

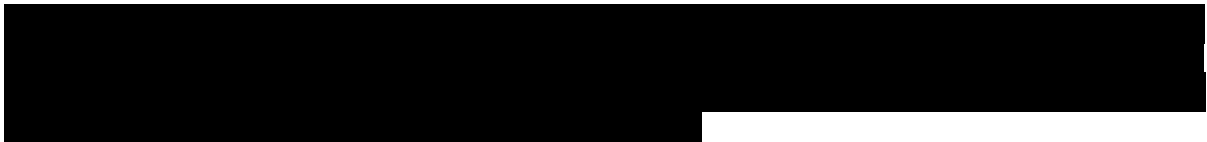
DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: VA248-16-AP-10708

1. **Contracting Activity:** Department of Veterans Affairs, VISN 08, and James A. Haley Veterans' Hospital. The Network Contracting Office (NCO) 08 is the contracting agency and the Department of Veterans' Affairs Veterans Integrated Service Network (VISN) 08, James A. Haley Veteran Affairs Hospital (JAHVAH). The Purchase Request Number (2237) is 673-17-1-042-0004.
2. **Nature and/or Description of the Action Being Processed:** This is a request for other than full and open competition in accordance with Federal Acquisition Regulation (FAR) 13.5 Test Program for certain commercial items. The requested procurement is for research service from the affiliate, University of South Florida (USF), Division of Research and Compliance located at 3650 Spectrum BLVD, Tampa, FL 33612. These services are requested by the JAHVAH Research & Development service to help meet the goals and objectives for the review, processing, and monitoring of research protocols. This includes the informed consent process and any investigation of non-compliance activities, as required by laws including Code of Federal Regulations, Title 38 PART 16 – Protection of Human Subjects (§ 16.101 - 16.124) and PART 17 - MEDICAL (§§ 17.30 - 17.1008).

The Government anticipates that the resulting action will be a firm fixed price contract for services with duration of one (1) base year and four (4) option years. The estimated period of performance for the base year of the contract will be from March 3, 2017 through March 2, 2018 with four (4) – one (1) year options thereafter.



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

Specifically, the services required to meet the project's need include:

- Initial and continuing review (or de novo) of research involving human and animal subjects and biological agents. Review of amendments, procedural changes, unanticipated problems and other adverse events;
- Ensure compliance with Veterans Health Administration (VHA), Handbook, 1200.05, Requirements for the Protection of Human Subjects in Research, VHA Directive 1200 RESEARCH AND DEVELOPMENT PROGRAM, VHA Handbooks 1058.03 Assurance of Protection for Human Subjects in Research and VHA Handbook 1058.01 Research Compliance Reporting Requirements for research including the reporting of unanticipated problems and noncompliance to the facility director per the said Handbook;
- Form committees dedicated to the review and oversight of Veteran Affairs (VA) regulated research;
- Process “paper” – Animal Component of Research Protocol (ACORP) applications for animal research
- Investigate issues of noncompliance with the approved protocols;

- Attend VA Research & Development (R&D) Committee meetings (two members of Research Integrity & Compliance (RI&C) to address concerns and provide updates on programmatic issues);
- Coordinate VA mandated training for animal research;
- Coordinate certification for Institutional Animal Care & Use Committee (IACUC) approved research staff including without compensation (WOC) appointments;
- Coordinate information regarding financial conflicts of interest in research and associated management plans;
- Semi-annual review of IACUC program including meetings with Facility Director by the IACUC Chairperson and VA R&D Committee member;
- Maintenance of Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) accreditation for the animal research program (reaccreditation occurs every three years);
- Maintenance of Association for the Accreditation of Human Research Protection Programs (AAHRPP) accreditation for the human subjects research program
- Attend JAHVH site visits for interviews with Office of Research Oversight (ORO) personnel; and
- Attend quarterly meetings with JAHVH and R&D staff.

4. Statutory Authority Permitting Other than Full and Open Competition:

The statute of authority that permits other than full and open competition is located at 41 USC §3304(a) (1), (3) (B) and is implemented by FAR 6.302-1 “Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements.” The authority to implement FAR 6.302-1 is at (a) (2) “When the supplies or service are available from only one responsible source, full and open competition need not be provided for.” The application for implementation is at FAR 6.302-1 (b), (1) (i).

FAR13.5 Simplified Procedures for Certain Commercial Items: The authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented by restricting competition on this procurement via FAR 13.106-1(b)(2).

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 required services were carefully reviewed by the Associate Chief of Staff (ACOS) of Research and Development, Contracting Officer Representative, and Contracting Officer prior to determining its feasibility for competition and the decision to establish a service contract. The USF Division of Research and Compliance is the only locally affiliated educational institution with the appropriate resources and experienced personnel with the unique expertise to conduct an IRB in accordance with VHA Handbook 1058.03 Assurance of Protection for Human Subjects in Research and in VHA Handbook 1058.01 Research Compliance Reporting Requirements in the field of maintaining accreditation.

Although there were other organizations that offered similar services, the USF is the only local institution that can provide this unique service with the experience and expertise required by the JAHVH to fully execute and meet all the Government’s requirements.

[REDACTED]

The JAHVAH affiliate “USF” is the incumbent contractor. T [REDACTED]

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

Market research shows regional universities that provide commercial services identical to JAHVAH. The services are provided locally via their specific location and to VA's in which an affiliation exist. Searches were conducted using the Internet by searching through the GSA E-Library, FPDS-NG ezSearch, Google Internet Search engines, and active non-profit universities ".edu" websites. These searches were used to compare commercial market price and cost comparisons for the same or similar services requested for this procurement.

[REDACTED]

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|------------|------------|------------|------------|------------|------------|------------|------------|
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |

[REDACTED]

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

The anticipated cost to the government to award this contract to the USF is [REDACTED] for the base year and [REDACTED] in the aggregate amount for the base year and four (4) options. The USF's Aggregate amount [REDACTED]

[REDACTED]

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

The key elements of the market research revealed that the service is a customary commercial service. Searches were conducted using the Internet by searching through the GSA E-Library, FPDS-NG ezSearch, Google Internet Search engines, active non-profit universities ".edu" websites, and vetbiz.gov. The market research revealed that IRB, IBC, and IACUC service are available on the

commercial market. [REDACTED]

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

The USF Division of Research Integrity and Compliance have experts in the field of IRB reviews. The contractor's employees have successfully conducted over Four-Hundred (400) IRB's [REDACTED] continue. Said services were conducted successfully for the review, processing, and monitoring of research protocols, including the informed consent process, and any investigation of non-compliance activities, as required by the governing laws of 38 CFR 16 & 17.

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

JAHVAH, BLR&D will continue to fully review and evaluate the market availability of comparable services. The Contracting Officer posted a Request for Information (RFI) at the Government Point of Entry (GPE), Federal Business Opportunities (FBO) prior to requesting an approval for Justification and Approval (J&A) for other than full and open competition. The RFI explained the requirement along with providing the Performance Work Statement. [REDACTED]

[REDACTED] informed consent process, investigation of non-compliance activities, use of laws including Code of Federal Regulations, Title 38 PART 16 – Protection of Human Subjects (§ 16.101 - 16.124) and PART 17 - MEDICAL (§§ 17.30 - 17.1008), compliance with Veterans Health Administration (VHA) handbooks 1058.03 Assurance of Protection for Human Subjects in Research and in Veterans Health Administration (VHA) Handbook 1058.01.

Once this J&A is approved, a special notice of intent will be posted in the GPE, FBO prior to award. This will further serve as notification about the Governments intent to contract with the USF for these services.

1. **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.

[Redacted Signature]

Chief of Research and Development
James A. Haley VAMC

2. **Approvals in accordance with the VHAPM, Volume 6, Chapter VI: OFOC SOP.**

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

[Redacted Signature]

Cyrouse Himid Houshyani
Contracting Officer
NCO 08
Medical Sharing, 1663 Contracting

Date

- b. **Product Line Supervisor Review:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

[Redacted Signature]

Product Line Supervisor
NCO 08
Medical Sharing, 1663 Contracting

- c. **Director of Contracting /Designee:** I certify the justification meets requirements for other than full and open competition.

[Redacted Signature]

NCO 08, Division Chief
Specialized Contracts

- d. **SAO East Director, Veterans Health Administration:** I certify the justification meets requirements for other than full and open competition.

[Redacted Signature]

SAO East Director