equipment items include, but are not limited to histology processing equipment similar to or identical to equipment used by the department to establish a fundamental capacity to perform research methodologies and expand its basis to theoretical analyses within the domain of neuroscience.

The Northwest MIRECC 's existing Standard Operating Procedures are based on the performance characteristics of the listed Leica Biosystems equipment. Acquisition of dissimilar items may require extensive revalidation and protocol refinement, jeopardize budget and project milestone timelines. The Government has spent 5-20 years (depending on the exact project) working up exacting protocols and methodologies which have cost hundreds of thousands to millions in development and validation. The Government estimates it would cost up to \$200,000 in man-hours to revalidate equipment alone. In addition, some experiments would need to be run over again. Samples would have to be regenerated or purchased depending on the case. In some situations the samples cannot be rederived or replaced because the samples were unique and consumed. The Government estimates it would take one year to revalidate existing protocols and methodologies using dissimilar equipment. This could negatively impact MIRECC's ability to compete for grants and could cost an additional ~\$3 million in lost funding opportunities. Additionally, the estimated one year delay and potential for lost funding could reduce the capacity for the Government to make timely transitional research insights impacting clinical care of traumatic brain injury, post-traumatic stress disorder and broader Veteran mental health care delivery. However, it is difficult to know or quantify in advance as some aspects of this work are immediately impactful on healthcare and other aspects take 20 years.

To accomplish the Government's goals, the Government elects a brand name justification of the above listed items. The above listed items accomplish the Government's performance requirements. By extension, other methodologies are as yet unproven, would require substantial duplication of cost to vet feasibility and adaptability and would contribute unacceptable delays in fulfilling the agency's immediate requirements.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** This requirement is for Leica Biosystems brand name items. As such, these items are available from two sources, the manufacturer, Leica Biosystems, and their Government sales authorized distributor, Government Scientific Source, a small business.
7. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** The expectation is through competition the pricing will be fair and reasonable. Barring that, the pricing can be compared to the items found on GSA Schedules (with the small business distributor, GSS).
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** As described in Section 6 above, market research, in accordance with FAR Part 10, was conducted by sending a sources sought notice to all possible VIP verified SD/VOSB firms advising of the pending acquisition and soliciting inquiries from interested parties. I received no positive responses. An inquiry to the manufacturer indicated they are the sole distributors of their Peloris instruments; however GSS holds an FSS contract for these same items. In addition, Dr. Meabon conducted market research by reviewing GSS. Leica. Tecan, Sakura, TissueTek, Precisionary, Fischer Scientific, RMC Boekeler via in person interviews, peer consultation, product and trade show attendance, scientific conferences, consultation with OHSU collaborators, VA Histology Core, UW Histology Core, and consultation with the Allen Institute Histology Core Manager. The end-user group developed study data that must be continued within the established methodology and therefore requires this exact equipment.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** This requirement for the brand name items listed above satisfy the Government's requirements as listed under the Section 3 above, meet the performance history and standards of the research unit and are consistent with brands used to establish the research program. Acquisition of dissimilar items would require extensive revalidation and protocol refinement, jeopardize budget and project milestone timelines and reduce the capacity for the department to make timely translational research insights impacting clinical care of traumatic brain injury, post-traumatic stress disorder and broader Veteran mental health care delivery.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** The manufacturer, Leica Biosystems; GSS provided a market research quote to the end-user.
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:** No further actions or future acquisitions are planned for acquisitions of this nature. This approval is sought for a single requirement for fulfillment associated with histology building activation.
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.

James Meabon   
James Meabon, PhD  
Research & Development  
VA Puget Sound Healthcare System

13. **Approvals in accordance with the [VHAPM Part 806.3 OFOC SOP](#):**

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

KAREN R. RHODES  
333239

Digitally signed by KAREN R.  
RHODES 333239  
Date: 2019.08.21 06:58:23 -07'00'

Karen Rhodes, Contracting Officer  
NCO20, Supply 2  
J&A Tracker 2019-08-05T11:17:56

VHAPM Part 806.3 Other Than Full and Open Competition (OFOC) SOP  
Attachment 2: Request for Sole Source Justification Format >SAT

- b. **One Level Above the Contracting Officer (Required over SAT but not exceeding \$700K):** I certify the justification meets requirements for other than full and open competition.

Michael J. Allred  Digitally signed by Michael J.  
Allred 1779380  
Date: 2019.08.21 08:12:51 -07'00'

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1779380  
Mike Allred, Branch Chief  
NCO20, Supply 2

- c. **NCO 20 Additional Approvals: Division Chief (Required between SAT - \$700K):** I certify the justification meets requirements for other than full and open competition.

Peggy L. Corcoran  Digitally signed by Peggy L.  
Corcoran 1568934  
Date: 2019.08.21 09:56:35 -06'00'

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Peggy Corcoran, Division Chief  
NCO20