

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# 583-15-3-6024-0224
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 Laboratory Animal Resource Center (LARC) Services.
3. **Description of Supplies or Services:** This contract request is for Laboratory Animal Resource Center (LARC) Services. LARC services consist 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 Handbook 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 MOU between IUSM and RLR VAMC. 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. For further explanation, please refer to VA Form 2268 for IACUC Services OSDBU Control Number 2015-009-002 concurrence memo dated January 15, 2015.

The anticipated value of this requirement is \$460,086 for the base and one (1) 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 Laboratory Animal Resource Center (LARC) hosted by IU as the VA LARC of Record. 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.

IU shall provide necessary medical care for the animals including artificial tears, trimming teeth, ophthalmic antibiotics, weaning, etc. The contractor 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 Indiana University. The veterinarian will be a member of the IACUC review committee as such will review all animal care and use applications and necessary consultation. 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, 2015 through March 31, 2016 with one (1) option year period. This contract will be a Requirements Contract, therefore the following are realistic estimates based on historical data, the current number of research investigators conducting studies, and protocols for newly funded grants. Actual obligation of these funds will occur with each subsequent task order to the base contract.

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| Base Period (4/1/15 – 3/31/16): | \$230,220 |
| Option Year 1 (4/1/16 – 3/31/17): | \$230,640 |
| Total Contract (Base +1 OY): | \$460,086 |

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 1200.07, "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. **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 (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, and maintains PHS Policy and VA policy on the use of animals as required in VA Handbook 1200.07, "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 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 September 1, 2014 thru June 30, 2015

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|------------|---------|-----------------------|---------|
| Dog | \$14.94 | Rabbit | \$5.76 |
| Frog tank | \$2.00 | Rat | \$0.67 |
| Guinea Pig | \$3.12 | Swine | \$14.89 |
| Mouse Cage | \$0.79 | Piglet (group housed) | \$6.48 |

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|-----------------|--------|------------------|---------|
| GLP Mouse Cage | \$1.04 | Large Swine | \$19.45 |
| Biohazard Cage | \$1.04 | Ossabaw Facility | \$6.00 |
| Quarantine Cage | \$4.02 | Zebra Fish Rack | \$0.87 |

These services are currently being provided by the IU School of Medicine under contract VA251-12-C-0023; which is a base plus one option year contract and the current total dollar value of this contract is \$656,889.15. 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. The IGCE is based upon prior year usage which was determined using contract pricing on VA251-12-C-0023. Pricing 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.

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. Market Survey (FAR 10):** 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 similar services available from other facilities 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://research.oregonstate.edu/larc/laboratory-animal-resources-center-larc-contacts>
<https://www.ttuhsc.edu/centers/larc/>

<http://www.larc.ucsf.edu/>

9. **Other Considerations:** IUSM is the only facility in the area that has a Memorandum of Understanding between RLRVAMC and the LARC of record for the support of animal research. 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, the nature of the research work being conducted, and VHA Handbook 1200.07's requirement that these services be conducted by the affiliate (IUSM); 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 D. Frymier
320908

Digitally signed by Lisa D. Frymier 320908
DN: cn=goi,dc=va,ou=internal,cn=people,
o=2342-19200300,100.1.1-lisa.frymier@va.gov, cn=Lisa D. Frymier 320908
Date: 2015.01.20 08:52:35 -0500

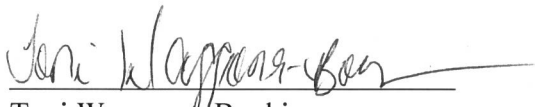
Lisa Frymier
Contracting Officer

1/20/2015

Date

Network 11 Contracting Office

- 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

1-21-15

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

Date

Deputy Senior Procurement Executive (DSPE)
Office of Acquisition and Logistics
Department of Veterans Affairs

- 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.

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