

|   |  |  |                    |                        |
|---|--|--|--------------------|------------------------|
| <b>AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT</b> |  |  | 1. CONTRACT ID NO. | PAGE OF PAGES<br>1   5 |
|---|--|--|--------------------|------------------------|

|   |   |                                  |                                |
|---|---|----------------------------------|--------------------------------|
| 2. AMENDMENT/MODIFICATION NO.<br><p style="text-align: center;">One (1)</p> | 3. EFFECTIVE DATE<br><p style="text-align: center;">Jul 7, 2000</p> | 4. REQUISITION/PURCHASE REQ. NO. | 5. PROJECT NO. (if applicable) |
|---|---|----------------------------------|--------------------------------|

|   |      |  |      |
|---|------|--|------|
| 6. ISSUED BY<br>National Institutes of Health<br>National Heart, Lung, and Blood Institute, Procurement Section<br>RKL2, Room 6143<br>6701 Rockledge Drive, MSC 7902<br>Bethesda, Maryland 20892-7902 | CODE | 7. ADMINISTERED BY (if other than Item 6)<br>Kathleen E. Jarboe, Contracting Officer, (301) 435-0364 | CODE |
|---|------|--|------|

|                       |               |     |   |
|-----------------------|---------------|-----|---|
| <b>“ALL OFFERORS”</b> |               | ( ) | 9A. AMENDMENT OF SOLICITATION NO.<br><p style="text-align: center;">NHLBI-RR-P-00-595</p> |
|                       |               | X   | 9B. DATED (SEE ITEM 13)<br><p style="text-align: center;">June 12, 2000</p>               |
|                       |               |     | 10A. MODIFICATION OF CONTRACT/ORDER NO.   |
|                       |               |     | 10B. DATED (SEE ITEM 13)  |
| CODE                  | FACILITY CODE |     |   |

**11. THIS ITEM APPLIES TO AMENDMENTS OF SOLICITATIONS**

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers  is extended,  is not extended.

Offerors must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

(a) By completing Items 8 and 15, and returning 1 copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and a amendment number s. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

**12. ACCOUNTING AND APPROPRIATION DATA (if required)**

**13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.**

|     |   |
|-----|---|
| ( ) | A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.  |
|     | B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b). |
|     | C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:  |
|     | D. OTHER (Specify type of modification and authority)   |

**E. IMPORTANT:** Contractor  is not,  is required to sign this document and return \_\_\_\_\_ copies to the issuing office.

**14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by U CF section headings, including solicitation /contract subject matter where feasible.)**

- Purpose:**
- 1) To extend the **DUE DATE** from July 27 to **August 11, 2000**. The time for receipt on August 11 still is 12:00 pm EDT.
  - 2) To amend Section B, Article B.1., Brief Description of Supplies or Services.
  - 3) To amend Section F, Article F.2., Deliveries.
  - 4) To amend Section L.2., Instructions to Offerors.
  - 5) To amend Section M., Evaluation Factors for Award.
  - 6) To amend Sections C.1., Statement of Work and C.2., Services to be Performed.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

|   |   |  |                  |
|---|---|--|------------------|
| 15A. NAME AND TITLE OF SIGNER (Type or print)                                   | 16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)<br><p style="text-align: center;">Debra C. Hawkins</p> |  |                  |
| 15B. CONTRACTOR/OFFEROR<br><br><i>(Signature of person authorized to sign.)</i> | 15C. DATE SIGNED  | 16B. UNITED STATES OF AMERICA<br>BY _____<br><i>(Signature of Contracting Officer)</i> | 16C. DATE SIGNED |

## SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

**ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES**, the third and fourth sentences are amended to read as follows: Most of the existing facilities were built in the 1990s with public funds on lands withdrawn from the public domain for use by the Air Force. To address the national need for maintenance and preservation of a large proportion of chimpanzees nationwide, NCRR has assumed ownership of approximately 300 chimpanzees and is seeking a Contractor to operate and maintain the associated long-term care facility, as well as provide overall facility operation and maintenance.

## SECTION F - DELIVERIES OR PERFORMANCE

**ARTICLE F. 2. DELIVERIES**, is amended to increase from two (2) to three (3) the quantity of the following reports to be delivered: (c) Emergency Telephone Roster, (g) Incident and Accident Reports, and (i) Major Alterations and Renovations Report.

## SECTION L - INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

### 2. INSTRUCTIONS TO OFFERORS

#### a. GENERAL INSTRUCTIONS

**(10) Care of Live Vertebrate Animals**, is amended to correct the mailing address for obtaining additional information. 6705 Rockledge Drive, Suite 1050, MSC 7982, Bethesda, MD 20892-7982 replaces the Executive Blvd. address shown in the RFP.

Also, the title of the notice is corrected to read: **Notice to Offerors of Requirement for Adequate Assurance of Protection of Vertebrate Animal Subjects - (SEPTEMBER 1985)**.

#### b. TECHNICAL PROPOSAL INSTRUCTIONS

##### (1) Technical Discussions

##### (b) Personnel

(5) Personnel Qualifications and Requirements, is amended to add the following between the first and second paragraphs:

Three differing approaches could be used for preparing the Contract proposal: An existing entity could propose expansion to include a satellite facility, and the satellite facility could either 1) negotiate its own animal Assurance with OLAW and register separately with USDA, or 2) use the parent organization's existing animal Assurance and USDA Registration; or 3) a coalition of investigators could propose to create a new entity de novo.

In addition, the first sentence of the third paragraph (formerly the second paragraph) is amended to read as follows: "Offerors must either be able to document the existing experience and capabilities of currently employed professional and technical personnel that would transfer from the offeror's main facility to the APF, and/or propose the minimally acceptable qualifications for staff to be hired."

The final change in this section is a revision of the Program Administrator responsibilities. The revised version reads as follows:

Program Administrator - The Program Administrator will have significant responsibility. He/she will support all necessary administrative functions for the APF, and could in the first approach described in (b)(5) above, work closely with the Contractor's main site regarding IACUC approvals, personnel actions, payrolls, report preparations, etc. NIH believes that many support services could be provided to the APF from the main location of a Contractor's institution, and the Program Administrator could coordinate these interactions. Alternatively, a new institutional entity would employ a Program Administrator who would completely manage the provision of these functions.

## SECTION M - EVALUATION FACTORS FOR AWARD, is amended to read as follows:

### 1. General

The major evaluation factors for this solicitation include technical (which encompasses experience), past performance, cost/price, and small disadvantaged business factors. Although technical factors are of paramount consideration in the award of the contract, cost/price is also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price.

Offerors are advised that award will be made to that offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below. Three differing approaches could be used for preparing the Contract proposal: An existing entity could propose expansion to include a satellite facility, and the satellite facility could either 1) negotiate its own animal Assurance with OLAW and register separately with USDA, or 2) use the parent organization's existing animal Assurance and USDA Registration; or 3) a coalition of investigators could propose to create a new entity de novo.

2. Mandatory Qualification Criterion

Listed below is a mandatory qualification criterion. The offeror shall include all information that documents and/or supports the qualification criterion in one clearly marked section of its proposal.

The qualification criterion establishes conditions that must be met at the time of receipt of the initial proposal by the Contracting Officer in order for your proposal to be considered any further for award.

The offeror must either already have an Office for Laboratory Animal Welfare (OLAW, formerly OPRR) Assurance Number, and have a United States Department of Agriculture (USDA) R Registration, and have previously demonstrated the ability to provide high quality care for chimpanzees; or as an alternative for the purposes of preparing a Contract proposal, declare that it will submit an Assurance when requested by OLAW, and apply for USDA registration if it is selected to be the Contractor, and have previously demonstrated the ability to provide high quality care for chimpanzees. This ability to care for chimpanzees could be demonstrated in several ways, such as possession of an Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) accreditation and file number. The APF shall be operated in compliance with the list of references in the Statement of Work, and the offeror must be able to meet the security requirements of the HAFB.

3. Technical Evaluation Criteria

The technical evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

| <u>Criterion</u> | <u>Weight</u> |
|------------------|---------------|
|------------------|---------------|

|  |    |
|--|----|
| Competence in the operation and maintenance of a large chimpanzee facility conforming to all Federal laws, Federal policies, NRC and ILAR recommendations. | 50 |
|--|----|

This criterion includes proposed procedures for veterinary care and animal husbandry of chimpanzees; dealing with biohazards; obtaining IACUC approvals; preventing the APF chimpanzees from breeding; and maintaining or developing, as necessary, information technology capabilities required for the chimpanzee database (please refer to the Statement of Work for specific requirements).

|   |    |
|---|----|
| Competence and experience of current professional and support personnel, and proposed plan for the acquisition of additional personnel. | 20 |
|---|----|

Personnel must possess extensive experience in nonhuman primate medicine and infectious diseases. The professional staff (e.g., Principal Investigator, Deputy Principal Investigator and two additional veterinarians) will be evaluated, as appropriate, with respect to speciality board certification by the American College of Laboratory Animal Medicine, advanced degrees, state veterinary licenses, and residency training in laboratory animal medicine. The technical staff (e.g., Program Administrator, Information Technologist,

**Behaviorist, Clinical Technician, Colony Manager, and laboratory animal caretakers) will be evaluated with respect to American Association for Laboratory Animal Science technician certification and work experience (please refer to the Statement of Work for specific personnel and staffing requirements).**

**Provision of needed support activities and ability to generate necessary reports.** 15

Please refer to the Statement of Work for specific requirements.

**Evidence of commitment to provide the management oversight, support, staffing, quality control, assistance, and resources needed to perform the work at the APF.** 15

Please refer to the Statement of Work for specific requirements.

## **SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT**

**Article C.1. Statement of Work** - Please note that the number of chimpanzees has changed slightly since the RFP was issued. Rather than continually updating these changes, the number of chimpanzees in the colony and the distribution among age and gender will be updated during negotiations to provide the most current information available at that time.

### **a. Background Information**

The third paragraph is amended to read as follows:

"This contract for operation and maintenance of chimpanzees will not alter ownership of the animals. Title to the animals at the onset of the contract will be held by the Federal Government. However, the Federal Government reserves the right to transfer title (ownership) of these animals to other entities, in which event, those animals will be relocated off of the HAFB. The APF is located on HAFB, a United States military installation. The APF will be a tenant activity on the installation. The use of the real property owned by the United States on HAFB that makes up the APF is permitted by the Department of the Air Force to the National Institutes of Health. That permit governs the ways and uses to which the property may be put. In its operation of the APF, the contractor is subject to the requirements of the permit as though it were the permittee. More specifically, without limitation, and as fully specified in the permit, tenant activities are subject to the regulations governing access to the installation. These regulations will impede the free access of the contractor and its officers, employees, subcontractors, and visitors. Nothing in this contract will relieve the contractor from full compliance with the requirements of the permit."

### **Article C.2. Services to be Performed**

#### **a. General Requirements**

The following sentence in paragraph 2 is deleted: "The capacity of the facility is 350 chimpanzees, and the Contractor is expected to be able to perform the contract at capacity if necessary."

Also, the second sentence of the last paragraph in this section is amended to read as follows: "The HAFB will pay the APF's combined utility costs for electric and water and collection and treatment of sewage up to \$10,000 per month, but the Contractor will be responsible for any costs over this figure."

#### **b. Specific Requirements**

##### **1. Operation and maintenance of a large chimpanzee facility**

**B. Transport and Subsequent Use of Animals**, is amended to insert the following as the fourth and fifth sentences of the first paragraph: "Under no circumstances will any chimpanzee moved off of the HAFB be returned to the APF."

**C. Biosafety**, the fourth sentence of the first paragraph is amended to read as follows: "The APF must have the support of an experienced environmental health and safety department."

The first sentence of the second paragraph is amended to read as follows: "The Principal Investigator of this Contract, (and director of environmental health and safety at the Contractors' main facility, if applicable) will have the authority to take intervening action in the event any visitor or employee of the Contractor or the HAFB is in danger."

The last paragraph is amended to read as follows: "Although specific plans are not required in the proposals from the offerors, the successful Contractor will comply with the HAFB regarding Safety and Health requirements, policies regarding hazardous materials and solid and hazardous wastes, employment of felons or illegal aliens, and procedures and requirements for access of the Contractor's personnel to the HAFB facility. Reference should be made to FAR 5352.242-9000, Contractor Access to Air Force Installations, May 1996, and 5352.223-9001, Health and Safety on Government Installations, June 1997, and the permit from the Air Force to the NIH."

D. **IACUC and IAMC**, the first paragraph is amended to read as follows: "Three differing approaches could be used for preparing the Contract proposal: An existing entity could propose expansion to include a satellite facility, and the satellite facility could either 1) negotiate its own animal Assurance with OLAW and register separately with USDA, or 2) use the parent organizations' existing animal Assurance and USDA Registration; or 3) a coalition of investigators could propose to create a new entity de novo. The Contractor must have an Institutional Animal Care and Use Committee (IACUC) that complies with all Office of Laboratory Animal Welfare and USDA requirements. In addition, the Contractor must develop and implement compliant procedures for IACUC review and inspection associated with the APF."

E. **Prevention of Breeding**, is amended to read as follows: "Breeding of additional animals at the APF is not allowed, and must be prevented, either by means of effective physical separation of the sexes or by long-term use of a contraceptive method already proven to be effective in chimpanzees. All animals born more than 10 months after the start of this contract will belong to the Contractor, will be the Contractor's responsibility, and no additional per diem or other animal number-related fees will be paid by this Contract. In addition, any chimpanzee born on the APF will be permanently removed to a location off of the HAFB as soon as reasonably possible, and at the Contractor's expense. Accidental births of chimpanzees will be considered unacceptable performance of this contract."

2. **Conform to all Federal laws, Federal policies, NRC and ILAR recommendations, and AAALAC accreditation**, the first paragraph is amended to read as follows:

It is a Mandatory Qualification Criterion for this contract that the offeror must either already have an OLAW, formerly Office of Protection from Research Risks [OPRR] Assurance Number, have a USDA R Registration, and have previously demonstrated the ability to provide high quality care for chimpanzees, or as an alternative for the purposes of preparing a Contract proposal, declare that they will submit an Assurance when requested by OLAW, and apply for USDA registration if they are selected to be the Contractor, and have previously demonstrated the ability to provide high quality care for chimpanzees. The ability to care for chimpanzees could be demonstrated in several ways, such as possession of an Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) accreditation and file number. The Contractor must maintain these requirements, and the APF must be operated in compliance with: a) The Animal Welfare Act (P.L. 89-544, as amended) Rules and Regulations published in the Code of Federal Regulations (CFR), Title 9 (Animals and Animal Products), Chapter 1, Subchapter A (Animal Welfare), Parts 1, 2, and 3; b) Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, updated 1996; c) The Guide for the Care and Use of Laboratory Animals, revised 1996; d) Biosafety in Microbiological and Biomedical Laboratories (CDC-NIH 1993); e) Occupational Health and Safety in the Care and Use of Research Animals (NRC 1997); f) U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training (OPRR) 1996; g) Chimpanzees in Research, Strategies for their Ethical Care, Management, and Use (NRC 1997); h) Report of the AVMA Panel on Euthanasia, JAVMA 202(2), 229-249, 1993; i) The Psychological Well-Being of Nonhuman Primates, (ILAR) 1998; j) 29 CFR 1910.1030, Bloodborne Pathogen Standard; and k) the permit between the Department of the Air Force and the NIH.