

DEPARTMENT OF VETERANS AFFAIRS

**Justification and Approval (J&A)
For
Other Than Full and Open Competition (>\$150K)**

Acquisition Plan Action ID: VA250-17-AP-1126

- 1. Contracting Activity:** Department of Veterans Affairs, VISN 10, Richard L. Roudebush VA Medical Center, 1481 W 10th Street, Indianapolis, IN 46202. Transaction# 583-17-3-8024-0069.
- 2. Nature and/or Description of the Action Being Processed:** Single Source procurement of a base plus one (1) option year firm fixed price service contract for Laboratory Animal Resource Services (LARC) with the Indiana University School of Medicine (IUSM).

FAR13.5 Simplified Procedures for Certain Commercial Items: The services requested are commercial in nature; this request for LARC services provides veterinarian care and husbandry care to the animals currently housed at IUSM; Veterinarian care and husbandry care are commercial in nature.

- 3. Description of Supplies/Services Required to Meet the Agency's Needs:** The period of performance to begin on April 1, 2017 through March 31, 2018 and the Independent Government Estimate for this base plus one (1) option year contract is \$485,460.00 (base year of \$242,424.00). This procurement request for Laboratory Animal Resource Center (LARC) Services consists of purchasing, housing, feeding, and providing daily medical care of animals that are used for research purposes in conjunction with the Institutional Animal Care and Use Committee (IACUC).

VA animal care and use programs must follow VA policy on the use of animals found in VHA Handbooks [1200.01](#), "Research and Development Committee" and [1200.07](#), "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 (LARC), 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 LARC Services. VHA Handbook [1200.07](#), paragraph 7 (e) states "All VA animal facilities and affiliates, or other animal facilities that house animals purchased with VA funds, or used for VA or VA research and education corporation projects must be accredited by AAALAC."

LARC Services must be conducted under the oversight of the VA's affiliated IACUC, which is mandated by VHA Handbooks [1200.01](#) and [1200.07](#) via the Memorandum of Understanding (MOU) between IUSM and RLR VAMC dated January 15, 2015. IUSM is the only AAALAC accredited University in the state of Indiana that also has an MOU Affiliate Agreement with the RLR VAMC and is therefore the only source that can provide these services.

This requirement is being requested to continue collaborative animal research services between the RLR VAMC Research Service and the IUSM. RLR VAMC holds a Memorandum of Understanding with IUSM concerning the Use of LARC Services. IU will be responsible for purchasing animals required for VA funded grant research, provide housing for mice, rats and other animals used for VA research purposes, provide biohazard housing as needed to

ensure all animals remain virus free, and provide appropriate feed for all VA housed research animals. This includes purchase of special diets as required to ensure animals are cared for appropriately.

IUSM shall provide necessary medical care for the animals including artificial tears, trimming teeth, ophthalmic antibiotics, weaning, etc. IUSM shall ensure that Veterinarian services are being provided to care for the housed animals. The Attending Veterinarian (AV) shall be Board Certified ALCAM Veterinarian approved by the Institutional Animal Care and Use Committee (IACUC) located at IUSM. The veterinarian will be a member of the IACUC review committee and as such, will review all animal care, use applications, and provide necessary animal consultation services. AV will attend any applicable IACUC meetings; participate in any applicable IACUC reviews and/or inspections. Services will also include vet visits and consultation to include diagnostic and therapeutic measures, on call service including telephone consultations.

This contract will include base period of 12 months, beginning April 1, 2017 through March 31, 2018 with one (1) option year period. This contract will be an Indefinite Delivery-Indefinite Quantity Contract, therefore the following dollar values are realistic estimates based on historical data, the current number of research investigators conducting studies, and includes protocols for newly funded grants. Actual obligation of these funds will occur with each subsequent task order to the base contract. The guaranteed minimum for this procurement is \$10,000 for the life of the contract.

The anticipated value of this requirement is \$485,460.00 for the base and one (1) one-year option periods.

Base Period (4/1/17 – 3/31/18):	\$242,424
Option Year 1 (4/1/18 – 3/31/19):	\$243,036
Total Contract (Base +1 OY):	\$485,460

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

- () (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
- () (2) Unusual and Compelling Urgency per FAR 6.302-2;
- () (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
- () (4) International Agreement per FAR 6.302-4
- () (5) Authorized or Required by Statute FAR 6.302-5;
- () (6) National Security per FAR 6.302-6;
- () (7) Public Interest per FAR 6.302-7;

- (X) FAR 13.5 in accordance with 41 USC 1901;

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 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 [1200.07](#), "Use of Animals in Research", which incorporates compliance with USDA Animal Welfare Act Regulations and PHS Policy. VHA Handbook [1200.07](#) 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 [1200.07](#)) Therefore, the animals currently housed and overseen by the existing Research program between IUSM 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 LARC Services. IUSM is the only AAALAC accredited University in the state of Indiana that also has an MOU Affiliate Agreement with the RLR VAMC and is therefore the only source that can provide these services.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Competition is not being sought for this requirement. There are no other facilities in the state of Indiana that can provide the required services on the animals currently housed at IUSM under the VA Research Program (as stated in above in paragraph's 3 and 5), that also maintains accreditation with the AAALAC, maintains compliance with USDA Animal Welfare Act Regulations, maintains PHS Policy, adheres to VA policy on the use of animals as required in VA Handbooks [1200.01](#) and [1200.07](#).
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The anticipated price is noted in paragraph #3 above. A comparison has been made with past and similar contracts as well as current pricing listed on IUSM's LARC website <http://medicine.iu.edu/larc/services-and-information/per-diem/>:
Effective July 1, 2016 thru June 30, 2017

Dog	\$16.00	Rabbit	\$6.17
Frog tank	\$2.07	Rat	\$0.71
Zebra Fish (per row)	\$0.16	Swine	\$15.95
Mouse Cage	\$0.85	Piglet (group housed)	\$6.93
GLP Mouse Cage	\$1.12	Large Swine	\$20.83
Biohazard Cage	\$1.12	Ossabaw Facility	\$6.43
Quarantine Cage	\$4.31		

These services are currently being provided by the IUSM under contract VA251-15-D-0056; which is a base plus one option year contract and the current total dollar value of this contract is \$535,306.00. There is clear pricing history to use in determining if 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. Pricing was evaluated over fiscal year 14 through fiscal year 16 and is due to annual cost increases, changing regulatory requirements, the estimated volume of animals to be covered, and the estimated number of newly funded research grants at the RLR VAMC with approved animal protocols. The number of newly funded research investigators is estimated to be lower than the current contract's needs due to a decline in VA funds for Research Grants; which is why the IGCE is slightly lower than the current contract's dollar value (listed above).

Services for related animal purchases and care will fluctuate depending on number of funded investigators, the cost of specific animal purchases, as well as length of stay and care required.

8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research

Was Not Conducted: Market research determined that the IUSM was the only University in the state of Indiana that provides the AAALAC accredited LARC 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 [1200.07](#) 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 [1200.07](#)).

Market research was conducted via the Internet and current and historic contract pricing data for LARC Services, as well as searches for LARC services provided by other Universities nationwide (used for the purpose of price comparison). The following websites were used to conduct Market Research:

http://en.wikipedia.org/wiki/Laboratory_animal_sources
http://en.wikipedia.org/wiki/National_Center_for_Research_Resources
http://en.wikipedia.org/wiki/American_Association_for_Laboratory_Animal_Science
<http://medicine.iu.edu/larc/>
<http://medicine.iu.edu/larc/services-and-information/per-diem/>
<http://oregonstate.edu/dept/larc/>
<http://oregonstate.edu/dept/larc//larc-diem-and-service-fees-fy17>
<https://www.ttuhscc.edu/centers/larc/>
<https://www.ttuhscc.edu/centers/larc/PerDiemFees.aspx>
<http://larc.ucsf.edu/>

- 9. Any Other Facts Supporting the Use of Other than Full and Open Competition:** These services can only be provided by Universities that have been approved/accredited by the Association for Assessment and Accreditation for Laboratory Animal Care (AAALAC). IUSM is the only known University in the state of Indiana with AAALAC accreditation. Also, LARC Services must be conducted under the oversight of the VA's affiliated Institutional Animal Care and Use Committee (IACUC) per VHA Handbooks 1200.01 and 1200.07. IUSM has an approved Memorandum of Understanding dated January 15, 2015 for Animal Research Support that outlines IUSM as the approved IACUC of record. Therefore, only IUSM can perform these LARC services.

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

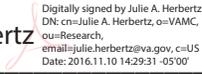
Indiana University School of Medicine
Trustees of Indiana University
Research and Sponsored Program
980 Indiana Avenue, Rm 2232
Indianapolis, IN 46202

11. 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:

Given the unique nature of this requirement, the nature of the research work being conducted, and VHA Handbooks 1200.01 and 1200.07's requirement that these services be conducted by the affiliate (IUSM); this procurement will be conducted as a single source basis under FAR 13.106-1(b).

Chapter VI: Other Than Full and Open Competition (OFOC) SOP
Attachment 3: Request for Sole Source Justification Format >\$150K

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.


Julie A. Herbertz

Julie Herbertz
Program Specialist, Research Service
Richard L. Roudebush VA Medical Center

11/10/16

Date

13. Approvals in accordance with the [VHAPM, Volume 6, Chapter VI: 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.


Lisa D.
Frymier
320908

Lisa Frymier
Contracting Officer
Network Contracting Office 10

11/10/2016

Date

b. **Director of Contracting /Designee (Required over \$150K but not exceeding \$700K):** I certify the justification meets requirements for other than full and open competition.

Toni Waggoner-Boykin
Supervisory Contract Specialist
Branch Chief, IN Services Team
Network Contracting Office 10

11/15/2016

Date