

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

1. **Contracting Organization:** Department of Veterans Affairs, VISN 11, Richard L. Roudebush VA Medical Center, 1481 W 10th Street, Indianapolis, IN 46202. Transaction# 583-15-3-6024-0225
2. **Description of Action:** The proposed action is a sole source solicitation of a contract to Indiana University's School of Medicine (IUSM) to provide Institutional Animal Care and Use Committee Services.
3. **Description of Supplies or Services:** This contract request is for Institutional Animal Care and Use Committee Services for the oversight and care of various species of animals for VA funded research grants that contain animal protocols as they are funded. VA animal care and use programs must follow VA policy on the use of animals found in Handbook 1200.7, "Use of Animals in Research", which incorporates compliance with Animal Welfare Act (7 USC 54:2131-2159) as implemented in the US Department of Agriculture Animal Welfare act Regulations (9 CFR Parts 1, 2, and 3: USDA AWAR), with special emphasis on Section 2.31 (IACUC), 2.32 (Personnel Qualifications) and 2.33 (Attending Veterinarian and Adequate Veterinary Care) and the Health Research Extension Act of 1985 (PL 99-158: 495) as implemented in Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals. All VA animal care and use programs are accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC, International) and only Universities that are approved and accredited by the AAALAC may conduct IACUC Services. Indiana University School of Medicine is the only AAALAC certified University in the state of Indiana.

This acquisition allows the VA to establish or maintain an essential capability for animal research for 43 currently VA funded and potential research grants that at present, cannot be performed at the Roudebush VA Medical Center's (RLRVAMC) Research staff. The anticipated value of this requirement is \$452,573 for the base and four one-year option periods.

This requirement is being requested to continue collaborative animal research services between the RLRVAMC Research Service and the Indiana University School of Medicine. RLRVAMC holds a Memorandum of Understanding with the Indiana University School of Medicine (IUSM) concerning the the Use of Institutional Animal Care and Use Committee (IACUC) hosted by IU as the VA IACUC of Record.

This contract will include base period of 12 months, beginning April 1, 2014 through March 31, 2016 with four (4) one-year option periods of one (1) year each. This contract will be a Requirements Contract, therefore the following are realistic estimates based on historical data and protocols for newly funded grants which are the most accurate information available. Actual obligation of these funds will occur with each subsequent task order to the base contract.

Base Period (4/1/15 – 3/31/16):	\$71,232
Option Year 1 (4/1/16 – 3/31/17):	\$79,788
Option Year 2 (4/1/17 – 3/31/18):	\$89,364
Option Year 3 (4/1/18 – 3/31/19):	\$100,089
Option Year 4 (4/1/19 – 3/31/20):	\$112,100
Total Contract (Base +4 OY):	\$452,573

Services in this contract include:

- Institutional Animal Care and Use (IACUC) oversight that review all VA animal protocols, modifications, and post-approval oversight, annual and monthly reports to the Roudebush VAMC Research Service
- Contractor shall provide maintenance of all documents reviewed by its IACUC in connection with VA research protocols, including communication with investigators. Such documents must be made available to approved VA representatives upon request

4. Statutory Authority:

- (X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements;
- () (2) Unusual and Compelling Urgency;
- () (3) Industrial Mobilization, Engineering, Developmental or Research Capability, or Expert Services;
- () (4) International Agreement
- () (5) Authorized or Required by Statute;
- () (6) National Security; or
- () (7) Public Interest

- 5. Validity of Use of Statutory Authority:** The Richard L. Roudebush VA Medical Center Research Service administers VA Research Grants which have been approved for the use of animals for research. VA animal care and use programs must follow VA policy on the use of animals found in Handbook 1200.7, "Use of Animals in Research", which incorporates compliance with USDA Animal Welfare Act Regulations and PHS Policy. VHA HANDBOOK 1200.7 states, "Transporting animals into or through areas used by patients or visitors must be avoided whenever possible. When essential to do so, all reasonable means of minimizing health risks to patients and visitors posed by animal body fluids, waste, and aerosols need to be adopted." Unnecessary transport over longer distances would cause undue stress to

research animals and violate VA Policy in regards to the care of research animals which mandates that the general health of animals is safeguarded and that undue stress is avoided, with appropriate attention paid to environmental factors such as temperature, ventilation, and humidity. (VHA HANDBOOK 1200.7) Therefore the animals currently housed and overseen by the existing Research program between IU and RLRVAMC cannot be moved to another location/vendor and is imperative to the continuity of the current/ongoing research studies that they remain housed at IUSM.

All VA animal care and use programs are accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC, International) and only Universities that are approved and accredited by the AAALAC may conduct IACUC Services. Indiana University School of Medicine is the only AAALAC certified University in the state of Indiana.

6. **Actions to Promote Competition:** Competition is not being sought for this requirement. There are no other facilities in the local area that can provide the required services on the animals currently housed at IUSM under the VA Research Program, that can also maintain accreditation with the AAALAC, maintain compliance with USDA Animal Welfare Act Regulations, and maintain PHS Policy and VA policy on the use of animals as required in VA Handbook 1200.7, "Use of Animals in Research." Given the unique nature of this requirement and the nature of the research work being conducted, services must continue to be met through the sole source provisions of FAR 6.302.
7. **Determination of Fair and Reasonable Price:** The anticipated price is noted in #2 above. A comparison has been made with past and similar contracts. These services are currently being provided by the IU School of Medicine under contract VA251-12-C-0044; which is a base plus two option year contract and the current total dollar value of this contract is \$168,782.55. There is clear pricing history to use in determining if current proposed pricing is fair and reasonable.

The Independent Government Estimate will also be used to assist in determining if the prices offered are considered fair and reasonable. The IGCE is based upon prior year usage which includes the number of investigators being overseen by the IUSM's IACUC and includes a 12% increase that was evaluated over fiscal year 12 through fiscal year 14 and is due to annual cost increases, increases in changing regulatory requirements, plus an increase in the greater volume of animals to be covered corresponding to the number of newly funded research grants at the RLRVAMC with approved animal protocols.

8. **Market Survey (FAR 10):** Market research determined that the IUSM was the only University in the state of Indiana that provides the AAALAC accredited IACUC services through which to acquire care, feeding and housing for these animals. IUSM has the only facility that is directly accessible to VA Research Investigators' laboratories. VHA HANDBOOK 1200.7 states, "Transporting animals into or through areas used by patients or visitors must be avoided whenever possible. When

essential to do so, all reasonable means of minimizing health risks to patients and visitors posed by animal body fluids, waste, and aerosols need to be adopted.” Unnecessary transport over longer distances would cause undue stress to research animals and violate VA Policy in regards to the care of research animals which mandates that the general health of animals is safeguarded and that undue stress is avoided, with appropriate attention paid to environmental factors such as temperature, ventilation, and humidity. (VHA HANDBOOK 1200.7).

Market research was conducted via the Internet and current and historic contract pricing data for IACUC Services and the care of animals, as well as searches for similar services available from other facilities for the purpose of price comparison.

The following websites were used to conduct Market Research:

<http://www.aaalac.org/about/index.cfm>

<http://www.aaalac.org/accreditedorgsdirectorysearch/aaalacprgms.cfm>

<https://www.aalas.org/iacuc>

<https://www.aalas.org/iacuc/resources/iacuc-resources/iacuc-webpages>

<https://www.aalas.org/get-involved/branches/branch-listings>

<http://rushsite001.squarespace.com/>

<http://iacuc.utk.edu/>

<http://www.iacuc.pitt.edu/>

<http://en.wikipedia.org/wiki/IACUC>

9. **Other Considerations:** IUSM is the only facility in the area that has a Memorandum of Understanding between RLRVAMC and the IACUC of record for the support of animal research; therefore serves as our own subcommittee for approval of our animal use. IUSM is the only University in the state of Indiana that has received accreditation from the AAALAC and that currently provides care to the animals under the ongoing VA Research program. Utilizing IUSM’s facility to provide these services ensures continuity, closer oversight and adherence to VA regulation.
10. **Listing of Sources that expressed, in writing, an interest in the acquisition:** Indiana University School of Medicine, Trustees of Indiana University, Research and Sponsored Program, 980 Indiana Avenue, Rm 2232, Indianapolis, IN 46202.
11. **Statement of Actions to Overcome Barriers to Competition:** Given the unique nature of this requirement and the nature of the research work being conducted, services must continue to be met through the sole source provisions of FAR 6.302-1
12. **Requirements Certification:** I certify that the requirement outlined in this justification is a bonafide 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.

(this signature is the requestor’s supervisor, fund control point official, chief of service, someone with responsibility and accountability)

Julie Herbertz

1/6/15

Name: Julie Herbertz
Title: Program Specialist, Research Services
Facility: Station 583-Roudebush

Date

13. Approvals in accordance with FAR 6.304 *This part if filled out by Contracting Staff as part of the Justification*

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

Lisa Frymier
Contracting Officer
Network 11 Contracting Office

Date

- b. **Director of Contracting /Designee (Required \$150K and above):** I certify the justification meets requirements for other than full and open competition.

Toni Waggoner-Boykin
Supervisory Contract Specialist
Network 11 Contracting Office

Date

- c. **SAO (If over 650K):** I certify the justification meets requirements for other than full and open competition.

Ricky Lemmon
SAO Director
Service Area Office, Central

Date

- d. **VHA HCA Review and Approval:** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and recommend approval (if over \$12.5 million) or approve (\$650K to 12.5 million) for other than full and open competition.

Norbert Doyle
Chief of Procurement and Logistics
VHA, Head of Contracting Activity (HCA)

Date

- e. **VA Deputy Senior Procurement Executive Approval (over \$12.5 million but not exceeding \$50 million):** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for other than full and open competition.

C. FORD HEARD
Deputy Senior Procurement Executive (DSPE)
Office of Acquisition and Logistics
Department of Veterans Affairs

Date

- f. **VHA Senior Procurement Executive Approval (over \$50 million):** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for other than full and open competition.

Jan R. Frye
Deputy Assistant Secretary for Acquisition and Logistics
Senior Procurement Executive (SPE)
Department of Veterans Affairs

Date