DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Center for
Research Resources
Bethesda, Maryland 20892

March 2, 2005

Jean Barnes
Executive Director
Primate Freedom Project
PO Box 1623
Fayetteville, GA 30214

Re: FOI Case No. 30282

Dear Ms. Barnes:

This is a partial response to your July 13, 2004 Freedom of Information Act (FOIA) request addressed to me at the National Center for Research Resources. You requested a copy of all contracts DHHS, NIH, NCRR has with all eight National Primate Research Centers. You also requested a copy of all contracts with any facilities, public or private, that receive funding for the housing, maintenance, purchase, or any other outlay of tax monies involving any primate, including those primates owned by NIH. Please note, as previously stated in my August 23, 2004 letter to you, that NCRR can only respond as it relates to records held by this center; records maintained by DHHS agencies or NIH institutes/centers must be requested from them directly.

Rather than continuing to delay our response in order to obtain both contracts that are responsive to your request, we are processing this request in two parts. I have enclosed 178 pages responsive to your request. This includes the contract awarded to the Alamogordo Primate Facility (APF); and those portions of the technical proposal that were incorporated into the contract. It is Department of Health and Human Services (DHHS) and NIH FOIA policy to expunge cost and fixed fees; estimated costs; fringe benefits; labor/overhead rates; line item costs; negotiated costs; EIN number; names of non-key personnel; number of personnel; resumes other than that of the principal investigator; names and information on subcontractors and consultants; and floor plans. This information has been removed in the enclosed material.

Additionally, 23 pages of records that originated with the United States Air Force were referred to that agency for its review and determination of releasability.

Requesters who ask for contracts into which proposals have been incorporated usually want to receive only material that will help in understanding the process that led to the awards or to improve their own methods of drafting proposals. Requesters usually do not want material that submitters believe would harm them if released. We have found that the spirit of the FOIA can be enhanced through a spirit of cooperation among requesters and those who have submitted materials.

We asked the originator of the proposal for advice and the material we are providing reflects that advice. If you feel that any material has been omitted that should have been

made available to you, please write to me and I will consult with the NIH Freedom of Information Officer.

Please be assured that I am continuing to process the other contract responsive to your letter of July 13, 2004.

Provisions of the FOIA and DHHS FOIA Regulations allow us to recover part of the cost of responding to your request. We will provide an invoice once our final response has been provided to you.

Sincerely,

Joyce A. McDonald

Joyce A. McDonald
Freedom of Information Coordinator
National Center for Research Resources
National Institutes of Health
6701 Democracy Boulevard
Room 978-MSC 4874
Bethesda, MD 20892-4874

Enclosure: 178 pages
(APF Contract and portions of technical proposal incorporated)

AWARD/CONTRACT

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 350)	RATING	PAGE OF	PAGES
		1	39

2. CONTRACT (Proc. inst. ident.) NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQUEST PROJECT NO.
N02-RR-1-2079/ADB#: CI102079	May 15, 2001	328045 (NIH 402)

5. ISSUED BY	CODE	6. ADMINISTERED BY (If other than Item 5)	CODE
National Institutes of Health National Heart, Lung, and Blood Institute Procurement Section, Contracts Operations Branch 6701 Rockledge Drive, Room 6142, MSC 7902 Bethesda, Maryland 20892-7902		Kathleen E. Jarboe, Contracting Officer (301) 435-0364	

7. NAME AND ADDRESS OF CONTRACTOR (No., street, city, county, State and ZIP Code)	8. DELIVERY: FOB ORIGIN [ ] OTHER (See below) [X]
Charles River Laboratories 251 Ballardvale Street Wilmington, MA 01887	9. DISCOUNT FOR PROMPT PAYMENT
CODE FACILITY CODE	10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN: ITEM: SEE ARTICLE G.3.

11. SHIP TO/MARK FOR	CODE	12. PAYMENT WILL BE MADE BY	CODE
SEE ARTICLE F.2.		SEE ARTICLE G.3.	

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION

[ ] 10 U.S.C. 2304(c) ( ) [X] 41 U.S.C. 253(C) (2)

14. ACCOUNTING AND APPROPRIATION DATA

CAN#: 18422426 ($1,527,000) CAN#: 18422443 ($2,973,000)
EIN#: [illegible] O.C.#: 2513 FUNDED AMOUNT: $4,500,000

15A. ITEM NO.	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
TITLE:	Operation and Maintenance of a Chimpanzee Long-Term Holding Facility				
TERM:	May 15, 2001 through May 14, 2011				
TYPE:	Cost-Plus-Fixed-Fee (Level of Effort)				
				15G. TOTAL AMOUNT OF CONTRACT	$ $42,763,289

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CONTRACTING OFFICER WILL COMPLETE ITEM 17 OR 18 AS APPLICABLE

17 [X] CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return 3 copies to issuing office.)

Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to the contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications as are attached or incorporated by reference herein. (Attachments are listed herein.)

18 [ ] AWARD (Contractor is not required to sign this document.) Your offer on Solicitation Number _____ including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your offer, and (b) this award/contract. No further contractual document is necessary.

19A. NAME AND TITLE OF SIGNER (Type or print)	20A. NAME OF CONTRACTING OFFICER
James C. Foster, Chairman, President & CEO	Robert Best
19B. NAME OF CONTRACTOR CHARLES RIVER LABORATORIES BY [signature] (Signature of person authorized to sign)	19C. DATE SIGNED 5/22/01
20B. UNITED STATES OF AMERICA BY [signature] (Signature of Contracting Officer)	20C. DATE SIGNED 5/23/01

DETAILED TABLE OF CONTRACT CONTENTS

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The Contractor shall operate and maintain a chimpanzee facility called the Alamogordo Primate Facility (APF) located on the Holloman Air Force Base (HAFB) in Alamogordo, New Mexico. This chimpanzee facility has the capacity to socially house 288 animals, including animals that have been used in biomedical research. 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, the National Center for Research Resources (NCRR) of the National Institutes of Health (NIH) has assumed ownership of approximately 257 chimpanzees at the APF (see Exhibit E attached to the Use Permit, Section J, Attachment 10). The Contractor shall operate and maintain the associated long-term care facility, as well as provide overall facility operation and maintenance. All the animals have been exposed to microorganisms such as hepatitis C virus (HCV) and Human Immunodeficiency Virus (HIV). Therefore, these animals have special needs for care and housing.

ARTICLE B.2. ESTIMATED COST AND FIXED FEE

a. The estimated cost of this contract is [ ]

b. The fixed fee for this contract is [ ] The fixed fee shall be subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract. Payment of fixed fee shall be made in equal monthly installments.

c. The Government's obligation, represented by the sum of the estimated cost plus the fixed fee, is $42,763,289.

d. Total funds currently available for payment and allotted to this contract are $4,500,000, of which [ ] represents the estimated costs, and of which [ ] represents the fixed fee. For further provisions on funding, see the LIMITATION OF FUNDS clause referenced in Part II, ARTICLE I.2. Authorized Substitutions of Clauses.

e. It is estimated that the amount currently allotted will cover performance of the contract through April 14, 2002.

f. The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor.

g. Future increments to be allotted to this contract are estimated as follows:

Period	Maximum Amount*
4/15/02 - 5/14/02	$280,859 (fund remainder of Year One)
5/15/02 - 5/14/03	$3,673,151 (Year Two)
5/15/03 - 5/14/04	$3,685,798 (Year Three)
5/15/04 - 5/14/05	[redacted] (Year Four)
5/15/05 - 5/14/06	(Year Five)
5/15/06 - 5/14/07	(Year Six)
5/15/07 - 5/14/08	(Year Seven)
5/15/08 - 5/14/09	(Year Eight)
5/15/09 - 5/14/10	(Year Nine)
5/15/10 - 5/14/11	[redacted] (Year Ten)

*The maximum cost estimates identified above do not include the [redacted] annual incentive fee, which would represent an incremental cost.

h. The Contractor will receive an annual incentive payment if:

i) No chimpanzee conceptions or births occur during the subject year;
ii) No serious deficiencies in animal care occur during the subject year (as determined by the Government Project Officer);
iii) Required reports are delivered in a timely manner;
iv) Contract costs are properly monitored and controlled, and monthly invoices are submitted in a timely manner; and
v) Contractor maintains a high level of responsiveness to the Contracting Officer and Government Project Officer and the Principal Investigator assumes an effective leadership role.

In the event an Incentive Payment is received, the Contractor shall provide a summary of how the incentive amount was distributed among its Project Staff and what portion was allocated to specific ongoing incentive programs. The administration and oversight of any incentive-related programs will be conducted in a manner consistent with the Quality Assurance Surveillance Plan (QASP) for this contract effort (See Section J, Attachment 9).

The maximum annual incentive amounts are as follows:

Year One (1)	$ [redacted]
Year Two (2)	$
Year Three (3)	$
Year Four (4)	$
Year Five (5)	$ [redacted]

Year Six (6)	$
Year Seven (7)	$
Year Eight (8)	$
Year Nine (9)	$
Year Ten (10)	$

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

a. **Items Unallowable Unless Otherwise Provided**

This article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer for: 1) Acquisition, by purchase or lease, of any interest in real property; 2) Special rearrangement or alteration of facilities; 3) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value {general purpose equipment is defined as any items of personal property which are usable for purposes other than research, such as office equipment and furnishings, pocket calculators, etc.}; 4) Travel Costs; 5) Consultant Costs; 6) Subcontract Costs; 7) Patient Care Costs; 8) Accountable Government Property {defined as both real and personal property with an acquisition cost of $1,000 or more and a life expectancy of more than two years} and "sensitive items" {defined and listed in the Contractor's Guide for Control of Government Property}, 1990, regardless of acquisition value; and 9) Research Funding.

b. **Travel Costs**

(1) Domestic Travel

(a) Total expenditures for domestic travel (transportation, lodging, subsistence, and incidental expenses) incurred in direct performance of this contract shall not exceed $180,092 for the ten (10) year period of performance without the prior written approval of the Contracting Officer.

(b) The Contractor shall invoice and be reimbursed for all travel costs in accordance with Federal Acquisition Regulations (FAR) 31.205-46.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

1. Other provisions of this contract notwithstanding, approval of the following items within the limits set forth is hereby granted without further authorization from the Contracting Officer.

a. **Overtime**

Overtime (premium) pay shall not exceed a total of $903,986.87 for the ten (10) year contract period of performance.

b. **Indirect Costs**

This contract limits the provisional use of the [ ] fringe benefit rate and the [ ] indirect cost rate to six (6) months, during which time the Contractor shall negotiate mutually acceptable provisional rates with the DFAS Indirect Cost Section, NIH.

c. **Pre-Contract Costs**

Within the dollar limitations set forth under SECTION B, ARTICLE B.2., the Contractor shall be entitled to reimbursement for costs incurred during the period May 4, 2001 through May 22, 2001 in an amount not to exceed $[ ] which if incurred after this contract had been entered into, would have been reimbursable under the provisions of this contract.

2. It is the Government's intent to approve all requests for facilities improvements, etc. upon the Contracting Officer's receipt, review and approval of appropriately detailed quotations and justifications. Examples of such expenditures include: personal computers and peripherals; purchase of modular units and related office furnishings; local physician consultation; purchase of a phone system/pagers; and capital expenditures.

2. The Government has accepted as appropriate all understandings that were provided in the Contractor's proposal and subsequent responses.

3. Technical Competence

All personnel assigned to work under this contract shall meet the minimum requirements for each of the skill levels to which they will be assigned, and be capable of performing the functions described in a competent and professional manner.

4. Contractor Requirements for Delivery of Services

Core Work Hours, Staff Scheduling and Absences

a. **Core Work Hours**

The Contractor shall provide service 7 days a week, 365 days a year to include weekends and Government holidays. Selected job groups within Contractor staff shall be designated essential employees and shall be required to report for duty

365 days a year including periods of inclement/severe weather or other adverse working conditions, unless directed otherwise by the Principal Investigator in consultation with the Project Officer and Contracting Officer.

The Contractor shall be required to document actual employee hours worked by use of a time sheet, time clock, or other time keeping method and shall only bill for actual hours worked. The Contractor shall ensure that actual employee hours worked and documented on time sheets or time clocks correspond with employee hours billed on monthly invoices prior to submission to the Government.

b. **Staffing Plans and Absences**

Contractor employees shall be deemed essential since they provide services that are vital to the survival and humane care of laboratory animals. The Contractor shall organize the workforce in a way that critical functions are performed even when unforeseen absences of personnel occur.

The Contractor shall maintain a flexible work schedule and shall propose the most cost-effective method of providing essential coverage after normal working hours, on weekends, Government holidays, and other periods of Government closure which may include staggered or alternative schedules.

The Contractor shall be required to maintain staffing levels sufficient to effectively carry out day-to-day operations as described in the Statement of Work. The Contractor shall establish a Minimum Staffing Plan to maintain minimum staffing levels at the APF. The Contractor shall implement the plan when the number of Contractor employees falls below the minimum acceptable level for more than 3 days due to illness, vacation, or attendance of Contractor sponsored activities. The Minimum Staffing Plan will be provided to the Project Officer and Contracting Officer within 30 days of contract implementation.

The on-site Contract Manager shall maintain a current emergency telephone roster to mobilize personnel as required for essential or emergency coverage. This roster shall be delivered by June 10, 2001, and within ten days of personnel changes. The Contractor shall provide a copy of the emergency telephone roster to the Government Project Officer, Contracting Officer, and Commander, 49th Fighter Wing.

5. Delegation of Duties

Delegation of technical duties for contract personnel shall be the prerogative of the Contractor. The Contractor shall be responsible for the selection, certification, assessment, supervision, management, and control of employees in performance of the Statement of Work. However, when necessary to ensure continued satisfactory

performance of the required services, the Government will request and the Contractor shall replace any person under this contract due to inappropriate behavior, poor performance, misconduct, endangering life, abuse of the U.S. Government property or inhumane treatment of animals, so long as this is consistent with applicable Federal and State employment law.

6. Training

In performing its responsibilities under the contract, the Contractor shall use only fully trained, experienced and technically proficient personnel. The Contractor shall provide to the Government Project Officer a detailed written description of employee qualifications and evidence of professional/ technical certifications for each employee proposed to perform work under this contract.

7. Occupational Safety and Health Training

a. The Contractor shall provide an effective training program in occupational safety and health. Prior to commencing any work, employees shall be properly trained in safe practices and informed of potential hazards by Contract managers and supervisors. The Contractor shall be responsible for insuring their staff are provided with, understand, and follow those safety instructions.

b. Once each employee has completed the Contractor's initial Occupational Safety and Health Training Program, an assurance statement of program completion containing the signature of each employee adjacent to the date of completion is to be delivered to the Government Project Officer. This statement shall be delivered sixty (60) calendar days after contract implementation for incumbent employees and thirty (30) calendar days after commencing work for new hires.

c. Specific areas to be covered shall include but not be limited to:

i) Safety Procedures when working with chimpanzees
ii) Emergency response and first aid training
iii) Safe handling of biohazardous material
iv) Waste management procedures
v) Hazard containment and spill clean-up procedures
vi) Fire safety and extinguisher use training
vii) Respirator use (when appropriate)
viii) Use of Material Safety Data Sheets (MSDS)
ix) Use of Biosafety cabinets and fume hoods, when appropriate
x) Safe operation of powered equipment
xi) Proper lifting techniques
xii) Hazards of drug and alcohol abuse in the workplace

d. The Contractor shall provide continuing training to address safety and health issues specific to the Statement of Work.

The Contractor shall provide the Government Project Officer a detailed Safety and Health Training Plan for ongoing training for Contractor personnel sixty (60) calendar days after contract implementation.

Other training may be identified by the Government or Contractor as needed. The Contractor shall submit all requests for additional training and associated costs to the Government Project Officer for approval.

8. Safety and Health

a. The Contractor shall establish and implement safety and health controls to protect the life and health of all persons on the Contract job site. The Contractor shall implement a Safety and Health Plan in accordance with the Contractor's Corporate personnel policies, with Federal laws, and with Air Force policies and procedures. The plan shall detail possible dangers that may be encountered while performing the job, proper protective equipment and procedures to be used, and an emergency plan in case of an accident. The Contractor shall be responsible for and shall comply with the following requirements:

i. Establish proper safety and health precautions to protect the work site, employees, other personnel frequenting the work site, animals, and the property of others;

ii. Instruct all employees in appropriate safety practices and inform them of all hazards associated with their work before the work commences;

iii. Provide all necessary insurance required by Article H.10 for the nature of the work employees shall be required to perform under this Contract;

iv. Provide employees with appropriate occupational medical care;

v. Provide employees with the appropriate protective clothing and equipment;

vi. Document and immediately report all safety hazards to the Government Project Officer;

vii. Document and immediately report all incidents or accidents to the Government Project Officer;

viii. Take any additional safety measures that the Government Project Officer or Contracting Officer may direct by written order.

9. Occupational Medical Program

a. The Contractor shall establish an Occupational Medical Program and provide employees with appropriate medical care to include pre-employment evaluations, occupational medical surveillance, and job-related emergency treatment.

b. The contractor shall conduct a pre-placement medical evaluation to determine if the applicant is currently medically and physically able to fulfill the requirements of the position without risk of injury or illness to themselves, other individuals or the animals; provide the applicant with position-related health and safety information; and provide the applicant with appropriate immunizations to reduce the risk of a work-related infection. The pre-placement medical evaluation shall include:

i) Occupational medical history
ii) Safety and health counseling
iii) Pre-employment drug screen
iv) Tetanus screening (immunization within last 10 years)
v) Baseline audiogram for employees exposed to elevated noise levels
vi) Pulmonary function for employees required to wear full face respirators
vii) Other appropriate immunizations and screenings determined by the species (chimpanzees) and potential hazards (HIV, HBV, HCV, and possibly HAV) that the contract employee will be exposed

c. The Contractor shall establish an Occupational Medical Surveillance Program equivalent to the NIH Animal Exposure Surveillance Program (See Section J, Attachment 14). Employees shall be required to participate in this program if they are involved in the direct care of animals or their living quarters, or have direct contact with live or dead animals, their viable tissues, body fluids or waste. The Contractor's Occupational Medical Surveillance Program shall be organized so that the level of surveillance is appropriate for the species and potential hazard that the contract employee will be exposed to, e.g.,

i) Chimpanzees
ii) Chimpanzee tissues

d. Routine collection and storage of serum for Contractor employees is not required after a baseline collection. However, the Contractor shall collect and store serum if a contractor employee sustains an injury involving percutaneous or mucous membrane exposure to blood or body fluids of chimpanzees and shall provide off-site storage of serum that is consistent with Federal Policy for the Protection of

Human Subjects.

e. In addition to the screenings and immunizations recommended in the NIH OMS Animal Exposure Surveillance Program, the Contractor shall perform periodic unannounced random drug screens on samplings of Contractor employees throughout the duration of the contract. Positive test results shall require total dismissal from the contract or substance abuse rehabilitation assistance at the discretion of the Government.

f. In the event that a medical question arises over the ability of a Contractor employee to perform the assigned duties or be free of a communicable disease, the Contracting Officer may require the Contractor to have an additional physical examination performed on the subject employee. The Contracting Officer may refer the results of this examination to competent medical authority of the Government's choosing for determination for continued suitability for employment.

10. The Contractor shall assume responsibility of the Alamogordo Primate Facility on June 1, 2001.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated May 11, 2001 attached hereto and made a part of this contract.

b. The following described documents are incorporated by reference and hereby made a part of this contract:

Contractor's initial proposal, dated February 7, 2001, pages 17-38, 42-48, 51-53, Appendix D (Occupational Health and Safety Program), and Appendix E (Proposed Project Schedule)

Contractor's revised proposal, dated March 1, 2001, pages 3-6 and 8-9

c. If there is any inconsistency between the Contractor's proposal and the work described in this ARTICLE, Paragraph a, the terms and conditions of this ARTICLE, Paragraph a, shall control.

ARTICLE C.2. REPORTING REQUIREMENTS

a. Technical Progress Reports

In addition to the required reports set forth elsewhere in this contract, the preparation and submission of regularly recurring Technical Progress Reports will be required during the period of performance of this contact. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods.

Two (2) or three (3) copies of the following reports will be required as follows:

(X) Monthly Progress Reports
(X) Annual Progress Reports
(X) Final Report
(X) Special Reports

Monthly Progress Reports

The Contractor must submit a monthly progress report to the Contracting Officer and the Project Officer. The monthly progress reports are due within ten (10) days following the end of the reporting period. The reports must summarize vacant positions and recruiting actions underway. The report must indicate dates vacancies occurred, recruiting status, anticipated dates of new hires, and the name of the prospective employee. An animal census and description of changes to the veterinary care and animal husbandry programs, if any, must be included. A description and justification of needed Alterations and Renovations must be submitted with an adequate lead time to allow NIH staff to review the request, and for repairs to be completed, to ensure that the facility continues to comply with relevant standards established by the U.S. Department of Agriculture (USDA) and the Public Health Service (PHS).

Annual Progress Reports

An annual summation of contract operations must be submitted by the anniversary date of the contract. The annual report will discuss the general health status of the animals, census status, physical facilities and related administrative activities (e.g., an inventory report), and include all applicable support documents such as the semi-annual IACUC review and site visit report. An inventory of animals supported under this contract must be made available to the Project Officer. This report must include identification of animals by ISIS number, name, sex, location including cage number, age, and any changes to, or additional, pertinent information. In addition, all mortality must be reported, along with a summary of relevant health and postmortem records. Also, a description of losses (or additions in the unlikely event any inadvertent progeny are born) from the colony must be included in this report. It is required that the Contractor use a

recognized program, preferably the ISIS-ARKS system, for documentation of the health and social status of the colony. A summary of this information should be furnished to ISIS at monthly intervals along with the current animal inventory, and must be reported to ISIS at least yearly.

Final Report

This report shall consist of the work performed and results obtained for the entire contract period of performance as stated in Section F of this contract. This report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall be submitted on or before the last day of the contract performance period. An annual report shall not be required for the period when the Final Report is due.

Special Reports

1. Emergency Telephone Roster - The Contractor must provide a list of key contract employees' work, pager and home telephone numbers. The report must be submitted to the Project Officer, Contracting Officer, and Commander, 49th Fighter Wing within 10 days of contract implementation, and within 10 days of personnel changes.

2. Minimal Staffing Plan - The Contractor must provide written procedures for maintaining adequate coverage during inclement weather or periods of other closure. The Minimal Staffing Plan will be provided to the Contract Officer and the Project Officer within 30 days of contract implementation.

3. Occupational Safety and Health Training Plan - The Contractor must provide the Project Officer and Contracting Officer a detailed written program for continuing education in animal facility safety and health requirements. This plan must be submitted not later than 60 days after contract implementation.

4. Initial Occupational Safety and Health Training Assurance Statement - An assurance statement of completion of the Contractor's initial Occupational Safety and Health Training session containing the signature of each employee adjacent to the date of completion must be provided to the Project Officer and Contracting Officer. Delivery must occur within 60 days of the hire date for new personnel.

5. Incident and Accident Reports - The Contractor must provide a detailed written report of all incidents in which Contractor staff sustain an on-the-job-injury or suspected job-related illness. The report must be provided to the Project Officer, Contracting Officer, and Commander, 49th Fighter Wing within 10 days of the incident's occurrence.

6. Equipment Inventory - The Contractor must conduct an equipment inventory and determine the working order of all major and specialized equipment. The condition of all items must be noted and submitted in a report to the Project Officer and Contracting Officer within 30 days after contract implementation.

7. Animal Death or Injury Report - The Contractor must report any instances of animal death or injury to the Project Officer, Contracting Officer and Office of Animal Care and Use (OACU), NIH within 24 hours.

8. Congressional/Media Interest Reports - The Contractor must report any requests for information or inquiries/allegations regarding activities at the APF. The Contractor shall promptly notify the Government Project Officer and Contracting Officer of any inquiries that may lead to or that have public, media, or congressional interest.

9. ACUC Reports of facility inspections and reviews shall be prepared by the Contractor semi-annually and provided to the Project Officer and Contracting Officer.

10. The Contractor shall prepare the APF "Annual Report of Research Facility" for the USDA on an annual basis and provide this report to the Project Officer and Contracting Officer.

11. The Contractor, in conjunction with the NCRR designee and the Director of the OACU, shall prepare a schedule of milestones as soon as possible, and will revise these as appropriate. Written progress reports may be requested by the Contracting Officer as often as once per month. These reports shall be delivered to the Project Officer and Contracting Officer.

Special reports 2 through 6 must be updated whenever significant changes occur to the relevant procedures at the APF.

SECTION D - PACKAGING, MARKING AND SHIPPING

{Please refer to the section in the Statement of Work entitled " Shipping of Animals to other Locations"}

SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.

b. For the purpose of this ARTICLE, the Project Officer is the authorized representative of the Contracting Officer.

c. Inspection and acceptance of reports will be performed at:

National Institutes of Health
National Center for Research Resources
Division of Comparative Medicine
Rockledge Building 1, Room 6030
6705 Rockledge Drive
Bethesda, Maryland 20892

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative during the contract period of performance. In addition, there may be on-site inspections to ascertain whether there are deficiencies in animal care, to assess the condition of the facility and as otherwise required for full performance of this work. The Contractor will be provided reports of any site visits. Any responses required of the Contractor will be set forth in these reports.

d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR Clause No. 52.246-5, INSPECTION OF SERVICES-COST REIMBURSEMENT (APRIL 1984)

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

The period of performance of this contract shall be from May 15, 2001 through May 14, 2011.

ARTICLE F. 2. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

a. The items specified below as described in SECTION C, ARTICLE C.2. will be required to be delivered F.O.B. Destination as set forth in FAR 52.247-35, F.O.B. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below [and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of the contract]:

Item	Description	Quantity	Delivery Schedule
(a)	Monthly Progress Report	2	Reports are due within ten (10) calendar days following the end of the reporting period
(b)	Annual Progress Report	2	Reports are due on an annual basis no later than the anniversary date of the contract
(c)	Final Report	2	Report is due on or before the last day of the contract performance period
(d)	Emergency Telephone Roster	3	Must be submitted within ten (10) calendar days of contract implementation (June 10, 2001), and within ten (10) calendar days of personnel changes.
(e)	Minimal Staffing Plan	2	Due within thirty (30) calendar days of contract implementation (June 30, 2001)
(f)	Occupational Safety and Health Training Plan	2	Due not later than thirty (30) calendar days after contract implementation (June 30, 2001)
(g)	Initial Occupational Safety and Health Training Assurance Statement	2	Due within thirty (30) calendar days of the hire date for new personnel
(h)	Incident and Accident Reports	3	Due within (10) calendar days of the incident's occurrence
(i)	Equipment Inventory	2	Due within (30) calendar days after contract implementation (June 30, 2001)
(j)	Major Alterations and Renovations Report	4	Due within (30) calendar days after contract implementation (June 30, 2001)
(k)	Animal Death or Injury Report	3	Due within 24 hours of the incident's occurrence

(l)	Congressional/Media Interest Report	2	Due within three (3) working days of the inquiry
(m)	ACUC Report	2	Due semi-annually
(n)	Report of Research Facility to USDA	2	Reports are due on an annual basis no later than the anniversary date of the contract
(o)	Schedule/Progress toward AAALAC Accreditation	2	Due as soon as possible upon contract implementation, and revised when requested by the Contracting Officer

*Please note that reports e through i must be updated whenever significant changes occur to the relevant procedures at the APF.

b. The above items shall be addressed and delivered to:

Addressee	Deliverable Item No.	Quantity
Project Officer Chimpanzee Management Plan (ChiMP) Comparative Medicine, NCRR, NIH 6705 Rockledge Drive, Suite 6030 Bethesda, Maryland 20892-7965	a through o	One (1)
Contracting Officer Procurement Section Contracts Operations Branch National Heart, Lung, and Blood Institute, NIH 6701 Rockledge Drive, Room 6142 Bethesda, Maryland 20892-7902	a through o	One (1)
Colonel Marc E. Rogers Commander, 49th Fighter Wing 490 1st Street, Suite 1700 Holloman AFB, NM 88330-8277	d, h and j	One (1)

Director Office of Animal Care and Use National Institutes of Health Building 31, Room B1C37 31 Center Drive Bethesda, Maryland 20892	j and k	One (1)

ARTICLE F.3. LEVEL OF EFFORT

a. In accomplishing the work set forth herein, the Contractor shall provide direct labor hours during the period set forth in ARTICLE F.1. The labor hours include vacation, sick leave, and holiday. It is estimated that the labor hours are constituted as follows:

Labor Category	Annual Labor Hours
Professional Staff:	
Principal Investigator	
Deputy Principal Investigator	
Two (2) additional Veterinarians	
Nurse/Occupational Safety and Health (OSH) Officer	
Veterinary Resident	
Support Staff:	
Program Administrator	
Information Technologist	
Behaviorist	
Trainer	
Clinical Laboratory Technician	
Colony Manager	
Laboratory Animal Supervisor	
Three (3) Enrichment Technicians	
Five (5) Laboratory Animal Caretakers - I	
Five (5) Laboratory Animal Caretakers - II	
Five (5) Laboratory Animal Caretakers - III	
Maintenance Supervisor	
Six (6) Maintenance Workers	
Administrative Secretary	

The total estimated labor hours for the ten years is [redacted]

The estimated annual labor hours will be assessed periodically to determine if the colony size warrants continuation of these levels. The Contractor agrees to work with the Government on adjusting estimated labor hours and total estimated cost to coincide with the size of the colony.

ARTICLE F.4. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (AUGUST 1989) with ALTERNATE I (APRIL 1984).

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. PROJECT OFFICER

The following Project Officer(s) will represent the Government for the purpose of this contract:

Dr. Raymond O'Neill

The Project Officer is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Government may unilaterally change its Project Officer designation.

ARTICLE G.2. KEY PERSONNEL

a. All personnel identified in this contract are considered to be essential for the successful performance of this contract; however, certain individuals will be designated key personnel.

b. The level of competence for key personnel will apply throughout the life of this contract. The contract may be amended from time to time during the course of the contract to either add or delete personnel, as appropriate.

c. The following individual(s) is/are considered to be essential to the work being performed hereunder:

NAME	TITLE
D. Rick Lee, DVM	Principal Investigator/Director
Darrel Florence, DVM, M.Sc.	Deputy Director

d. In addition to the contract Key Personnel noted above, the following labor categories are considered to be essential to the work being performed under this contract:

Clinical Veterinarians
Program Administrator
Behaviorist
Trainer
Enrichment Technicians
Laboratory Animal Caretakers
Maintenance Workers
Nurse/OSH Officer
Information Technologist
Clinical Laboratory Technician
Colony Manager
Administrative Secretary

ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST

Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts NIH(RC)-1 are attached and made part of this contract. The instructions and the following directions for the submission of invoices/financing request must be followed to meet the requirements of a "proper" payment request pursuant to FAR 32.9.

(1) Invoices/financing requests shall be submitted as follows:

An original and two copies to the following designated billing office:

Kathleen Jarboe
Contracting Officer
Procurement Section
Contracts Operations Branch
National Heart, Lung, and Blood Institute, NIH
Rockledge Building 2, Room 6143
6701 ROCKLEDGE DRIVE, MSC 7902
BETHESDA MD 20892-7902

(2) Inquiries regarding payment of invoices should be directed to the designated billing office, (301) 435-0366.

ARTICLE G.4. INDIRECT COST RATES

In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7(d)(2), "Allowable Cost and Payment" incorporated by reference in this contract in Part II, Section I, the cognizant Contracting Officer representative responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Director, Division of Financial Advisory Services
Office of Contracts Management
National Institutes of Health
6100 Building, Room 6B05
6100 EXECUTIVE BLVD MSC 7540
BETHESDA MD 20892-7540

Rates negotiated with this office are hereby incorporated without further action of the Contracting Officer.

ARTICLE G.5. GOVERNMENT PROPERTY

In addition to the requirements of the clause, GOVERNMENT PROPERTY, incorporated in Section I of this contract, the Contractor shall comply with the provisions of DHHS Publication, **Contractor's Guide for Control of Government Property,** 1990, which is incorporated into this contract by reference. Among other issues, this publication provides a summary of the Contractor's responsibilities regarding purchasing authorizations and inventory and reporting requirements under the contract. A copy of this publication is available upon request to the Contracts Property Administrator.

This contract's Contracts Property Administrator is:

Contracts Property Administrator
Division of Personal Property Services, NIH
6011 Building, Suite 637
6011 EXECUTIVE BLVD MSC 7670
BETHESDA, MD 20892-7670
(301) 496-6466

b. Notwithstanding the provisions outlined in the DHHS Publication, **Contractor's Guide for Control of Government Property**, 1990, which is incorporated in paragraph a. above, the Contractor shall use the form entitled, "Report of Government Owned, Contractor Held Property" for performing annual inventories required under this contract. This form is included as an attachment in SECTION J of this contract.

c. **Contractor-Acquired Government Property - Schedule I-A**

Pursuant to the clause, GOVERNMENT PROPERTY, incorporated in this contract, the Contractor is hereby authorized to acquire the property listed in the attached Schedule I-A for use in direct performance of the contract.

ARTICLE G.6. POST AWARD EVALUATION OF PAST PERFORMANCE

a. Contractor Performance Evaluations

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluations will be prepared annually to coincide with the anniversary date of the contract.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. Any disagreement between the parties regarding an evaluation will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

b. Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:

http://ocm.od.nih.gov/cdmp/cps_contractor.htm

The registration process requires the contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the contractor will be required to identify an alternate contact who will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. REIMBURSEMENT OF COSTS FOR INDEPENDENT RESEARCH AND DEVELOPMENT PROJECTS (Commercials Only)

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. This support is provided in the form of contracts and grants totaling approximately 7 billion dollars annually. PHS has established effective, time tested and well recognized procedures for stimulating and supporting this independent research by selecting from multitudes of applications those research projects most worthy of support within the constraints of its appropriations. The reimbursement through the indirect cost mechanism of independent research and development costs not incidental to product improvement would circumvent this competitive process.

To ensure that all research and development projects receive similar and equal consideration, all organizations may compete for direct funding of independent research and development projects they consider worthy of support by submitting those projects to the appropriate Public Health Service grant office for review. Since these projects may be submitted for direct funding, the Contractor agrees that no costs for any independent research and development project, including all applicable indirect costs, will be claimed under this contract.

ARTICLE H.2. NEEDLE EXCHANGE

a. Pursuant to Public Law(s) cited in paragraph b., below, contract funds shall not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

b.

Public Law and Section No.	Fiscal Year	Period Covered
P.L. 106-554, Section 505	2001	(10/1/00 - 9/30/01)

ARTICLE H.3. ANIMAL WELFARE ASSURANCE

Intramural NIH has modified their Office for Laboratory Animal Welfare (OLAW, formerly OPRR) Assurance to include the APF (See Section J, Attachment 11), and may request and hold a United States Department of Agriculture (USDA) R Registration for the APF, or may only request courtesy inspections. It is expected that USDA and AAALAC representatives will periodically inspect the APF and issue reports to the Contractor and NIH. Major Alterations and Renovations will be needed to the APF to correct deficiencies that the USDA may categorize as "must be replaced or repaired." The Contractor will be responsible for obtaining estimates for these repairs, and the workscope of the contract and funds for its completion will be modified as necessary. After discussion with NIH staff members, attempts will likely be made to address deficiencies identified during AAALAC inspections. This shall include an explicit requirement that the Animal Care and Use (ACU) program at the APF seek AAALAC accreditation. Preparations for seeking accreditation should be implemented as quickly as possible and a schedule of milestones prepared between the NCRR and the Contractor. In keeping with the provisions of NIH Policy Manual 3040-2 (See Section J, Attachment 12), the Director, NCRR, or designee and the Director, Office of Animal Care and Use (OACU) shall assist the Contractor to prepare for and seek AAALAC accreditation of the ACU program at the APF. Due to the geographic and operational isolation of APF ACU activities relative to the other components identified in the Assurance, it is the intent that the APF be a separately accredited component, rather than being associated with one of the existing AAALAC files. A license from the Drug Enforcement Agency will need to be obtained by veterinary staff of the Contractor.

ARTICLE H.4. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

(1) The Small Business Subcontracting Plan, dated May 1, 2001, is attached hereto and made a part of this contract.

(2) The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

b. Subcontracting Reports

(1) The Contractor shall submit the original and 1 copy of Subcontracting Report for Individual Contracts, SF-294 in accordance with the instructions on the report as referenced in Public Law 95-507, Section 211. Regardless of the effective date of this contract, the Report shall be submitted on the following dates for the entire life of this contract:

April 30th
October 30th

The Report shall be sent to the following address:

Kathleen Jarboe
Contracting Officer
Procurement Section
Contracts Operations Branch
National Heart, Lung, and Blood Institute, NIH
6701 Rockledge Drive, Room 6142
Bethesda, Maryland 20892-7902

(2) The Contractor shall submit 1 copy of Summary Subcontract Report, SF-295 in accordance with the instructions on the report as referenced in Public Law 95-507, Section 211. The Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

October 30th

The first report shall be submitted after the first full year of this contract in addition to any fractional part of the year in which this contract became effective. This Report shall be mailed to the following address:

Office of Small and Disadvantaged Business Utilization
Department of Health and Human Services
Hubert H. Humphrey Bldg., Room 517-D
200 Independence Avenue, S.W.
Washington, D.C. 20201

(3) The contractor shall also send an "Information Copy" of the SF-295 to the Cognizant Commercial Representative (CMR) at the address provided by the SBA. The Contractor should call SBA Headquarters in Washington, DC at (202) 205-6475 for the correct address if unknown.

ARTICLE H.5. SALARY RATE LIMITATION LEGISLATION PROVISIONS

a. Pursuant to Public Law(s) cited in paragraph b., below, no NIH Fiscal Year funds may be used to pay the direct salary of an individual through this contract at a rate in excess of applicable amount shown for the fiscal year covered. Direct salary is exclusive of fringe benefits, overhead, and general and administrative expenses (also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's

appointment whether that individual's time is spent on research, teaching, patent care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor. The per year salary rate limit also applies to individuals proposed under subcontracts. It does not apply ot fees paid to consultants. If this is a multiple year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate exceeds any salary rate ceiling established in future HHS appropriation acts.

b.	Public Law No.	Fiscal Year	Dollar Amount of Salary Limitation
	106-554	FY-01	Executive Level I*

c. Direct salaries which will be paid with FY-01 funds are limited to the Executive Level I rate which was in effect on the date(s) the expense was incurred.

*For contract expenditures using FY-01 funds, the period 10/1/00 - 12/31/00 the Executive Level I rate is $157,000. Effective 1/1/01, for contract expenditures using FY-01 funds, the Executive Level I rate is increased to $161,200 and will remain at that level until such time as it is determined to raise the Executive Schedule annual rates. See the web site listed below for Executive Schedule rates of pay.

FY-01 EXECUTIVE LEVEL SALARIES:
http://www3.opm.gov/oca/01tables/execses/html/01execsc.htm

ARTICLE H.6. PUBLICATION AND PUBLICITY

The contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Institutes of Health, under Contract No. N02-RR-1-2079.

ARTICLE H.7. PRESS RELEASES

a. Pursuant to Public Law(s) cited in paragraph b., below, the contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project that will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

b.	Public Law and Section No.	Fiscal Year	Period Covered
	P.L. 106-554, Section 507	2001	(10/1/00 - 9/30/01)

ARTICLE H.8. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477).** All telephone calls will be handled confidentially. The e-mail address is **Htips@os.dhhs.gov** and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

Information regarding procedural matters is contained in the NIH Manual Chapter 1754, which is available on http://www1.od.nih.gov/oma/oma.htm

ARTICLE H.9. ANTI -LOBBYING

a. Pursuant to Public Law(s) cited in paragraph c., below, contract funds shall not be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself.

b. Contract funds shall not be used to pay salary or expenses of the contractor or any agent acting for the contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

c.	Public Law and Section No.	Fiscal Year	Period Covered
for a., above:	P.L. 106-554, Section 503(a)	FY-2001	10/1/2000 - 9/30/2001
for b., above:	P.L. 106-554, Section 503(b)	FY-2001	10/1/2000 - 9/30/2001

ARTICLE H.10. INSURANCE

a. The Contractor shall assume full responsibility for the protection of the personnel furnishing the services under this contract in accordance with the personnel policies of the Contractor, such as providing workmen's compensation, health examinations, and social security payments. Such personnel shall not be considered at any time, employees of the Federal Government. At a minimum, the Contractor shall provide insurance as specified in FAR Clause 28.307.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING PAGES CONTAIN A LISTING(S) OF GENERAL CLAUSES WHICH ARE APPLICABLE TO THIS CONTRACT.

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT SERVICE CONTRACT - FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (March 2000)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.arnet.gov/far/.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

FAR CLAUSE NO.	DATE	TITLE
52.202-1	Oct 1995	Definitions
52.203-3	Apr 1984	Gratuities (Over $100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
52.203-6	Jul 1995	Restrictions on Subcontractor Sales to the Government (Over $100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures(Over $100,000)
52.203-8	Jan 1997	Cancellation, Recission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
52.203-12	Jun 1997	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
52.204-4	Jun 1996	Printing/Copying Double-Sided on Recycled Paper (Over $100,000)
52.209-6	Jul 1995	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over $100,000)
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over $500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)

52.215-15	Dec 1998	Pension Adjustments and Asset Reversions
52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.216-7	Mar 2000	Allowable Cost and Payment
52.216-8	Mar 1997	Fixed Fee
52.219-8	Oct 1999	Utilization of Small Business Concerns (Over $100,000)
52.219-9	Oct 1999	Small Business Subcontracting Plan (Over $500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3	Aug 1996	Convict Labor
52.222-26	Feb 1999	Equal Opportunity
52.222-35	Apr 1998	Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Jan 1999	Employment Reports on Disabled Veterans and Veterans of the Vietnam Era
52.223-6	Jan 1997	Drug-Free Workplace
52.223-14	Oct 1996	Toxic Chemical Release Reporting
52.225-1	Feb 2000	Buy American Act - Balance of Payments Program - Supplies
52.225-13	Feb 2000	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
52.227-3	Apr 1984	Patent Indemnity

52.227-14	Jun 1987	Rights in Data - General
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	Jun 1996	Interest (Over $100,000)
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Jun 1997	Prompt Payment
52.232-34	May 1999	Payment by Electronic Funds Transfer--Other Than Central Contractor Registration
52.233-1	Dec 1998	Disputes
52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	Oct 1995	Penalties for Unallowable Costs (Over $500,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over $100,000)
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate I (Apr 1984)
52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B, Advance Understandings.
52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
52.245-5	Jan 1986	Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract)
52.246-25	Feb 1997	Limitation of Liability - Services (Over $100,000)
52.249-6	Sep 1996	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays
52.253-1	Jan 1991	Computer Generated Forms

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES:

HHSAR CLAUSE NO.	DATE	TITLE
352.202-1	Apr 1984	Definitions - Alternate I (Apr 1984)
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.232-9	Apr 1984	Withholding of Contract Payments
352.233-70	Apr 1984	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings
352.270-5	Apr 1984	Key Personnel
352.270-6	Jul 1991	Publication and Publicity
352.270-7	Apr 1984	Paperwork Reduction Act

[End of GENERAL CLAUSES FOR A COST-REIMBURSEMENT SERVICE CONTRACT - Rev. 3/2000].

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations.

It is expected that the following clause(s) will be made part of the resultant contract:

FAR Clause 52.249-14, EXCUSABLE DELAYS (APRIL 1984) is deleted and HHSAR Clause 352.249-14, EXCUSABLE DELAYS (APRIL 1984) is substituted therefor.

FAR Clause 52.232-20, LIMITATION OF COST, is deleted in its entirety and FAR Clause 52.232-22, LIMITATION OF FUNDS (APRIL 1984) is substituted therefor. **Note: When this contract is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.**

FAR Clause 52.236-13, ACCIDENT PREVENTION (Over $100,000) (NOVEMBER 1991) is deleted in its entirety and FAR Clause 52.236-13, ACCIDENT PREVENTION (Over $100,000) (NOVEMBER 1991), ALTERNATE I (NOVEMBER 1991) is substituted therefor.

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

(1) FAR 52.215-17, Waiver of Facilities Capital Cost of Money (OCTOBER 1997).

(2) FAR 52.217-2, Cancellation Under Multiyear Contracts (JULY 1996).

(3) FAR 52.222-4, Contract Work Hours and Safety Standards Act - Overtime Compensation - General (JULY 1995).

(4) FAR 52.223-5, Pollution Prevention and Right-to-Know Information (APRIL 1998).

(5) FAR 52.223-10, Waste Reduction Program (AUGUST 2000)

(6) FAR 52.230-2, Cost Accounting Standards (APRIL 1998).

(7) FAR 52.230-6, Administration of Cost Accounting Standards (NOVEMBER 1999).

(8) FAR 52.237-2, Protection of Government Buildings, Equipment and Vegetation (APRIL 1984).

(9) FAR 52.237-3, Continuity of Services (JANUARY 1991).

(10) FAR 52.237-10, Identification of Uncompensated Overtime (OCTOBER 1997).

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION/PUBLIC HEALTH SERVICE ACQUISITION REGULATION (HHSAR)/(PHSAR) (48 CHAPTER 3) CLAUSES:

(1) HHSAR 352.270-9, Care of Live Vertebrate Animals (JANUARY 2001).

c. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:

The following clauses are attached and made a part of this contract:

(1) NIH (RC)-7, Procurement of Certain Equipment (APRIL 1984) (OMB Bulletin 81-16).

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

This contract incorporates the following clauses in full text.

FEDERAL ACQUISITION REGULATION (FAR)(48 CFR CHAPTER 1) CLAUSES:

a. FAR Clause 52.244-6, **SUBCONTRACTS FOR COMMERCIAL ITEMS AND COMMERCIAL COMPONENTS** (OCTOBER 1998)

(a) **Definition.**

Commercial item, as used in this clause, has the meaning contained in the clause at 52.202-1, Definitions.

Subcontract, as used in this clause, includes a transfer of commercial items between divisions, subsidiaries, or affiliates of the Contractor or subcontractor at any tier.

(b) To the maximum extent practicable, the Contractor shall incorporate, and require its subcontractors at all tiers to incorporate, commercial items or nondevelopmental items as components of items to be supplied under this contract.

(c) Notwithstanding any other clause of this contract, the Contractor is not required to include any FAR provision or clause, other than those listed below to the extent they are applicable and as may be required to establish the reasonableness of prices under Part 15, in a subcontract at any tier for commercial items or commercial components:

(1) 52.222-26, Equal Opportunity (E.O. 11246);
(2) 52.222-35, Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era (38 U.S.C. 4212(a));
(3) 52.222-36, Affirmative Action for Workers with Disabilities (29 U.S.C. 793); and
(4) 52.247-64, Preference for Privately Owned U.S.-Flagged Commercial Vessels (46 U.S.C. 1241) (flow down not required for subcontracts awarded beginning May 1, 1996).

(d) The Contractor shall include the terms of this clause, including this paragraph (d), in subcontracts awarded under this contract.

ARTICLE I.5. SERVICE CONTRACT ACT

This contact is subject to the Service Contract Act of 1965, as amended. The following clauses are hereby incorporated and made a part of this contract. All clauses incorporated by reference have the same force and effect as if they were given full text. Upon request, the Contracting Officer will make their full text available.

a. **FAR Clause 52.222-41, SERVICE CONTRACT ACT OF 1965,** as amended (MAY 1989).

b. **FAR Clause 52.222-42, STATEMENT OF EQUIVALENT RATES FOR FEDERAL HIRES** (MAY 1989)

In compliance with the Service Contract Act of 1965, as amended, and the regulations of the Secretary of Labor (29 CFR Part 4), this clause identifies the classes of service employees expected to be employed under the contract and states the wages and fringe benefits payable to each if they were employed by the contracting agency subject to the provisions of 5 U.S.C. 5341 or 5332.

THIS STATEMENT IS FOR INFORMATION ONLY: IT IS NOT A WAGE DETERMINATION

Employee Class	Monetary Wage-Fringe Benefit
Program Administrator	$14.00/hour
Information Technologist	$20.00/hour
Behaviorist	$18.00/hour
Clinical Laboratory Technician	$13.00/hour
Colony Manager (On-Site Supervisor)	$12.00/hour
Laboratory Animal Caretakers	$11.00/hour

(End of Clause)

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

1. Statement of Work, dated May 11, 2001, 10 pages.
2. Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1, May, 1997, 4 pages.
3. Small Business Subcontracting Plan, May 1, 2001, 7 pages.
4. Safety and Health, HHSAR Clause 352.223-70, January, 2001, 1 page.
5. Procurement of Certain Equipment, NIH(RC)-7 (OMB Bulletin 81-16), April, 1984, 1 page.
6. Wage Rate Determination Number 1994-2361 (Rev. 15), dated September 26, 2000, 9 pages.
7. Government Property - Schedule I-A, May, 2001, 2 pages.
8. Report of Government Owned, Contractor Held Property, 1 page.
9. Quality Assurance Surveillance Plan, May 10, 2001, 3 pages.
10. Department of the Air Force Permit to the NIH to use Property Located on Holloman Air Force Base, New Mexico, dated April 30, 2001, 23 pages.
11. NIH Intramural Research Program Animal Welfare Assurance Revision (A4149-01), dated May 4, 2001, 3 pages.
12. NIH Policy Manual 3040-2, Animal Care and Use in the Intramural Program, dated November 1, 1999, 32 pages.
13. Memorandum of Understanding, dated April 20, 2001, 4 pages.
14. NIH Policy Manual 3044-2, Protection of NIH Personnel who Work with Nonhuman Primates, dated February 9, 1993, 3 pages.

PART IV - SECTION K - REPRESENTATIONS AND CERTIFICATIONS

The following documents are incorporated by reference in this contract:

1. Representations and Certifications, dated February 7, 2001.

END of the SCHEDULE
(CONTRACT)

STREAMLINED STATEMENT OF WORK (SOW)
FOR THE OPERATION AND MAINTENANCE OF THE
ALAMOGORDO PRIMATE FACILITY (APF)
Revised 5/11/01

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BACKGROUND

PREVIOUS RFP - An RFP and an amendment were issued in the summer of 2000 to solicit proposals to operate and maintain the APF. The original RFP, amendment, and other items such as Appendices are available from the Contracting Officer, Kathleen Jarboe (301-435-0364). The APF buildings have in the past been operated by the Coulston Foundation (CF), and before this by New Mexico State University. Proposals submitted in response to the original RFP were received, but all were rated unacceptable by a review group of non-government experts. The RFP and amendment, and discussions with representatives of chimpanzee facilities who declined to propose in response to the RFP, were used as references to create this streamlined statement of work (SOW) for the revised RFP. Since the previous RFP was unsuccessful in generating an acceptable offer, an attempt was made in this document (originally issued in December 2000) to indicate areas where NIH was willing to negotiate with potential offerors to reach mutually favorable solutions. This document was revised in May 2001 to reflect what was proposed by the Contractor, to address what weaknesses in the proposal were found by the Technical Evaluation Group, and to conform to relevant NIH Policy Manuals and associated Memoranda that result from conditions imposed by having Intramural NIH include the APF within their overall animal assurance with OLAW.

H.R. 3514

A new law, H.R. 3514, the "Chimpanzee Health Improvement, Maintenance, and Protection Act" was signed by the President on 12/20/00. For the first year of operation of this contract, the new law is expected to have a negligible effect. Any effects after the initial year are expected to be minimal, but may depend on negotiations among the Contractor, NIH, the Air Force, and further legislative clarifications and amendments.

MAINTENANCE OF CHIMPANZEES IS REQUIRED, NO RESEARCH IS REQUIRED - there are multiple reasons to eliminate the need for the Contractor to perform research for 3 years, as suggested in the original RFP. Among these are: 1. simplification of personnel, ACUC, and administrative requirements, 2. a desire on the part of the Air Force to have on-base research terminate, 3. since many of the chimpanzees are already HIV-infected or HCV-exposed, they are not optimal subjects for additional unrelated research projects given that many other research chimpanzees are currently underutilized, and 4. if the chimpanzees are needed for ongoing or new research, they can be transferred off-base in the coming years at the expense of the Principal Investigator holding a research grant or contract.

DURATION OF CONTRACT WILL BE 10 YEARS, WITH LIKELY FOLLOW-ON CONTRACTS, IN NEW MEXICO. - NCRR staff members believe that the likely duration of the contract and all subsequent follow-on contracts will depend mainly on the number of chimpanzees that will be transferred to new facilities currently under construction at the University of Louisiana - Lafayette in New Iberia, the University of Texas in Bastrop, and the Southwest Foundation for Biomedical Research in San Antonio Texas. It is presently unknown which animals will be included at these sites, but some or all of the 257 at the APF are obvious candidates. The shortest foreseen duration of the contract would be 10 years, the longest potential cumulative duration of all follow-on contract periods would be 50 years in Alamogordo. Periodic adjustments in the number of animal caretaker and maintenance staff will be needed as the numbers of chimpanzees housed at the APF changes appreciably.

DESCRIPTION OF COLONY DEMOGRAPHY - 257 chimpanzees presently at the APF are caged in single sex groups. However, definite plans are in place to move 5 HCV-infected

animals from the APF in May or June of 2001, and these 5 are not included in the tabulation presented below.

NCRR has efforts underway to possibly move 1 diabetic chimpanzee, and possibly move no more than 20 chronically infected HCV positive animals in the first year of the Contract. Few of the 257 chimpanzees are vasectomized or implanted with Norplant. NO MORE ANIMALS CAN BE BROUGHT ON BASE, OR EXCHANGED FOR EXISTING ANIMALS. Any NCRR-owned animals taken off the base cannot be returned to the base. The number of chimpanzees is expected to decrease over time as they are needed elsewhere for research protocols, they die due to natural causes, or possibly are retired to sanctuaries. All the animals have been exposed to microorganisms such as hepatitis C virus (HCV) and Human Immunodeficiency Virus (HIV), or both.

The age categories of the 118 females and 134 males as of June 1, 2001, are as follows:

Age Category (Yrs.)	No. Females	No. Males
0-4	4	0
5-9	13	9
10-14	22	29
15-19	43	43
20-24	13	15
25-29	14	24
30-34	4	8
35-39	3	4
40 or over	2	2

OWNERSHIP ISSUES

The NIH WILL RETAIN TITLE to the chimpanzees, except if an appropriate transferee who will take title is identified. The animals will then be moved off-base at the expense of the transferee. There is no requirement or expectation for the Contractor to take title to the chimpanzees.

DESCRIPTION OF EXISTING FACILITIES AND RESOURCES - The APF will occupy a series of closely located buildings on the HAFB. Each of Buildings 1301, 1302, 1303, and 1304 will house approximately 72 animals, in 12 dens holding approximately 6 animals each. Thus, the theoretical caging capacity is approximately 288, and the maximal expected number is 257 chimpanzees. Mechanical support for 1301-4 is provided by equipment in Building 1300. Buildings 1300-4 were built and first occupied in the 1990s, and are reasonably well preserved and functional, with some exceptions. The adjacent administrative wing of Building 1264 can function reasonably well as administrative and office space in an interim period. The adjacent Building 1269 can be used as refrigerated food storage for a short interim period until refrigerated trailers can be brought in. Various site and Building schematics of the above buildings are available from the Contract Officer. The caging in 1301-4 meets or exceeds required size minimums, and is a valuable facility that is worth repairing as necessary. If repairs are required to a specific area housing up to 24 animals, there is sufficient capacity within Buildings 1301-1304 to move animals to allow repairs to be completed.

PERSONNEL - Since there are few additional relevant potential employers in Alamogordo, and the University of New Mexico in Las Cruces and other towns are an hour or more away, it is expected that nearly all staff for this contract may be employed by the contract at [ ] effort. Some CF staff members may no longer be needed by the CF after the day of

transition of the APF to the new Contractor, and the Contractor is encouraged to carefully consider hiring selected former CF staff members on a case-by-case basis.

The following description is the present estimate of the staff that will be required, but some future negotiations will likely be necessary once experience in operating the facility is obtained:

6 PROFESSIONAL STAFF, SALARY AND BENEFITS
Director, Deputy Director, two additional Veterinarians, Veterinary Resident, and Nurse/OSH Officer

6 TECHNICAL STAFF, SALARY AND BENEFITS
Program Administrator, Information Technologist, Behaviorist, Clinical Technician, Colony Manager, Secretary

20 ANIMAL CARE STAFF, 1-2 supervisory and 19-18 other, including one or more enrichment technicians

7 MAINTENANCE STAFF, 1 supervisory and 6 other

2 CONSULTANTS AND NECROPSY SERVICE - the perceived advantage of having consultants is that they would not have to be retained as full-time employees, and some would not necessarily have to be located in New Mexico. An off-site veterinary pathologist and related services (such as those available from other locations of the Charles River Laboratories or the Southwest Foundation for Biomedical Research) will be needed to necropsy animals, and process and interpret necropsy tissues. In addition, the APF should develop a formal agreement with an Alamogordo or Las Cruces physician who will provide scheduled and emergency consultations and care, related to potential zoonoses acquired from chimps.

DIAGRAM OF POSSIBLE REPORTING STRUCTURES WITHIN THE APF - this has been proposed in Appendix A of the original proposal, which has been incorporated by reference in this contract.

ON-SITE TRAINING - new hire training and periodic refresher training for all employees will be needed for employees at all levels. Guidance regarding these issues can be obtained from OLAW, the Guide for the Care and Use of Laboratory Animals, AALAS, ACLAM, and AAALAC.

TRAVEL TO PROFESSIONAL MEETINGS - The 6 professional staff described above could attend 1 professional meeting per year at the Contract's expense. The veterinary staff must stagger this attendance to allow 24/7 coverage of the APF.

ANIMAL CARE - the Contractor's proposal describes the proposed plan for animal care, and the relevant portions have been incorporated by reference in this contract. In addition, in accordance with the revision to the NIH-held animal assurance dated May 4, 2001, APF contractor staff will receive training comparable to that provided by the Training Coordinator, Animal Care and Use, which will be approved by the Director, OACU, and presented by Contractor personnel at the APF.

MAJOR CHALLENGES - The major challenges at the APF result from the desert climate with its rapidly fluctuating temperatures, and the biosafety considerations for these chimpanzees. A walk-through every 2 hours for temperature monitoring, security reasons, and gross observation of the animals is advisable. Protective clothing, appropriate showering, proper waste disposal, and other BL2/BL3 biosafety practices are necessary.

DIET - standard commercially available chow supplemented with fresh fruits and vegetables

SANITATION - hosing of floors 2 times/day, periodic pressure washing of cage surfaces

HEALTH CARE - periodic physicals and TB testing for all chimpanzees, serum and DNA and possibly semen banking, blood sampling and shipping for off-site HIV and HCV testing, standard vaccinations and other standard preventative health care for chimpanzees, veterinary care for unexpected health problems and wounding from cagemates, and rare instances of euthanasia when ordered by a veterinarian considering the best interests of a particular chimpanzee.

PREVENTION OF BREEDING/GROUPING OF CHIMPANZEES - The CF has already divided the 257 animals into cages containing animals of the same sex, and this may continue to be the primary method used to prevent breeding. In this case, some shields may need to be placed to prevent inter-cage copulation. However, since non-single housing is a primary need for environmental enrichment, and not all adult male chimpanzees can be co-housed with other male chimpanzees, other allowable methods to prevent breeding can include vasectomy, tubal ligation, Norplant implants, and pregnancy terminations. Vasectomizing all the male chimpanzees could allow greater flexibility for forming social groups, thereby providing enhanced environmental enrichment, and can be proposed by the Contractor. The Contractor must first consult with, and obtain approval from, the Project Officer before regroupings of more than 6 chimpanzees are done in any one month. NIH expects that no conceptions of chimpanzees at the APF will occur, and for surgical terminations to be performed if they do occur. The Air Force will require that any chimpanzee that is born at the APF be removed, probably with its mother, within 30 days of birth. The Contractor will not be responsible for chimpanzees that are already pregnant on the day of transition from the CF, but may be asked by NIH to surgically terminate the pregnancy.

ENVIRONMENTAL ENRICHMENT- The Behaviorist will provide environmental enrichment to all 257 animals. A primary need of chimpanzees is to be housed with other conspecifics whenever possible (in the opinion of the Behaviorist). The chimpanzees should be allowed access to the outdoors when climatically advisable, and be provided indoor shelter when necessary. Buildings 1301, 1302, 1303, and 1304 each include 12 cages with indoor and outdoor sections that together hold approximately 6 animals per cage.

INFORMATION TECHNOLOGY - According to the transfer document signed in May 2000, each animal's records transferred with the animal from CF to NCRR. However, the state of the accuracy and completeness of these records located in New Mexico is unknown. Cooperation with the International Species Information System (ISIS) will be required. ISIS will provide a computer, ARKS and other software packages, access to animal records for the 257 chimpanzees, and training in the use of their software. Security procedures such as the use of passwords and backup copies, and LAN system implementation and maintenance will be needed.

CLINICAL LAB ACCESS - access to on-site or off-site clinical lab capabilities will be necessary to maintain the health of the 257 chimpanzees.

NECROPSY - approximately 2-3% of the APF chimpanzee population may die each year. As specified in the Memorandum of Understanding between the Director, NCRR and the Deputy Director of Intramural Research, any instances of animal death or injury must be reported by phone or email to both the Project Officer and the Director, NIH OACU, within 24 hours. Any such incidents deemed to be significant deficiencies according to PHS Policy will be verbally reported the OLAW and followed-up in writing upon completion of appropriate ACUC investigations and implementation of corrective actions. In the case of a death from an unknown cause, a necropsy must be done under BL2 containment. The contractor's proposal contains detailed discussions of how necropsies will be done, including renovation of space to be dedicated for necropsy, and obtaining help from veterinarians from elsewhere in the Contractor's organization if necessary, and those portions have been incorporated in this contract by reference.

ADMINISTRATIVE - NCRR staff believe that a variety of logistical methods mixing on-site and off-site capabilities can be used to satisfy administrative requirements. Various types of umbrella liability, employee injury, renter's insurance for damage to the buildings and theft of contents, vehicle insurance, etc. will be needed by the Contractor. One definite need is that all costs for operating and maintaining the APF must receive separate accounting from other costs to the Contractor for other sites and tasks. Inspections by the Contract's Program Officer and/or Contract Officer are to be expected, but it is not likely that a NIH representative will usually be located on-site.

USDA, OLAW, AAALAC - Intramural NIH has amended its Office for Laboratory Animal Welfare (OLAW, formerly OPRR) Assurance to include the APF, and may request and hold a United States Department of Agriculture (USDA) R Registration for the APF, or instead request only courtesy inspections. It is expected that both USDA and AAALAC representative(s) will periodically inspect the APF and issue reports to the Contractor and NIH. Major Alterations and Renovations may be needed to the APF to correct deficiencies that the USDA may categorize as "must be replaced or repaired." The Contractor will be responsible for obtaining estimates for these repairs, and the workscope of the contract and funds for its completion will be modified as necessary. After discussion with NIH staff members, attempts will be made to address deficiencies identified during AAALAC inspections. The APF will become accreditable by AAALAC, as discussed in the master contract document and on page 2 of the Memorandum of Understanding between the Director of NCRR and the Deputy Director of Intramural Research. In addition, as noted on page 7 of NIH Policy Manual 3040-2, the NIH Director of Animal Care and Use will review and approve all animal facility construction and renovation plans.

A license from the Drug Enforcement Agency to one or more veterinary staff of the APF for the use of drugs in chimpanzees at the APF will be required.

ACUC - Since Intramural NIH will hold the OLAW assurance, the designees of this subdivision of NIH will manage the ACUC in accordance with the Memorandum of Understanding between the Director of NCRR and the Deputy Director of Intramural Research. The ACUC will be constituted and meet in New Mexico, and will provide the functions required by OLAW , USDA, and pages 11-16 of NIH Policy Manual 3040-2. Required reports from the ACUC are described in the master Contract document. Members from the Contractor's staff and outside members with appropriate qualifications will be appointed by the Director of the Division of Comparative Medicine, NCRR, to serve on the ACUC. Furthermore, the Director of NCRR or a designee, will appoint or identify a senior veterinarian to serve as the Animal Program Director (APD) for the APF. As specified in the Memorandum of Understanding between the Director, NCRR and the Deputy Director of Intramural Research, any instances of animal death or injury must be reported by phone or email to both the Project Officer and the Director, NIH OACU, within 24 hours. Any such incidents deemed to be significant deficiencies according to PHS Policy will be verbally reported to OLAW and followed-up in writing upon completion of appropriate ACUC investigations and implementation of corrective actions.

REPORTS TO NIH - These are described in the master Contract document.

PAYROLL/TAXES/HIRING+TERMINATION/BILLING/PURCHASING - The Contractor's proposal describes an acceptable plan of on- and off-site sources that will accomplish these tasks.

SECURITY - The HAFB has a manned guard booth that restricts vehicular access to the large HAFB. During non-regular business hours, a walk-through of the various APF buildings every 2-4 hours for temperature monitoring, security reasons, and gross observation of the

animals is advisable. Plans in the Contractor's proposal for replacing all or some of the walk-throughs by use of video and other electronic surveillance methods must be approved in advance by the APF ACUC and the Project Officer, and be submitted to the Director, NIH OACU. It is expected that the person performing the walk-through should carry a cell phone but not a gun.

WRITTEN SOPS - After an initial operating period, SOPs need to be written that cover most aspects of animal care and health, occupational safety and health for the staff, and for reporting and administrative requirements. SOPs relevant to OSH should be approved by the Nurse/OSH Director, and SOPs relevant to Animal Care should be approved by the ACUC.

ADVISORY COMMITTEE - An advisory committee of 5-6 members should periodically (at least annually) review the APF's operation and serve as an advisory body for programmatic issues. Plans for possible facility modernization and major repairs should be presented to the advisory committee. The Contractor's answer to Question 5 in their proposal amendment describes the planned APF Advisory Committee. The Project Officer has the right to refuse the appointment of any named member that the Project Officer believes would be disruptive to the functioning of the committee, or be detrimental to NIH's interests.

OCCUPATIONAL SAFETY AND HEALTH (OSH)/ ANIMAL EXPOSURE SURVEILLANCE PLAN (AESP) - the Contractor's proposal describes the proposed plan for OSH and AESP. In addition, in accordance with the revision to the NIH-held animal assurance dated May 4, 2001, the APF contractor will provide appropriate OSH services to its employees, and the appropriateness of those services will be confirmed by NIH's Division of Safety. In addition, NIH Policy Manuals 3040-2 (especially page 7) and 3044-2 must be followed. An on-site Nurse/OSH Officer and access to a physician consultant located in Alamogordo (or a nearby town) will be needed.

PREEMPLOYMENT PHYSICAL EXAMS, HEALTH SCREENING, and VACCINATIONS for hepatitis B, measles, vaccinia, mumps, and rubella are needed, as appropriate for each individual employee. Contractor personnel entering the HAFB must comply with all relevant HAFB Health and Safety requirements. Persons having active tuberculosis are excluded from work with contract chimpanzees. All appropriate personnel should be immunized against hepatitis A and C, HIV, and other relevant diseases as safe and effective vaccines become available.

CONTINUED HEALTH SURVEILLANCE AND A SERUM BANK - A schedule for periodic blood banking, TB testing, and revaccination of employees with chimpanzee contact must be followed.

Plans for EMERGENCY CARE on a 24/7 basis should be developed and provided to all employees.

PREEMPLOYMENT AND CONTINUED TRAINING REGARDING OSH for microbiological biosafety and prevention of chimpanzee-related injuries will be necessary.

WASTES - At present, urine and feces from the chimpanzees are treated at the same sewage treatment plant that receives potentially HIV and HCV-contaminated human sewage. Sharps such as hypodermic needles, soiled personnel protective equipment, and animal tissues that are potentially biohazardous must be appropriately treated and disposed, probably through an appropriate commercial company such as Stericycle of El Paso, Texas.

FACILITIES OPERATION, MAINTENANCE, AND MODERNIZATION

MAINTENANCE - Maintenance and minor repairs to the interior and exterior, and for grounds maintenance of the APF will be charged to the Contract.

MODERNIZATION - The successful Contractor should develop a proactive method by which necessary MAJOR repairs are identified, evaluated, and implemented in a timely manner. The methods for this are expected to vary depending on the scope and severity and expense of the repair.

USDA INSPECTIONS – The Contractor will be responsible for ensuring the APF complies with standards established by the U.S. Department of Agriculture (USDA) and the Public Health Service (PHS). However, major Alterations and Renovations may be needed to the APF to correct deficiencies that the USDA may categorize as "must be replaced or repaired." The Contractor will be responsible for obtaining estimates for these repairs, and the workscope of the contract and funds for its completion will be modified as necessary. After discussion with NIH staff members, attempts will be made to address deficiencies identified during AAALAC inspections. The APF will become accreditable by AAALAC, as discussed in the contract document and on page 2 of the Memorandum of Understanding between the Director of NCRR and the Deputy Director of Intramural Research. As noted on page 7 of NIH Policy Manual 3040-2, the NIH Director of Animal Care and Use will review and approve all animal facility construction and renovation plans.

SHIPPING OF ANIMALS TO OTHER LOCATIONS - If and when a transferee is willing to accept chimpanzees from the APF, and the ChiMP office of NCRR has approved the transfer in writing, the Contractor MUST cooperate with the shipping effort. A list of relevant regulations and considerations for shipping of chimpanzees is available from the Contract Officer.

COSTS - No invasive biomedical research will be required or allowed under this contract, and no direct or indirect costs for any independent research and development project can be charged to this contract.

PREDICTABLE COSTS TO THE CONTRACTOR - NCRR will pay for maintenance of essential professional, technical, and administrative infrastructure, plus equipment, supplies, travel, etc. The use of "per diem" charges for daily care of the chimpanzees does not appear to be a preferable method for computing costs to the contract.

RENT - The lease of the APF buildings to NIH and sublease to the contractor is expected to cost no more than $1/yr.

UTILITIES - As discussed in the Use Permit, the Air Force will provide electricity, gas, water, and disposal of wastewater up to an aggregate cost of $4,500 per month. Any costs above $4,500 per month will be paid by NIH via the Contract, unless the Contractor has been negligent in the use of utilities.

UNPREDICTABLE COSTS TO THE CONTRACTOR - If the Contractor notes, or the USDA identifies, deficiencies that require MAJOR repairs or corrections to the buildings, then the costs of such repairs and/or corrections will be additive to the planned cost of the contract.

TRANSITION PERIOD FOR CONTROL OF THE APF FROM CF TO THE CONTRACTOR - On the day the new contract begins, the CF will vacate the APF (but possibly not the biocontainment area of the HAFB). The 257 NCRR-owned animals are located in Buildings 1301-4 already. Approximately 14 infants owned by CF will need to be relocated by the CF from Building 1303 (a.k.a. B-1) either before the contract begins or shortly thereafter. None of the approximately 300 CF-owned monkeys previously located, or currently located as of June 1, 2001, in corn cribs on the HAFB will be part of the APF.

USED EQUIPMENT – Although the APF is presently under operation, it appears unwise to assume that any of the movable supplies (or equipment not listed in the Contractor's Final Price Revision Attachment B) in use in 1300-4, 1269, or 1264 will be left when these buildings are vacated by the CF. A recommended preliminary plan would be for the Contractor to purchase a minimal set of equipment and all necessary supplies for the first day of operation, and subsequently purchase additional equipment as required after an inventory of equipment can be done of equipment that was left behind. The Contractor's Final Price Revision contains a list of used equipment, which NIH believes can and will be purchased by the Contractor from the CF using funds furnished by the Contract.

REQUESTS FOR TOURS AND CONGRESSIONAL/MEDIA INTEREST- As discussed in NIH Policy Manual 3040-2, NIH animal facilities have controlled access and need not be opened to the public, for a variety of reasons. Requests by outside individuals or groups to visit NIH animal facilities should be coordinated through the Office of Animal Care and Use, OIR, the Division of Public Safety, ORS, and the project Officer. The Project Officer and the NIH Office of Communications shall be notified, in writing, of all such requests.

Requests for information or inquiries/allegations regarding activities at the APF to the Contractor will be forwarded to the Director, NCRR, or designee, who will promptly notify the NIH OACU of any inquiries that lead to or that have public, media, or congressional interest.

DATE OF INITIATION - The Contractor will assume responsibility for operation of the APF on June 1, 2001.

sow501r1

INVOICE/FINANCING REQUEST INSTRUCTIONS FOR NIH COST-REIMBURSEMENT TYPE CONTRACTS, NIH(RC)-1

General: The contractor shall submit claims for reimbursement in the manner and format described herein and as illustrated in the sample invoice/financing request.

Format: Standard Form 1034, "Public Voucher for Purchases and Services Other Than Personal," and Standard Form 1035, "Public Voucher for Purchases and Services Other Than Personal-- Continuation Sheet," or reproduced copies of such forms marked ORIGINAL should be used to submit claims for reimbursement. In lieu of SF-1034 and SF-1035, claims may be submitted on the payee's letter-head or self-designed form provided that it contains the information shown on the sample invoice/financing request.

Number of Copies: As indicated in the Invoice Submission Clause in the contract.

Frequency: Invoices/financing requests submitted in accordance with the Payment Clause shall be submitted monthly unless otherwise authorized by the contracting officer.

Cost Incurrence Period: Costs incurred must be within the contract performance period or covered by precontract cost provisions.

Billing of Costs Incurred: If billed costs include: (l) costs of a prior billing period, but not previously billed; or (2) costs incurred during the contract period and claimed after the contract period has expired, the amount and month(s) in which such costs were incurred shall be cited.

Contractor's Fiscal Year: Invoices/financing requests shall be prepared in such a manner that costs claimed can be identified with the contractor's fiscal year.

Currency: All NIH contracts are expressed in United States dollars. When payments are made in a currency other than United States dollars, billings on the contract shall be expressed, and payment by the United States Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

Costs Requiring Prior Approval: Costs requiring the contracting officer's approval, which are not set forth in an Advance Understanding in the contract shall be so identified and reference the Contracting Officer's Authorization (COA) Number. In addition, any cost set forth in an Advance Understanding shall be shown as a separate line item on the request.

Invoice/Financing Request Identification: Each invoice/financing request shall be identified as either:

(a) Interim Invoice/Contract Financing Request — These are interim payment requests submitted during the contract performance period.

(b) Completion Invoice — The completion invoice is submitted promptly upon completion of the work; but no later than one year from the contract completion date, or within 120 days after settlement of the final indirect cost rates covering the year in which this contract is physically complete (whichever date

is later). The completion invoice should be submitted when all costs have been assigned to the contract and all performance provisions have been completed.

(c) Final Invoice — A final invoice may be required after the amounts owed have been settled between the Government and the contractor (e.g., resolution of all suspensions and audit exceptions).

Preparation and Itemization of the Invoice/Financing Request: The contractor shall furnish the information set forth in the explanatory notes below. These notes are keyed to the entries on the sample invoice/financing request.

(a) Designated Billing Office Name and Address — Enter the designated billing office name and address, identified in the Invoice Submission Clause of the contract, on all copies of the invoice/financing request.

(b) Invoice/Financing Request Number — Insert the appropriate serial number of the invoice/financing request.

(c) Date Invoice/Financing Request Prepared — Insert the date the invoice/financing request is prepared.

(d) Contract Number and Date — Insert the contract number and the effective date of the contract.

(e) Payee's Name and Address — Show the contractor's name (as it appears in the contract), correct address, and the title and phone number of the responsible official to whom payment is to be sent. When an approved assignment has been made by the contractor, or a different payee has been designated, then insert the name and address of the payee instead of the contractor.

(f) Total Estimated Cost of Contract — Insert the total estimated cost of the contract, exclusive of fixed-fee. For incrementally funded contracts, enter the amount currently obligated and available for payment.

(g) Total Fixed-Fee — Insert the total fixed-fee (where applicable). For incrementally funded contracts, enter the amount currently obligated and available for payment.

(h) Billing Period — Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.

(i) Amount Billed for Current Period — Insert the amount billed for the major cost elements, adjustments, and adjusted amounts for the period.

(j) Cumulative Amount from Inception — Insert the cumulative amounts billed for the major cost elements and adjusted amounts claimed during this contract.

(k) Direct Costs — Insert the major cost elements. For each element, consider the application of the paragraph entitled "Costs Requiring Prior Approval" on page 1 of these instructions.

(l) Direct Labor — Include salaries and wages paid (or accrued) for direct performance of the contract.

(2) Fringe Benefits — List any fringe benefits applicable to direct labor and billed as a direct cost. Fringe benefits included in indirect costs should not be identified here.

(3) Accountable Personal Property — Include permanent research equipment and general purpose equipment having a unit acquisition cost of $1,000 or more and having an expected service life of more than two years, and sensitive property regardless of cost (see the DHHS Contractor's Guide for Control of Government Property). Show permanent research equipment separate from general purpose equipment. Prepare and attach Form HHS-565, "Report of Accountable Property," in accordance with the following instructions:

List each item for which reimbursement is requested. A reference shall be made to the following (as applicable):

- The item number for the specific piece of equipment listed in the Property Schedule.
- The COA letter and number, if the equipment is not covered by the Property Schedule.
- Be preceded by an asterisk (*) if the equipment is below the approval level.

Further itemization of invoices/financing requests shall only be required for items having specific limitations set forth in the contract.

(4) Materials and Supplies — Include equipment with unit costs of less than $1,000 or an expected service life of two years or less, and consumable material and supplies regardless of amount.

(5) Premium Pay — List remuneration in excess of the basic hourly rate.

(6) Consultant Fee — List fees paid to consultants. Identify consultant by name or category as set forth in the contract's advance understanding or in the COA letter, as well as the effort (i.e., number of hours, days, etc.) and rate being billed.

(7) Travel — Include domestic and foreign travel. Foreign travel is travel outside of Canada, the United States and its territories and possessions. However, for an organization located outside Canada, the United States and its territories and possessions, foreign travel means travel outside that country. Foreign travel must be billed separately from domestic travel.

(8) Subcontract Costs — List subcontractor(s) by name and amount billed.

(9) Other — List all other direct costs in total unless exceeding $1,000 in amount. If over $1,000, list cost elements and dollar amounts separately. If the contract contains restrictions on any cost element, that cost element must be listed separately.

(l) Cost of Money (COM) — Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed.

(m) Indirect Costs--Overhead — Identify the cost base, indirect cost rate, and amount billed for each indirect cost category.

(n) Fixed-Fee Earned — Cite the formula or method of computation for the fixed-fee (if any). The fixed-fee must be claimed as provided for by the contract.

(o) Total Amounts Claimed — Insert the total amounts claimed for the current and cumulative periods.

(p) Adjustments — Include amounts conceded by the contractor, outstanding suspensions, and/or disapprovals subject to appeal.

(q) Grand Totals

The contracting officer may require the contractor to submit detailed support for costs claimed on one or more interim invoices/financing requests.

SAMPLE INVOICE/FINANCING REQUEST

(a) Billing Office Name and Address

NATIONAL INSTITUTES OF HEALTH
National Cancer Institute, RCB
EPS, Room
6120 EXECUTIVE BLVD MSC
Bethesda, MD 20892-

(b) Invoice/Financing Request No.

(c) Date Invoice Prepared

(d) Contract No. and Effective Date

(e) Payee's Name and Address

ABC CORPORATION
100 Main Street
Anywhere, U.S.A. zip code
Attention: Name, Title, and Phone Number
of Official to Whom Payment is Sent

(f) Total Estimated Cost of Contract

(g) Total Fixed Fee

(h) This invoice/financing request represents reimbursable costs from Aug. l, 1982 through Aug. 31, 1982

		(i) Amount Billed for Current Period	(j) Cumulative Amount From Inception
(k)	Direct Costs		
	(l) Direct Labor	$ 3,400	$ 6,800
	(2) Fringe Benefits	600	1,200
	(3) Accountable Personal Property (Attach Form HHS-565)		
	Permanent Research	3,000	6,000
	General Purpose	2,000	2,000
	(4) Materials and Supplies	2,000	4,000
	(5) Premium Pay	100	150
	(6) Consultant Fee-Dr. Jones 1 day @ 100 (COA #3)	100	100
	(7) Travel (Domestic)	200	200
	(Foreign)	200	200
	(8) Subcontract Costs	-0-	-0-
	(9) Other	-0-	-0-
	Total Direct Costs	$11,600	$20,650
(l)	Cost of Money (Factor) of (Appropriate Base)	2,400	3,600
(m)	Indirect Costs -- Overhead		
	_____% of Direct Labor or Other Base (Formula)	4,000	6,000
(n)	Fixed-Fee Earned (Formula)	700	1,400
(o)	Total Amount Claimed	$18,700	$31,650
(p)	Adjustments		
	Outstanding Suspensions		(1,700)
(q)	Grand Totals	$18,700	$29,950

"I certify that all payments requested are for appropriate purposes and in accordance with the contract."

Name of Official) (Title)

DHHS SMALL, DISADVANTAGED, WOMAN, HUBZone, VETERAN-OWNED SMALL BUSINESS SUBCONTRACTING PLAN

DATE OF PLAN: 5/1/01

CONTRACTOR: CHARLES RIVER LABORATORIES

ADDRESS: 251 BALLARDVALE ST.
WILMINGTON, MA 01887

DUNN & BRADSTREET NUMBER: 019716729

SOLICITATION OR CONTRACT NUMBER: NHLBI-RR-P-01-704

ITEM/SERVICE (Description): OPERATION AND MAINTENANCE OF A CHIMPANZEE LONG TERM HOLDING FACILITY.

TOTAL CONTRACT AMOUNT: $ [redacted]* $ _____
Total contract or Base-Year, if options — Option #1 (if applicable)

$ _____ Option #2 (if applicable) $ _____ Option #3 (if applicable) $ _____ Option #4 (if applicable)

TOTAL MODIFICATION AMOUNT, IF APPLICABLE $ _____
TOTAL TASK ORDER AMOUNT, IF APPLICABLE $ _____

PERIOD OF CONTRACT PERFORMANCE (Month, Day & Year): 06/01/01-05/31/11

The following is a suggested model for use when developing subcontracting plans as required by P.L. 95-507 and implemented by Federal Acquisition Regulations (FAR) Subpart 19.7. While this model plan has been designed to be consistent with statutory and regulatory requirements, other formats of a subcontracting plan may be acceptable; however, failure to include the essential information as exemplified in this model may be cause for either a delay in acceptance or the rejection of a bid or offer when a subcontracting plan is required. Further, the use of this model is not intended to waive other requirements that may be applicable under statute or regulation. "SUBCONTRACT," as used in this clause, means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime contractor or subcontractor calling for supplies or services required for performance of the contract or subcontract.

Subcontracting Plan
(Rev. October 2000)

* EXCLUDING ANNUAL INCENTIVE

1. Type of Plan (check one)

X Individual plan (all elements developed specifically for this contract and applicable for the full term of this contract).

_____ Master plan (goals developed for this contract) all other elements standardized and approved by a lead agency Federal Official; must be renewed every three years and contractor must provide copy of lead agency approval.

_____Commercial products/service plan, including goals, covers the offerer's fiscal year and applies to the entire production of commercial items or delivery of services sold by either the entire company or a portion thereof (e.g., division, plant, or product line); this includes planned subcontracting for both commercial and Government business.

2. Goals

State separate dollar and percentage goals for Small Business (SB), Small Disadvantaged Business (SDB), Woman-owned Small Business (WOSB), Historically Underutilized Business Zone (HUBZone) Small Business, Veteran, and "Other" than small business (OTHER) as subcontractors, for the base year and each option year, as specified in FAR 19.704 (break out and append option year goals, if applicable) or project annual subcontracting base and goals under commercial plans.

a. Total estimated dollar value of ALL planned subcontracting, i.e., with ALL types of concerns under this contract is $[redacted] (b + g = a)

b. Total estimated dollar value and percent of planned subcontracting with SMALL BUSINESSES (including SDB, WOB, HUBZone, Veteran, – owned):
(% of "a") $[redacted] and 28.5 % Federal Goal 23%

c. Total estimated dollar value and percent of planned subcontracting with SMALL DISADVANTAGED BUSINESSES: (% of "a") $ [redacted] and 5.6 % Federal Goal 5%

d. Total estimated dollar value and percent of planned subcontracting with WOMAN-OWNED SMALL BUSINESSES: (% of "a") $ [redacted] and _____ % Federal Goal 5%

e. Total estimated dollar and percent of planned subcontracting with HUBZone SMALL BUSINESSES: (% of "a") $ [redacted] and _____ % Federal Goal 2.0%

f. Total estimated dollar and percent of planned subcontracting with VETERAN SMALL BUSINESSES* (% of "a") $ [redacted] and _____ %

g. Total estimated dollar and percent of planned subcontracting with "OTHER" THAN SMALL BUSINESSES: (% of "a") $ [redacted] and 71.5 %

*Note: Service-disabled veteran goal should be included as part of veteran small business goal.

h. Provide a description of ALL the products and/or services, to be subcontracted under this contract, and indicate the size and type of business supplying them (check all that apply).

Product/Service	Other	SB	SDB	WOSB	HUBZoneSB	Veteran
FEED	X					
PRODUCE		X	X			
LAB SUPPLIES	X					
UNIFORMS	X					
DISINFECTANX		X				
ENRICHMENT MAT	X	X				
BEDDING		X				
PHYSICALS		X				
FUEL		X				
MISCELLANEOUS	X	X	X			

i. Provide a description of the method used to develop the subcontracting goals for small, disadvantaged, woman, HUBZone, veteran, and service-disabled veteran –owned small business concerns. Address efforts made to ensure that maximum practicable subcontracting opportunities have been made available for those concerns and explain the method used to identify potential sources for solicitation purposes. Explain the method and state the quantitative basis (in dollars) used to establish the percentage goals. Also, explain how the areas to be subcontracted to small, disadvantaged, woman, HUBZone, veteran, and service-disabled veteran –owned small business concerns were determined and how the capabilities of these concerns were considered for subcontract opportunities. Identify any source lists or other resources used in the determination process. (Attach additional sheets, if necessary.)

j. Indirect costs have ____ have not X been included in the dollar and percentage subcontracting goals above (check one).

k. If indirect costs have been included, explain the method used to determine the proportionate share of such costs to be allocated as subcontracts to small, disadvantaged, woman, HUBZone, veteran, and service-disabled veteran -owned small business concerns.

3. Program Administrator:

NAME/TITLE: C non Key personnel
ADDRESS: _____
TELEPHONE/E-MAIL: _____

Duties: Has general overall responsibility for the company's subcontracting program, i.e., developing, preparing, and executing subcontracting plans and monitoring performance relative to the requirements of those subcontracting plans. Other duties include, but are not limited to, the following activities:

a. Developing and promoting company-wide policy initiatives that demonstrate the company's support for awarding contracts and subcontracts to small, disadvantaged, woman, HUBZone, veteran, and service-disabled veteran -owned small business concerns; and for assuring that these concerns are included on the source lists for solicitations for products and services they are capable of providing.

b. Developing and maintaining bidder source lists of small, disadvantaged, woman, HUBZone, veteran, and service-disabled veteran –owned small business concerns from all possible sources;

c. Ensuring periodic rotation of potential subcontractors on bidder's lists;

d. Ensuring that requests for contracts (RFC) are designed to permit the maximum practicable participation of small, disadvantaged, woman, HUBZone, veteran, and service-disabled veteran –owned small businesses;

e. Accessing various sources for the identification of small, small disadvantaged, woman-owned and HUBZone, veteran, and service-disabled veteran –owned small business concerns to include the SBA's PRO-Net System, the Federal Acquisition Computer Network (FACNET) Contractor Registration Database, the National Minority Purchasing Council Vendor Information Service, the Office of Minority Business Data Center in the Department of Commerce, local small business and minority associations, contact with local chambers of commerce and Federal agencies' Small Business Offices;

f. Establishing and maintaining contract and subcontract award records;

g. Participating in Business Opportunity Workshops, Minority Business Enterprise Seminars, Trade Fairs, Procurement Conferences, etc;

h. Ensuring that small, disadvantaged, woman, HUBZone, veteran, and service-disabled veteran -owned small business concerns are made aware of subcontracting opportunities and assisting concerns in preparing responsive bids to the company;

i. Conducting or arranging for the conduct of training for purchasing personnel regarding the intent and impact of Public Law 95-507 on purchasing;

j. Monitoring the company's subcontracting program performance and making any adjustments necessary to achieve the subcontract plan goals;

k. Preparing, and submitting timely, required subcontract reports;

l. Coordinating the company's activities during the conduct of compliance reviews by Federal agencies; and

m. Other duties: _____

4. Equitable Opportunity

Describe efforts the offeror will make to ensure that small, disadvantaged, woman, HUBZone, veteran, and service-disabled veteran - owned small business concerns will have an equitable opportunity to compete for subcontracts. These efforts include, but are not limited to, the following activities:

a. Outreach efforts to obtain sources:
   1. Contacting minority and small business trade associations; 2) contacting business development organizations and local chambers of commerce; 3) attending small, disadvantaged, woman, HUBZone, veteran, and service-disabled veteran –owned small business procurement conferences and trade fairs; 4) requesting sources from the Small Business Administrations (SBA) PRO-Net System and other SBA resources; and 5) Conducting market surveys to identify new sources.

b. Internal efforts to guide and encourage purchasing personnel:
   1) Conducting workshops, seminars, and training programs;
   2) Establishing, maintaining, and utilizing small, disadvantaged, woman, HUBZone, veteran and service-disabled veteran –owned small business source lists, guides, and other data for soliciting subcontractors; and
   3) Monitoring activities to evaluate compliance with the subcontracting plan.

c. Additional efforts:
   ONCE CONTRACT IN EFFECT LOCAL LEVEL EVALUATION CAN BE MADE.

5. Flow Down Clause

The contractor agrees to include the provisions under FAR 52.219-8, "Utilization of Small Business Concerns," in all acquisitions exceeding the simplified acquisition threshold that offers further subcontracting opportunities. All subcontractors, except small business concerns, that receive subcontracts in excess of $500,000 ($1,000,000 for construction) must adopt and comply with a plan similar to the plan required by FAR 52.219-9, "Small Business Subcontracting Plan." (Flow down is not applicable for commercial items/services as described in 52.212-5(e) and 52.244-6(c).)

6. Reporting and Cooperation

The contractor gives assurance of (1) cooperation in any studies or surveys that may be required; (2) submission of periodic reports which show compliance with the subcontracting plan; (3) submission of Standard Form (SF) 294, "Subcontracting Report for Individual Contracts," and attendant Optional Form 312, SDB Participation Report and SF-295, "Summary Subcontract Report," in accordance with the instructions on the forms; and (4) ensuring that subcontractors agree to submit Standard Forms 294 and 95.

Reporting Period	Report Due	Due Date
Oct 1 - Mar 31	SF-294/of 312	4/30
Apr 1 - Sept 30	SF-294/of 312	10/30
Oct 1 - Sept 30	SF-295	10/30

Special instructions for commercial products plan: SF295 Report is due on 10/30 each year for the previous fiscal year ending 9/30.

a. Submit SF-294 and attendent optional Form 312 to cognizant Contracting Officer

b. Submit SF-295 to cognizant Contracting Officer and to the:

Office of Small and Disadvantaged Business Utilization
Department of Health and Human Services
200 Independence Avenue, SW
Humphrey H. Building, Room 517-D
Washington, D.C. 20201

c. Submit "information" copy to SBA Commercial Market Representative (CMR); visit the SBA at http://www.sba.gov/gc and click on assistance directory to locate your nearest CMR.

7. Record keeping

The following is a recitation of the types of records the contractor will maintain to demonstrate the procedures adopted to comply with the requirements and goals in the subcontracting plan. These records will include, but not be limited to, the following:

a. Small, disadvantaged, woman, HUBZone, veteran, and service-disabled veteran –owned small business source lists, guides and other data identifying such vendors;

b. Organizations contacted in an attempt to locate small, disadvantaged, and woman, HUBZone, veteran, and service-disabled veteran - owned small business sources;

c. On a contract-by-contract basis, records on all subcontract solicitations over $100,000, which indicate for each solicitation (1) whether small business concerns were solicited, and, if not, why not; (2) whether HUBZone small business concerns were solicited, if not, why not; (3) whether small disadvantage business concerns were solicited, if not, why not; (4) whether woman-owned small business concerns were solicited, and if not, why not; (5) whether veteran or service-disabled veteran-owned small business concerns and (6) the reason for the failure of solicited small, disadvantaged, and woman, HUBZone, veteran, and service-disabled veteran –owned small business concerns to receive the subcontract award;

d. Records to support other outreach efforts, e.g., contacts with minority and small business trade associations, attendance at small and minority business procurement conferences and trade fairs;

e. Records to support internal guidance and encouragement provided to buyers through (1) workshops, seminars, training programs, incentive awards; and (2) monitoring performance to evaluate compliance with the program and requirements; and

f. On a contract-by-contract basis, records to support subcontract award data including the name address, and business type and size of each subcontractor. (This item is not required for company or division-wide commercial products plans.)

g. Additional records: _____

SIGNATURE PAGE

(applies to Master or Commercial type plans)

This master or commercial type subcontracting plan is submitted by:

Contractor: CHARLES RIVER LABORATORIES

Contractor Signature [non key personnel]

Typed Name: _____

Title: _____

Date Prepared: 5/1/01

And Is Accepted By:

Agency: _____

Contracting Officer Signature: _____

Typed Name: _____

Date: _____

HSAR 352.223-70 SAFETY AND HEALTH (JANUARY 2001)

(a) To help ensure the protection of the life and health of all persons and to help prevent damage to property, the Contractor shall comply with all Federal, State and local laws and regulations applicable to the work being performed under the contract. These laws are implemented and/or enforced by the Environmental Protection Agency, Occupational Safety and Health Administration and other agencies at the Federal, State and local levels (Federal, State and local regulatory/enforcement agencies).

(b) Further, the Contractor shall take or cause to be taken additional safety measures as the Contracting Officer in conjunction with the project or other appropriate officer, determines to be reasonably necessary. If compliance with these additional safety measures results in an increase or decrease in the cost or time required for performance of any part of work under this contract, an equitable adjustment will be made in accordance with the applicable "Changes" Clause set forth in this contract.

(c) The Contractor shall maintain an accurate record of, and promptly report to the Contracting Officer, all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; and/or damage to property incidental to work performed under the contract and all violations for which the Contractor has been cited by any Federal, State or local regulatory/enforcement agency. The report shall include a copy of the notice of violation and the findings of any inquiry or inspection, and an analysis addressing the impact these violations may have on the work remaining to be performed. The report shall also state the required action(s), if any, to be taken to correct any violation(s) noted by the Federal, State or local regulatory/enforcement agency and the time frame allowed by the agency to accomplish the necessary corrective action.

(d) If the Contractor fails or refuses to comply promptly with the Federal, State or local regulatory/enforcement agency's directive(s) regarding any violation(s) and prescribed corrective action(s), the Contracting Officer may issue an order stopping all or part of the work until satisfactory corrective action (as approved by the Federal, State or local regulatory/enforcement agencies) has been taken and documented to the Contracting Officer. No part of the time lost due to any stop work order shall be subject to a claim for extension of time or costs or damages by the Contractor.

(e) The Contractor shall insert the substance of this clause in each subcontract involving toxic substances, hazardous materials, or operations. Compliance with the provisions of this clause by subcontractors will be the responsibility of the Contractor.

(End of clause)

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PROCUREMENT OF CERTAIN EQUIPMENT

Notwithstanding any other clause in this contract, the Contractor will not be reimbursed for the purchase, lease, or rental of any item of equipment listed in the following Federal Supply Groups, regardless of the dollar value, without the prior written approval of the Contracting Officer.

67 - Photographic Equipment
69 - Training Aids and Devices
70 - General Purpose ADP Equipment, Software, Supplies and Support (Excluding 7045-ADP Supplies and Support Equipment.)
71 - Furniture
72 - Household and Commercial Furnishings and Appliances
74 - Office Machines and Visible Record Equipment
77 - Musical Instruments, Phonographs, and Home-type Radios
78 - Recreational and Athletic Equipment

When equipment in these Federal Supply Groups is requested by the Contractor and determined essential by the Contracting Officer, the Government will endeavor to fulfill the requirement with equipment available from its excess personal property sources, provided the request is made under a contract. Extensions or renewals of approved existing leases or rentals for equipment in these Federal Supply Groups are excluded from the provisions of this article.

94-2361 NM,ALBUQUERQUE 09/26/00
FOR OFFICIAL USE ONLY BY FEDERAL AGENCIES PARTICIPATING IN MOU WITH DOL
WASHINGTON D.C. 20210

William W.Gross
Director

Division of
Wage Determinations

Wage Determination No.: 1994-2361
Revision No.: 15
Date Of Last Revision: 09/15/2000

State: New Mexico

Area: New Mexico Counties of Bernalillo, Catron, Cibola, Colfax, De Baca, Guadalupe, Harding, Los Alamos, McKinley, Mora, Rio Arriba, San Juan, San Miguel, Sandoval, San Socorro, Taos, Torrance, Valencia

Fringe Benefits Required Follow the Occupational Listing

OCCUPATION TITLE	MINIMUM WAGE RATE
Administrative Support and Clerical Occupations	
Accounting Clerk I	6.82
Accounting Clerk II	7.85
Accounting Clerk III	9.83
Accounting Clerk IV	12.47
Court Reporter	10.04
Dispatcher, Motor Vehicle	10.04
Document Preparation Clerk	8.47
Duplicating Machine Operator	8.47
Film/Tape Librarian	9.09
General Clerk I	6.24
General Clerk II	7.39
General Clerk III	8.47
General Clerk IV	9.83
Housing Referral Assistant	11.62
Key Entry Operator I	6.86
Key Entry Operator II	8.57
Messenger (Courier)	6.78
Order Clerk I	7.18
Order Clerk II	8.57
Personnel Assistant (Employment) I	8.09
Personnel Assistant (Employment) II	9.09
Personnel Assistant (Employment) III	10.04
Personnel Assistant (Employment) IV	11.62
Production Control Clerk	11.62
Rental Clerk	9.09
Scheduler, Maintenance	9.09
Secretary I	9.09
Secretary II	10.04
Secretary III	11.62
Secretary IV	13.19
Secretary V	16.44
Service Order Dispatcher	9.09
Stenographer I	9.09
Stenographer II	10.21
Supply Technician	13.19
Survey Worker (Interviewer)	10.04
Switchboard Operator-Receptionist	7.59

ATTACHMENT 6

Test Examiner	10.04
Test Proctor	10.04
Travel Clerk I	7.91
Travel Clerk II	8.53
Travel Clerk III	9.07
Word Processor I	8.32
Word Processor II	9.35
Word Processor III	10.45
Automatic Data Processing Occupations	
Computer Data Librarian	10.45
Computer Operator I	10.45
Computer Operator II	10.64
Computer Operator III	14.06
Computer Operator IV	15.63
Computer Operator V	17.90
Computer Programmer I (1)	12.09
Computer Programmer II (1)	13.84
Computer Programmer III (1)	17.43
Computer Programmer IV (1)	21.08
Computer Systems Analyst I (1)	15.73
Computer Systems Analyst II (1)	20.31
Computer Systems Analyst III (1)	23.91
Peripheral Equipment Operator	10.45
Automotive Service Occupations	
Automotive Body Repairer, Fiberglass	15.20
Automotive Glass Installer	13.70
Automotive Worker	13.70
Electrician, Automotive	15.20
Mobile Equipment Servicer	11.32
Motor Equipment Metal Mechanic	15.20
Motor Equipment Metal Worker	13.70
Motor Vehicle Mechanic	15.20
Motor Vehicle Mechanic Helper	11.32
Motor Vehicle Upholstery Worker	13.70
Motor Vehicle Wrecker	13.70
Painter, Automotive	15.20
Radiator Repair Specialist	13.70
Tire Repairer	10.94
Transmission Repair Specialist	15.20
Food Preparation and Service Occupations	
Baker	11.12
Cook I	9.75
Cook II	11.12
Dishwasher	6.21
Food Service Worker	6.21
Meat Cutter	11.12
Waiter/Waitress	7.15
Furniture Maintenance and Repair Occupations	
Electrostatic Spray Painter	14.49
Furniture Handler	11.32
Furniture Refinisher	14.49
Furniture Refinisher Helper	11.32
Furniture Repairer, Minor	13.70
Upholsterer	14.49
General Services and Support Occupations	
Cleaner, Vehicles	6.21
Elevator Operator	6.21
Gardener	9.82
House Keeping Aid I	5.38
House Keeping Aid II	6.21

Janitor	6.21
Laborer, Grounds Maintenance	7.15
Maid or Houseman	5.33
Pest Controller	10.45
Refuse Collector	6.21
Tractor Operator	9.01
Window Cleaner	7.15
Health Occupations	
Dental Assistant	10.93
Emergency Medical Technician (EMT)/Paramedic/Ambulance Driver	10.93
Licensed Practical Nurse I	11.53
Licensed Practical Nurse II	11.53
Licensed Practical Nurse III	12.90
Medical Assistant	9.77
Medical Laboratory Technician	9.77
Medical Record Clerk	9.77
Medical Record Technician	13.54
Nursing Assistant I	7.10
Nursing Assistant II	7.98
Nursing Assistant III	8.71
Nursing Assistant IV	9.77
Pharmacy Technician	12.19
Phlebotomist	9.77
Registered Nurse I	13.54
Registered Nurse II	16.57
Registered Nurse II, Specialist	16.57
Registered Nurse III	20.05
Registered Nurse III, Anesthetist	20.05
Registered Nurse IV	24.02
Information and Arts Occupations	
Audiovisual Librarian	10.38
Exhibits Specialist I	12.68
Exhibits Specialist II	15.48
Exhibits Specialist III	19.37
Illustrator I	12.68
Illustrator II	15.48
Illustrator III	19.37
Librarian	16.44
Library Technician	10.04
Photographer I	12.66
Photographer II	14.06
Photographer III	17.30
Photographer IV	19.37
Photographer V	23.43
Laundry, Dry Cleaning, Pressing and Related Occupations	
Assembler	6.00
Counter Attendant	6.00
Dry Cleaner	7.51
Finisher, Flatwork, Machine	6.00
Presser, Hand	6.00
Presser, Machine, Drycleaning	6.00
Presser, Machine, Shirts	6.00
Presser, Machine, Wearing Apparel, Laundry	6.00
Sewing Machine Operator	8.05
Tailor	8.51
Washer, Machine	6.44
Machine Tool Operation and Repair Occupations	
Machine-Tool Operator (Toolroom)	14.49
Tool and Die Maker	17.49
Material Handling and Packing Occupations	

Forklift Operator	11.24
Fuel Distribution System Operator	12.80
Material Coordinator	10.61
Material Expediter	10.61
Material Handling Laborer	8.63
Order Filler	9.83
Production Line Worker (Food Processing)	10.49
Shipping Packer	10.67
Shipping/Receiving Clerk	10.67
Stock Clerk (Shelf Stocker; Store Worker II)	10.67
Store Worker I	7.54
Tools and Parts Attendant	10.49
Warehouse Specialist	10.49
Mechanics and Maintenance and Repair Occupations	
Aircraft Mechanic	15.20
Aircraft Mechanic Helper	11.32
Aircraft Quality Control Inspector	16.56
Aircraft Servicer	12.80
Aircraft Worker	13.70
Appliance Mechanic	14.49
Bicycle Repairer	10.94
Cable Splicer	15.20
Carpenter, Maintenance	14.49
Carpet Layer	13.70
Electrician, Maintenance	15.20
Electronics Technician, Maintenance I	13.21
Electronics Technician, Maintenance II	16.30
Electronics Technician, Maintenance III	17.29
Fabric Worker	9.22
Fire Alarm System Mechanic	15.20
Fire Extinguisher Repairer	12.80
Fuel Distribution System Mechanic	15.20
General Maintenance Worker	13.70
Heating, Refrigeration and Air Conditioning Mechanic	15.20
Heavy Equipment Mechanic	15.20
Heavy Equipment Operator	13.76
Instrument Mechanic	15.20
Laborer	6.21
Locksmith	14.49
Machinery Maintenance Mechanic	15.20
Machinist, Maintenance	15.20
Maintenance Trades Helper	11.33
Millwright	15.20
Office Appliance Repairer	14.49
Painter, Aircraft	14.49
Painter, Maintenance	14.49
Pipefitter, Maintenance	15.20
Plumber, Maintenance	14.49
Pneudraulic Systems Mechanic	15.20
Rigger	15.20
Scale Mechanic	15.20
Sheet-Metal Worker, Maintenance	15.20
Small Engine Mechanic	13.70
Telecommunication Mechanic I	15.20
Telecommunication Mechanic II	16.02
Telephone Lineman	15.20
Welder, Combination, Maintenance	15.20
Well Driller	15.20
Woodcraft Worker	15.20
Woodworker	

Miscellaneous Occupations	
Animal Caretaker	8.08
Carnival Equipment Operator	9.01
Carnival Equipment Repairer	9.82
Carnival Worker	6.21
Cashier	7.43
Desk Clerk	8.52
Embalmer	15.82
Lifeguard	7.59
Mortician	15.82
Park Attendant (Aide)	9.52
Photofinishing Worker (Photo Lab Tech., Darkroom Tech)	7.59
Recreation Specialist	11.80
Recycling Worker	9.01
Sales Clerk	7.59
School Crossing Guard (Crosswalk Attendant)	6.21
Sport Official	7.59
Survey Party Chief (Chief of Party)	12.44
Surveying Aide	12.44
Surveying Technician (Instr. Person/Surveyor Asst./Instr.)	10.04
Swimming Pool Operator	11.21
Vending Machine Attendant	9.01
Vending Machine Repairer	11.21
Vending Machine Repairer Helper	8.07
Personal Needs Occupations	
Child Care Attendant	8.52
Child Care Center Clerk	10.62
Chore Aid	5.33
Homemaker	11.80
Plant and System Operation Occupations	
Boiler Tender	15.20
Sewage Plant Operator	14.49
Stationary Engineer	15.20
Ventilation Equipment Tender	10.60
Water Treatment Plant Operator	14.49
Protective Service Occupations	
Alarm Monitor	6.95
Corrections Officer	11.83
Court Security Officer	11.83
Detention Officer	11.83
Firefighter	10.33
Guard I	6.21
Guard II	6.95
Police Officer	14.96
Stevedoring/Longshoremen Occupations	
Blocker and Bracer	13.06
Hatch Tender	13.06
Line Handler	13.06
Stevedore I	13.28
Stevedore II	13.86
Technical Occupations	
Air Traffic Control Specialist, Center (2)	26.07
Air Traffic Control Specialist, Station (2)	17.98
Air Traffic Control Specialist, Terminal (2)	19.79
Archeological Technician I	12.56
Archeological Technician II	14.05
Archeological Technician III	17.40
Cartographic Technician	17.40
Civil Engineering Technician	17.40
Computer Based Training (CBT) Specialist/ Instructor	16.79

Drafter I	11.28
Drafter II	12.66
Drafter III	15.19
Drafter IV	17.29
Engineering Technician I	10.82
Engineering Technician II	12.14
Engineering Technician III	13.58
Engineering Technician IV	15.13
Engineering Technician V	18.01
Engineering Technician VI	21.75
Environmental Technician	13.95
Flight Simulator/Instructor (Pilot)	20.31
Graphic Artist	16.79
Instructor	15.72
Laboratory Technician	14.06
Mathematical Technician	15.13
Paralegal/Legal Assistant I	10.04
Paralegal/Legal Assistant II	13.19
Paralegal/Legal Assistant III	16.13
Paralegal/Legal Assistant IV	19.50
Photooptics Technician	15.13
Technical Writer	14.89
Unexploded (UXO) Safety Escort	16.57
Unexploded (UXO) Sweep Personnel	16.57
Unexploded Ordnance (UXO) Technician I	16.57
Unexploded Ordnance (UXO) Technician II	20.05
Unexploded Ordnance (UXO) Technician III	24.02
Weather Observer, Combined Upper Air and Surface Programs (3)	14.06
Weather Observer, Senior (3)	15.63
Weather Observer, Upper Air (3)	14.06
Transportation/ Mobile Equipment Operation Occupations	
Bus Driver	11.33
Parking and Lot Attendant	5.73
Shuttle Bus Driver	9.07
Taxi Driver	9.07
Truckdriver, Heavy Truck	12.22
Truckdriver, Light Truck	9.07
Truckdriver, Medium Truck	11.33
Truckdriver, Tractor-Trailer	12.22

ALL OCCUPATIONS LISTED ABOVE RECEIVE THE FOLLOWING BENEFITS:

HEALTH & WELFARE: $1.92 an hour or $76.80 a week or $332.80 a month.

VACATION: 2 weeks paid vacation after 1 year of service with a contractor or success weeks after 10 years, and 4 after 15 years. Length of service includes the whole sp continuous service with the present contractor or successor, wherever employed, and the predecessor contractors in the performance of similar work at the same Federal facility. (Reg. 29 CFR 4.173)

HOLIDAYS: A minimum of ten paid holidays per year: New Year's Day, Martin Luther Ki Jr.'s Birthday, Washington's Birthday, Memorial Day, Independence Day, Labor Day, Co Day, Veterans' Day, Thanksgiving Day, and Christmas Day. (A contractor may substitu any of the named holidays another day off with pay in accordance with a plan communi to the employees involved.) (See 29 CFR 4.174)

THE OCCUPATIONS WHICH HAVE PARENTHESES AFTER THEM RECEIVE THE FOLLOWING BENEFITS (as numbered):

1) Does not apply to employees employed in a bona fide executive, administrative, o professional capacity as defined and delineated in 29 CFR 541. (See CFR 4.156)

2) APPLICABLE TO AIR TRAFFIC CONTROLLERS ONLY - NIGHT DIFFERENTIAL: An employee is entitled to pay for all work performed between the hours of 6:00 P.M. and 6:00 A.M. rate of basic pay plus a night pay differential amounting to 10 percent of the rate basic pay.

3) WEATHER OBSERVERS - NIGHT PAY & SUNDAY PAY: If you work at night as part of a r tour of duty, you will earn a night differential and receive an additional 10% of ba

for any hours worked between 6pm and 6am. If you are a full-time employed (40 hours week) and Sunday is part of your regularly scheduled workweek, you are paid at your

basic pay plus a Sunday premium of 25% of your basic rate for each hour of Sunday wo which is not overtime (i.e. occasional work on Sunday outside the normal tour of dut considered overtime work).

HAZARDOUS PAY DIFFERENTIAL: An 8 percent differential is applicable to employees emp in a position that represents a high degree of hazard including working with or in c proximity to explosives and incendiary materials involved in research, testing, manufacturing, inspection, renovation, maintenance, and disposal. Such as: Screenin blending, dying, mixing, and pressing of sensitive explosives pyrotechnic compositio

as lead azide, black powder and photoflash power. All dry-house activities involvin propellants or explosives. Demilitarization, modification, renovation, demolition, maintenance operations on sensitive explosives and incendiary materials. All operat involving regarding and cleaning of artillery ranges.

A 4 percent differential is applicable to employees employed in a position that repr a low degree of hazard. Including working with or in close proximity to explosives incendiary materials which involves potential injury such as laceration of hands, fa arms of the employee engaged in the operation and, possibly adjacent employees, irri of the skin, minor burns and the like; minimal damage to immediate or adjacent work

equipment being used.

All operations involving, unloading, storage, and hauling of explosive and incendiar ordnance material other than small arms ammunition. (Distribution of raw nitroglyce

covered under high degree hazard.)

** UNIFORM ALLOWANCE **

If employees are required to wear uniforms in the performance of this contract (eith the terms of the Government contract, by the employer, by the state or local law, et the cost of furnishing such uniforms and maintaining (by laundering or dry cleaning) uniforms is an expense that may not be borne by an employee where such cost reduces hourly rate below that required by the wage determination. The Department of Labor w accept payment in accordance with the following standards as compliance:

The contractor or subcontractor is required to furnish all employees with an adequat number of uniforms without cost or to reimburse employees for the actual cost of the uniforms. In addition, where uniform cleaning and maintenance is made the responsib of the employee, all contractors and subcontractors subject to this wage determinati shall (in the absence of a bona fide collective bargaining agreement providing for a different amount, or the furnishing of contrary affirmative proof as to the actual c reimburse all employees for such cleaning and maintenance at a rate of $3.35 per wee $.67 cents per day). However, in those instances where the uniforms furnished are m

"wash and wear" materials, may be routinely washed and dried with other personal gar and do not require any special treatment such as dry cleaning, daily washing, or com

laundering in order to meet the cleanliness or appearance standards set by the terms

Government contract, by the contractor, by law, or by the nature of the work, there requirement that employees be reimbursed for uniform maintenance costs.

** NOTES APPLYING TO THIS WAGE DETERMINATION **

Source of Occupational Title and Descriptions:

The duties of employees under job titles listed are those described in the "Service Contract Act Directory of Occupations," Fourth Edition, January 1993, as amended by Third Supplement, dated March 1997, unless otherwise indicated. This publication ma obtained from the Superintendent of Documents, at 202-783-3238, or by writing to the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 Copies of specific job descriptions may also be obtained from the appropriate contra officer.

REQUEST FOR AUTHORIZATION OF ADDITIONAL CLASSIFICATION AND WAGE RATE (Standard Form (SF 1444))

Conformance Process:

The contracting officer shall require that any class of service employee which is no listed herein and which is to be employed under the contract (i.e., the work to be performed is not performed by any classification listed in the wage determination), classified by the contractor so as to provide a reasonable relationship (i.e., appro level of skill comparison) between such unlisted classifications and the classificat listed in the wage determination. Such conformed classes of employees shall be paid monetary wages and furnished the fringe benefits as are determined. Such conforming process shall be initiated by the contractor prior to the performance of contract wo such unlisted class(es) of employees. The conformed classification, wage rate, and/ fringe benefits shall be retroactive to the commencement date of the contract. (See

4.6 (C)(vi)) When multiple wage determinations are included in a contract, a separa 1444 should be prepared for each wage determination to which a class(es) is to be conformed.

The process for preparing a conformance request is as follows:

1) When preparing the bid, the contractor identifies the need for a conformed occupa

and computes a proposed rate(s).

2) After contract award, the contractor prepares a written report listing in order p

classification title(s), a Federal grade equivalency (FGE) for each proposed classification(s), job description(s), and rationale for proposed wage rate(s), incl information regarding the agreement or disagreement of the authorized representative

employees involved, or where there is no authorized representative, the employees themselves. This report should be submitted to the contracting officer no later tha days after such unlisted class(es) of employees performs any contract work.

3) The contracting officer reviews the proposed action and promptly submits a report

action, together with the agency's recommendations and pertinent information includi position of the contractor and the employees, to the Wage and Hour Division, Employm

Standards Administration, U.S. Department of Labor, for review. (See section 4.6(b) Regulations 29 CFR Part 4).

4) Within 30 days of receipt, the Wage and Hour Division approves, modifies, or disa

the action via transmittal to the agency contracting officer, or notifies the contra officer that additional time will be required to process the request.

5) The contracting officer transmits the Wage and Hour decision to the contractor.

6) The contractor informs the affected employees.

Information required by the Regulations must be submitted on SF 1444 or bond paper.

When preparing a conformance request, the "Service Contract Act Directory of Occupat (the Directory) should be used to compare job definitions to insure that duties requ are not performed by a classification already listed in the wage determination. Rem it is not the job title, but the required tasks that determine whether a class is in in an established wage determination. Conformances may not be used to artificially combine, or subdivide classifications listed in the wage determination.

Equipment That Could Transfer from CF to the New Contractor for Use at the APF

Building	Description	Existed as of 1/10/01?	CF agrees to transfer?
Centralized or Applicable to All Buildings			
	All caging bolted to the wall, and plumbing for lixits and washdown in 1301-4	y	
Essential	All electrical, plumbing, telephone, HVAC equipment in 1300-4, 1264	y	
Essential	All scales used for weighing animals in 1301-4	y	
	All dental equipment in 1301-4	y	
	All suction equipment in 1301-4	y	
	All record stands and record holders in 1301-4	y	
Essential	3 gurneys each for 1301-4	y	
Essential	Large generator outside of Bldg 1264	y	
Essential	TRANSFER CAGES ADDED MONDAY 1/22/01		
1301	8 cages in 2 study rooms	y	C
Essential	1 small and 1 large cage in sick ward	y	
	1 cage in the other sick ward	y	
Essential	Surgery room contents: surgical table	y	
Essential	operating instrument set	y	
Essential	portable light	y	
Essential	vacuum pump set	y	
	ultrasonic instrument cleaner	y	
Essential	ceiling light	y	
	endoscope set	y	
Essential	Craftsmen cabinet	y	
Essential	vacuum pump set	y	
	electrocautery	y	
Essential	ECG Machine	y	
	Iv infusion pump	y	
Essential	anesthesia machine set	y	
	stainless cabinet	y	
	2 refrigerator/freezers	y	
	dental descaler	y	
	microwave	y	
Essential	200 lb capacity scale	y	
	2 stainless cabinets	y	
	fluoroscope	y	
Essential	small steam autoclave in supply room	y	
	ultrasonic instrument cleaner in supply room	y	
Essential	walk in refrigerated food storage room	y	
Essential	TRANSFER CAGES ADDED MONDAY 1/22/01		
1302	8 cages in 2 study rooms	y	
Essential	1 small and 1 large cage in sick ward	y	
	1 cage in the other sick ward	y	
Essential	small double key drug cabinet in small office	y	
Essential	200 lb capacity scale	y	
Essential	2 refrigerator/freezers	y	
Essential	vacuum pump set	y	
	ultrasonic instrument cleaner	y	
	microwave	y	
Essential	heavy capacity floor scale	y	
Essential	walk in refrigerated food storage room	y	
Essential	TRANSFER CAGES ADDED MONDAY 1/22/01		
1303	3 large outdoor group cages	y	
Essential	2 cages in sick ward	y	
	1 cage in the other sick ward	y	
Essential	heavy capacity floor scale	y	
	[redacted]	y	
Essential	portable clinical x-ray unit	y	
Essential	Konica x-ray film developer	y	

Equipment That Could Transfer from CF to the New Contractor for Use at the APF

Building	Description	Existed as of 1/10/01?	CF agrees to transfer?
Essential	light boxes on wall to read x-ray films	y	
	stainless suply cabinet	y	
	vacuum pump set	y	
	ultrasonic instrument cleaner	y	
	2 microwaves	y	
	triple door freezer	y	
	2 freezers	y	
	2 refrigerator/freezers	y	
	walk in refrigerated food storage room	y	
	Hydralic pumps for squeeze cages x 2	y	
1304			
Essential	1 cage in sick ward	y	
Essential	1 cage in the other sick ward	y	
	dental descaler	y	
	vacuum pump set	y	
	ultrasonic instrument cleaner	y	
	dental hand instruments	y	
	microwave	y	
Essential	200 lb capacity scale	y	
	refrigerator/freezer	y	
Essential	walk in refrigerated food storage room	y	
Essential	TRANSFER CAGES ADDED MONDAY 1/22/01		
1300	boilers, pumps, HVAC controllers, water softener, etc	y	
1264			

NOTE: PRICE ALREADY REFLECTS DEPRECIATION

CF RESERVES THE RIGHT TO REMOVE ANY EQUIPMENT FROM THIS LIST PRIOR TO AN AGREEMENT BEING SIGNED.

Notes: Inventory will be kept for any item that originally cost > $5,000 or has an expected life of 5 years or more; all photocopiers and computer CPUs, monitors, and printers that originally cost >$200; and personal use items such as televisions, VCRs, and camcorders that originally cost > $200.

Additional Equipment Required at Contract Start-Up

	Item	Vendor	Cost
Essential	Portable X-Ray Machine		
Essential	Portable Ultrasound Machine *		
Essential	Surgical Autoclave		
Essential	Phone System		
Essential	Personal Computers and Peripherals (8 units)		
Essential	Darting Equipment (1 per building; 4 total)		

* Assumes CRL does not purchase leased unit currently housed in Building 1303.

REPORT OF GOVERNMENT OWNED CONTRACTOR HELD PROPERTY

CONTRACTOR:	CONTRACT NUMBER
ADDRESS	REPORT DATE: FISCAL YEAR:

CLASSIFICATION	BEGINNING OF PERIOD						
	ITEMS	$					
LAND < $25K							
LAND ≥ $25K							
BUILDING < $25K							
BUILDING ≥ $25K							
PROPERTY UNDER CONSTR < $25K							
PROPERTY UNDER CONSTR ≥ $25K							
PLANT EQUIP < $25K							
PLANT EQUIP ≥ $25K							
SPECIAL TOOLING < $25K							
SPECIAL TOOLING ≥ $25K							
SPECIAL TEST EQUIP < $25K							
SPECIAL TEST EQUIP ≥ $25K							
AGENCY PECULIAR < $25K							
AGENCY PECULIAR ≥ $25K							
MATERIALS < $25K (CUMULATIVE)							
PROPERTY UNDER MFR < $25K							
PROPERTY UNDER MFR ≥ $25K							

SIGNED BY:		DATE SIGNED:

QUALITY ASSURANCE SURVEILLANCE PLAN

1. **Purpose of the Quality Assurance Surveillance Plan (QASP)**
The QASP is intended to accomplish the following:
•Define the roles and responsibilities of participating government officials and outside experts
•Define the key performance requirements, standards of performance, method of surveillance, allowable performance standard deviations, and incentives against which the contractor's performance will be assessed (reference Performance Requirements Summary)
•Define the evaluation methodology that will be employed by the government in assessing the contractor's performance
•Define the award or incentive fee plan, as appropriate

2. **Roles and Responsibilities of Participating Government Officials**
The Project Officer (PO) will be responsible for monitoring, assessing, recording, and reporting on the technical performance of the contractor on a day-to-day basis.

The Contracting Officer (CO), or his/her representative, will have overall responsibility for overseeing the contractor's performance. The CO will also be responsible for the day-to-day monitoring of the contractor's performance in the areas of contract compliance, contract administration, cost control and property control; reviewing the PO's assessment of the contractor's performance; and resolving any differences. The CO may call upon the expertise of other individuals as required.

3. **Performance Requirements Summary**

Key Performance Requirement	Performance Standard	Allowable Deviation from Standard	Method of Surveillance	Incentive	Weight
Prevention of breeding & no serious deficiencies regarding the care of the animals	following Statement of Work	none	PO monitoring	See note below	35%
Submit reports	following delivery schedule and reporting requirements	not more than 10 calendar days delay in delivery schedule	PO and CO monitoring	See note below	20%

Monitor, control and report costs	(a) following contract terms for invoice submission; (b) contractor remains within or below cost estimates; (c) notifies CO immediately of any budget issues	(a) not more than 10 calendar days delay in submitting monthly invoices; (b) none; (c) within 14 calendar days	PO and CO monitoring	See note below	25%
Overall contract management	(a) contractor maintains high level of responsiveness to CO/PO; (b) effective leadership role of PI	(a) meets all requested due dates; (b) meets above standards and contract is continued each increment	PO and CO monitoring	See note below	20%

4. **Evaluation Methodology**
Even though the Government will monitor the Contractor's performance on a continuing basis, the volume of tasks performed by the Contractor makes technical inspections of every task impractical. Accordingly, the NHLBI will use a quality assurance review process to monitor the Contractor's performance under this contract. The Contractor's performance of each key performance requirement will be evaluated using the following rating scale.

ADJECTIVAL RATING	DEFINITION OF RATING	NUMERICAL RATING
Unsatisfactory	the contractor's performance fails to meet the standard	0
Poor	the contractor's performance meets the standard but major problems have been encountered	1
Satisfactory	the contractor's performance meets the standard with some problems encountered	2

Good	the contractor's performance meets the standard with minor inefficiencies	3
Excellent	the contractor's performance exceeds the standard	4
Outstanding	the contractor's performance substantially exceeds the standard with no problems or inefficiencies	5

In the event of an excusable delay (reference FAR 52. 249-14, Excusable Delays) the NHLBI and the Contractor shall work together to modify the contract in regard to the due dates of the deliverables. If such an event were to occur that would require a modification to the due dates of the deliverables, the Contractor's performance, where applicable in this QASP, shall be measured by the date agreed upon in the modification.

5. **Award/Incentive Fee Plan**

An annual incentive payment equal to [ ]Total Estimated Costs will be paid to the Contractor if the above key performance requirements are met. The incentive payment is incremental to the Total Estimated Cost of the contract. The incentive payments shall be used to fund employee recognition and reward programs, as well as a broad-based bonus program tied to contract performance that goes beyond its existing incentive programs and effectively shares any amounts received with all personnel who contribute to overall contract success. A portion of the incentive payments shall also be allocated to training and forms of recognition specifically tied to animal welfare and animal ethics initiatives.

In the event an Incentive Payment is received, the Contractor shall provide a summary of how the incentive amount was distributed among its Project Staff and what portion was allocated to specific ongoing incentive programs. The administration and oversight of any incentive-related programs will be conducted in a manner consistent with the Quality Assurance Surveillance Plan (QASP) for this contract effort.

The maximum annual incentive amounts are as follows:

Year One (1) [ ]
Year Two (2)
Year Three (3)
Year Four (4)
Year Five (5)
Year Six (6)
Year Seven (7)
Year Eight (8)
Year Nine (9)
Year Ten (10) [ ]

Attachment 10: Department of Air Force Permit to NIH to use Property Located at Holloman Air Force Base, dated April 30, 2001, 23 pages

Note: Because this attachment falls under the jurisdiction of the U.S. Air Force, it has been forwarded to the U.S. Air Force's Freedom of Information Office for review and determination of releasibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

MAY 4 2001

Mr. Denis Doyle
Director, Division of Assurances
Office of Laboratory Animal Welfare
6705 Rockledge Drive, Suite 1050
Rockville, MD 20892-7982

Dear Mr. Doyle:

Recent changes in the National Institutes of Health's (NIH) oversight, ownership and programmatic involvement of a large number of chimpanzees previously used in biomedical research resulted in a decision to place those animals and the associated animal activities under the NIH Intramural Research Program Animal Welfare Assurance (A4149-01). The proposed additions or clarifications to the components, facilities and practices described in that Assurance are stated below.

Paragraph I. We are adding an additional component, the Alamogordo Primate Facility (APF), located at Holloman Air Force Base (HAFB), New Mexico, to the definition of Institution. That component occupies facilities (identified in Paragraph III.H.) leased from HAFB and totally operated by a contractor, hereinafter referred to as the APF contractor..

Paragraph III.A. Under a separate Memorandum of Understanding (MOU), the Director, National Center for Research Resources (NCRR) has committed to provide necessary fiscal and personnel resources to oversee and manage the APF support contract and associated facility construction or renovation projects to maintain the Animal Care and Use (ACU) program and physical plant in compliance with applicable federal and/or state laws, regulations and applicable standards, to include the NIH Policy Manual 3040-2 and the NRC Guide for the Care and Use of Laboratory Animals (Guide). The APF will have an Animal Care and Use Committee (ACUC) and Animal Program Director (APD) appointed, by delegated authority, by the Director, NCRR, or designee.

Paragraph III.B. The names of the veterinarians providing care for the NIH-owned animals at the APF will be provided as soon as the full-time veterinary staff has been hired and moved on location.

Paragraph III.C. The names of the members of the APF ACUC will be provided as soon as the full-time staff has been hired and moved on location.

Paragraph III.G. The APF contractor will provide appropriate occupational safety and health services to its employees. The appropriateness of those services will be confirmed by NIH's Division of Safety.

Paragraph III.H. The total gross number of square feet in the APF animal facilities (including each satellite facility), the species of animals housed therein and the average daily inventory, by species, of animals in each facility is provided in the attached table (amendment to Attachment 8.)

Paragraph III.I. APF contractor staff will receive training from the Training Coordinator, Animal Care and Use or, per paragraph F.4.b. of PM 3040-2, via comparable training programs approved by the Director, OACU and presented by contractor personnel at the APF.

Paragraph IV. The ACU program at the APF is not currently accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC .) Beginning with the initial submission of our Animal Welfare Assurance, and as evidenced by our AAALAC file histories, it has always been the IRPs unswerving commitment to achieve and maintain AAALAC accreditation of all IRP components. As the APF is both geographically and operationally distinct from the remainder of the IRP ACU research programs, and in light of our commitment to seek AAALAC accreditation of the APF as quickly as we can bring the ACU program into an accreditable condition, per PHS Policy paragraph V. D., we hereby request a waiver from the requirement that "All of the institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated and accredited by AAALAC,..." We request that this waiver be for a period of 12 months, thus allowing the remainder of the IRP components to remain in Category 1 during that interval.

Request your review and approval of these amendments.

Please contact me or James F. Taylor, D.V.M.. Director, Office of Animal Care and Use, in the event clarification or additional information is necessary regarding this amendment to our Assurance.

Michael M. Gottesman, M.D.
Deputy Director for Intramural Research

Attachment

cc:
Dr. Vaitukaitis

Alamogordo Primate Facility

ASSURANCE NUMBER: A-4149-01
Date: **May 2001**

LABORATORIES, UNITS, OR BUILDINGS	Date(s) Facilities Inspected	Date(s) Animal Program Reviewed	NET SQ FT (INCL SERVICE AREA)	SPECIES HOUSED IN FACILITY	AVERAGE DAILY INVENTORY	SPRING REPORT SUBMISSION DATE	FALL REPORT SUBMISSION DATE
1264			2821 sq ft	None - admin			
1269			1000 sq ft	None - feed store			
1300			472 sq ft	None - mechanical			
1301			18, 695 sq ft	chimpanzees			
1302			18, 695 sq ft	chimpanzees			
1303			18, 695 sq ft	chimpanzees			
1304			18, 695 sq ft	chimpanzees			

ATTACHMENT 11

NIH POLICY MANUAL
3040-2 ANIMAL CARE AND USE IN THE INTRAMURAL PROGRAM
Issuing Office: OACU 496-5424
Release Date: 11/01/99

1. **Explanation of Material Transmitted:** Appendix 1, Section O is revised: (1) to change the title of "Facility Manager/Veterinarian" to "Facility Manager" and (2) to insert information on Facility Veterinarian certification of review. Links to on-line versions of the form have also been added. These on-line versions of the form may be completed on-line for user convenience.

2. **Filing Instructions:** Revise Appendix 1, Section O as follows.

Section O, OCCURRENCES:

Change existing title of "Facility Manager/Veterinarian" to "Facility Manager" so text reads as follows:

Facility Manager certification of resource capability in the indicated facility to support the proposed study.

After COMMENTS and *before* Attending Veterinarian certification of review, insert the following information:

Facility Veterinarian certification of review.

Name _____ **Signature** _____ **Date** _____

The online version at http://www3.od.nih.gov/oma/manualchapters/intramural/3040-2/ has been updated to reflect these changes. Appendix 1, pages 8 and 9 of the .pdf file have been updated to reflect these changes.

PLEASE NOTE: For information on:

- NIH Manual System, contact the Office of Management Assessment, OMA, on 496-2832, or enter this URL: http://www3od.nih.gov/oma/manualchapters/

A. Purpose:
This policy establishes responsibility for humane care and use of animals within the intramural program of the National Institutes of Health (NIH).

B. References:

See Appendix 2.

C. Definitions:

1. **Accreditation** - The recognition by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) or other Public Health Service (PHS)-recognized accrediting body that the animal facilities and management practices of a research institution are in accordance with the Guide (See C.11.)

2. **Adequate Veterinary Care** - The standards set forth in **Adequate Veterinary Care** by the American College of Laboratory Animal Medicine and the Animal Welfare Act regulations.

3. **Animal** - Any live or dead, vertebrate animal used or intended for use in research, experimentation, testing, training, or related purposes. This definition shall extend to animals that are acquired for the purpose of collecting tissues or other parts. (The acquisition and transportation of certain invertebrates and parts of certain vertebrates are also subject to Federal regulation.)

4. **Animal Exposure Surveillance Program (AESP)** - That portion of the NIH occupational health program, managed by the Occupational Medical Service, Division of Safety, specifically designed for all NIH personnel who work in animal facilities and who have significant contact, as determined by the Principal Investigator, with research animals or their tissues that have not been treated to assure freedom from pathogens, and others who work in areas where research animals are housed or used. Institute/Center (IC) programs outside the metropolitan Washington DC area, e.g. NIA, NIDA, NIEHS and NIAID-RML, shall implement equivalent programs.

5. **Animal Facility** - Any and all buildings, rooms, areas, enclosures, or vehicles, including satellite facilities, used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation. A satellite facility is any containment outside of a core animal facility or centrally designated or managed area in which animals are housed for more than 24 hours. (Per PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy. - See C.20))

Central Animal Facility An animal facility managed by the Veterinary Resources Program (VRP), Office of Research Services (ORS), and utilized by more than one IC.

Shared Animal Facility A core animal facility shared by more than one IC and managed by a Lead IC.

Study Area Any building room, area, enclosure or other containment outside of a core facility or centrally designated or managed area in which animals are housed more than 12 hours. (Per Animal Welfare Act regulations.)

6. **Animal Research Advisory Committee (ARAC)** - The intramural NIH Institutional Animal Research Advisory Committee includes the Chair of each IC Animal Care and Use Committee (ACUC). The Deputy Director for Intramural Research shall appoint the Chair, Executive Secretary and additional members in concert with the PHS Policy and the Animal Welfare Act regulations.

7. **ARAC Guidelines** - Guidelines developed and approved by the ARAC.

8. **Animal Study Proposal** - The form completed by a Principal Investigator and submitted to the Chair, IC-Animal Care and Use Committee (ACUC) for review and approval prior to the ordering of animals or initiation of the study. (See Appendix 1.)

9. **Animal Program Directors Committee** - A committee established to provide advice and guidance on veterinary issues to the Director, Office of Animal Care and Use. The committee includes the Animal Program Director of each IC. (See C.27)

10. **Animal Welfare Act Regulations (AWA Regulations)** - Regulations promulgated by the United States Department of Agriculture, Animal and Plant Health Inspection Service, pursuant to the authority in the Animal Welfare Act 7 U.S.C. 2131, et seq and contained in 9 CFR, Parts 1, 2, and 3.

11. **Guide** - The NRC Guide for the Care and Use of Laboratory Animals, which serves as the standard by which animal care and use programs are developed and assessed. The Guide is available from the Office of Animal Care and Use (OACU), OD, NIH, Building 31, Room B1C37, (301)496-5424.

12. **IC-Animal Care and Use Committee (IC-ACUC)** - A committee appointed (via delegated authority from the Director, NIH through the Deputy Director for Intramural Research) by the Director or Scientific Director (SD), of an IC that uses animals in its intramural research program. The committee oversees the IC's animal

program, facilities and procedures, including the key functions of reviewing and approving requests to use animals in research Animal Study Proposals.

13. **Institution** - The NIH intramural program including facilities in Bethesda, other NIH facilities separate from the main campus, or contracted or subcontracted activities performed in accordance with NIH Manual 3040-3 or other applicable acquisition regulations, in support of the intramural program.

14. **Institutional Assurance** - The Animal Welfare Assurance filed with the NIH Office for Protection from Research Risks (OPRR) certifying that the NIH intramural research program is in compliance with the PHS Policy.

15. **Institutional Official** - The NIH Deputy Director for Intramural Research (DDIR). The Director, NIH, as the Chief Executive Officer of the institution, has delegated to the DDIR the authority and responsibility for compliance of the NIH Intramural Research program with PHS Policy, the Guide, and the Animal Welfare Act regulations. This includes authority to direct the allocation of resources to correct deficiencies.

16. **Intraagency Agreement** - A formal written agreement that describes understandings between the parties occupying a Shared or Central Animal Facility. The Agreement assigns responsibilities and authorities and establishes a mechanism for funding and other resources needed to support the operation of the facility and/or care of animals housed in the facility. At a minimum, the Agreement shall: a) state the purpose of the agreement; b) delineate the period of the agreement; c) specify the authorities and responsibilities of each party; d) define the reimbursement, financial responsibilities of each party; e) describe the billing procedures to be utilized; and f) contain the concurrence of individuals authorized to sign the Agreement in accordance with the authority outlined in Section 601 of the Economy Act of 1932, as amended (U.S.C. 1535.) In addition, agreements in Shared Animal Facilities shall include: 1) the management plan/standard operating procedures of the facility; and 2) the composition, structure and function of the User Committee. In all agreements, the Lead IC Animal Program Director must be delegated the authority, from the Lead IC Scientific Director, to: a) ensure timely adequate veterinary care of all animals in the animal facility; b) ensure compliance with all applicable regulations, guidelines and policies; and c) maintain AAALAC accreditability of the animal care and use program and facility. (See NIH Manual 1165.)

17. **Lead Institute** - The user IC, which other user ICs authorize through an intraagency agreement, to manage a Shared Animal Facility(ies).

18. **NIAID-RML** - The NIAID - Rocky Mountain Laboratories (RML) animal care and use program is managed as a second, separate program from that based on the Bethesda campus and reports to the NIAID SD. The RML Attending Veterinarian (see C.26) serves as an Animal Program Director and the RML ACUC Chair serves as a member of the ARAC (see C.6)

19. **Office of Animal Care and Use (OACU)** - The office with authority to act on behalf of the Institutional Official to ensure that NIH programs and facilities for animal care and use are in compliance with this policy, theGuide, the PHS Policy and the Animal Welfare Act regulations. This authority is exercised by the Director, OACU.

20. **PHS Policy** - Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, Revised as of September 1986, or subsequent editions.

21. **Principles** - U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training - (See Appendix 3.)

22. **Principal Investigator** - A scientist designated by the Laboratory/Branch Chief or the Scientific Director responsible for conducting an animal study in compliance with this policy, the Guide, the PHS Policy, and the Animal Welfare Act regulations, and who certifies acceptance of this responsibility by signing the Animal Study Proposal.

23. **Refinement** - Refinements in animal research are those which alleviate or minimize the pain, distress or other adverse effects experienced by the animals involved, and/or enhance animal well-being. Refinements may be applied at any stage in the use of the laboratory animal, from its birth to its death. It can include such aspects of a procedure as: the source, transport, husbandry, and environment of the animals involved; the experimental design (e.g., group sizes are reduced), the techniques applied; the care of the animals before, during and after a procedure; the endpoints of the procedures; and the method of killing the animals.

24. **Satellite Facility** - See C.5.

25. **Study Area** - Any building room, area, enclosure or other containment outside of a core facility or centrally designated or managed area in which animals are housed more than 12 hours (per Animal Welfare Act regulations) - See C.5.

26. **User Committee** - An advisory committee for each Shared Animal Facility made up of senior intramural scientists, IC Animal Program Director(s) and appropriate management personnel from each Institute represented in the facility to advise the Facility Veterinarian on matters of space, personnel, finance, and other matters as specified in the Intraagency Agreement between ICs of the Shared Animal Facility.

27. **Veterinarian -**

ANIMAL PROGRAM DIRECTOR: A Doctor of Veterinary Medicine with training or experience in laboratory animal science and medicine, who is supervised by, and receives delegated program authority from the Scientific Director (via delegated authority from the Institutional Official) for all activities involving animals in an IC and is responsible for ensuring compliance with this policy, the Guide, the PHS Policy, and the Animal Welfare Act regulations. (The Animal Program Director serves as the "Attending Veterinarian" for the purposes of Animal Welfare Act interpretations.)

ATTENDING VETERINARIAN: The IC Animal Program Director or other veterinarian as delegated by the IC Animal Program Director. The Attending Veterinarian shall have the authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use for all animals acquired by the IC and maintained in NIH facilities. Veterinary care is provided directly by the sponsoring IC in its own facilities. Veterinary care is provided in Central or Shared Animal Facilities by the supporting IC or in consultation with the sponsoring IC(s) as defined through written agreements. Such agreements, which may include Standard Operating Procedures, are approved by the Scientific Director of the sponsoring IC and either the Director (or designee) of the ORS in VRP Central Animal Facilities, or by the Scientific Director (or designee) of the Lead IC in Shared Animal Facilities. In all cases, the ORS Animal Program Director in a Central Animal Facility or the Animal Program Director of the Lead IC in a Shared Animal Facility must be delegated the authority to ensure timely adequate veterinary care and to oversee the adequacy of other aspects of animal care and use for all animals in the facility.

FACILITY VETERINARIAN: A Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who receives delegated authority from the Animal Program Director responsible for that facility. The Facility Veterinarian has the responsibility and authority to ensure timely adequate veterinary care to all animals housed in the facility. The Facility Veterinarian is responsible for ensuring compliance with all applicable regulations, guidelines and policies, and for maintaining AAALAC accreditability of the animal care and use program and facility. The Facility Veterinarian has the responsibility and authority to report any issue of non-compliance to the Animal Program Director responsible for that facility and to the supporting and sponsoring IC Animal Care and Use Committees.

D. Applicability:

This policy is applicable to all NIH-conducted or supported intramural activities involving animals. All NIH components, contractors, or institutions with which NIH has collaborative or cooperative agreements are required to comply, as applicable, with the Animal Welfare Act regulations, and other Federal statutes and regulations relating to animals.

E. Policy:

The NIH policy is that each investigator or person involved in the care or use of animals adhere to the Principles and applicable humane and ethical policies as established or referenced herein and maintain animals in accordance with thePHS Policy on Humane Care and Use of Laboratory Animals, the Guide and the Animal Welfare Act regulations. The NIH, as an institution, shall seek to maintain Full Accreditation of its animal program.

It is NIH policy that adequate veterinary care shall conform to the standards set forth in Adequate Veterinary Care by the American College of Laboratory Animal Medicine and as described in the Animal Welfare Act regulations.

The Director, OACU; IC Scientific Director; IC-ACUC; IC Animal Program Director, Attending Veterinarian, and/or Facility Veterinarian are authorized to suspend any activity involving animals that have been previously approved if it is determined that the activity is not being conducted in accordance with the previously approved Animal Study Proposal or provisions of the Animal Welfare Act regulations, the Guide, or the Institution's Assurance. Suspension of an activity, however, will usually be initiated by the IC-ACUC following notification of the IC Scientific Director.

NIH animal facilities have controlled access and need not be opened to the public, for a variety of reasons. Requests by outside individuals or groups to visit NIH animal facilities should be coordinated through the Office of Animal Care and Use, OIR, and the Division of Public Safety, ORS. The Office of Communications shall be notified, in writing, of all such requests.

F. Responsibilities:

1. **The Deputy Director for Intramural Research (DDIR), NIH,** is responsible for ensuring compliance with this policy by all intramural ICs and others that use NIH facilities, and oversight of activities conducted under contract in support of intramural programs as performed in accordance with NIH Manual 3040-3 or other applicable acquisition regulations.

2. **The Director of the Office of Animal Care and Use,** has the authority delegated by the DDIR, for ensuring compliance of the Intramural Animal Care and Use program with this NIH Manual, the Animal Welfare Act regulations, thePHS Policy, the provisions of the Guide and other applicable policies and regulations. The Director, OACU shall:

    a. Maintain the Institutional Assurance of compliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals.

    b. Review semiannual IC animal care and use program evaluations for compliance with the Institutional Assurance. Forward copies of the IC semiannual evaluations to the DDIR.

    c. Maintain a list of IC-ACUC approved Animal Study Proposals.

    d. Review and approve all animal facility construction and renovation plans.

    e. Review and concur in all Central and Shared Animal Facility Intraagency Agreements addressing the management, or modifications thereto, of Central or Shared Animal Facilities, prior to their implementation.

    f. Conduct unannounced site visits of animal care and use programs and facilities.

    g. Act on behalf of the Institutional Official to implement appropriate corrective actions within the NIH Animal Care and Use program.

3. **The Scientific Director, acting for the IC Director and the Director, NIH, shall:**

    a. Be responsible for implementing and administering this policy for each IC that uses animals, and for taking appropriate action regarding recommendations from the IC Animal Program Director, or ACUC, or on requirements imposed by the Institutional Official.

    b. Ensure participation in the Animal Exposure Surveillance Program (AESP), managed by the Occupational Medical Service, of the Division of Safety. Participation is a requirement for all personnel who work in animal facilities and who have significant contact with research animals or their tissues that have not been treated to assure freedom from pathogens, and others who work in areas where research animals are housed or used. This shall include, at a minimum, Principal Investigators and their staff who use animals in their

research, and veterinarians and animal care staff members. Individuals electing not to participate in the AESP will be denied permission to participate in animal studies.

4. **Principal Investigators shall:**

   a. Submit a completed and signed Animal Study Proposal, containing at a minimum the information contained on the format shown in Appendix 1, to the IC-ACUC Chair for review and approval before requesting animals or initiating animal studies. Each investigator shall include, as applicable, discussion of the consideration of alternatives to painful procedures and an assurance that the proposed studies are not unnecessarily duplicative, as required by the Animal Welfare Act regulations.

   b. Complete the course, "Using Animals in Intramural Research: Guidelines for Principal Investigators" or participate in a comparable training experience approved by the Director, OACU, prior to approval of an Animal Study Proposal. This requirement may be waived by the IC-ACUC until the next offering of the course.

   c. Complete the triennial refresher training course for NIH Animal Care and Use program participants.

   d. Ensure NIH personnel listed on an Animal Study Proposal complete the course "Using Animals in Intramural Research: Guidelines for Animal Users" or participate in a comparable training experience approved by the Director, OACU. This requirement may be waived by the IC-ACUC until the next offering of the course. Ensure these personnel receive subsequent training, as appropriate, to perform their assigned duties. Further ensure these personnel complete the triennial refresher training course for NIH Animal Care and Use program participants.

   e. Comply with this policy, the Guide, the PHS Policy, and the Animal Welfare Act regulations.

   f. Submit, in writing, for review and approval by the IC-ACUC any proposed significant changes from procedures described in an approved Animal Study Proposal. This shall include refinements and additions to animal activities developed during conduct of the procedures.

5. **The IC Animal Program Director is responsible:**

    a. To his or her Scientific Director for the day-to-day implementation of the Intramural Animal Care and Use Program(s) within the IC.

    b. For ensuring compliance with this policy, the Guide, the PHS Policy, and the Animal Welfare Act regulations in the animal program.

    c. For ensuring that all animal care personnel demonstrate acceptable skill in assigned duties and performing techniques with the species of animal for which they are responsible.

6. **The IC Animal Program Director of a Lead IC for a Shared Animal Facility** - is responsible to the Lead IC SD for ensuring compliance with this policy, the Guide, the PHS Policy, and the Animal Welfare Act regulations. This responsibility and authority may be delegated in whole or in part to the Facility Veterinarian of the Shared Animal Facility. The Facility veterinarian is advised by a User Committee and appointed by the Animal Program Director of the Lead IC, with concurrence of the Scientific Directors of the other ICs and the Director, OACU.

7. **The Facility Veterinarian:**

    a. Ensures the provision of adequate veterinary care to all animals housed in the facility.

    b. Ensures that the day-to-day operation of the animal facility is in compliance with this policy.

    c. Ensures that all animal care personnel demonstrate acceptable skill in assigned duties and in performing techniques with the species of animal for which they are responsible.

    d. Ensures that daily facility operations, such as animal health care, husbandry and provision of supplies and equipment meet programmatic and regulatory requirements.

    e. In Shared Animal Facilities, acts on recommendations from the User Committee and obtains concurrence from the Scientific Director(s) on matters of space, personnel and finances as specified in the Intraagency Agreement between ICs of the Shared Animal Facility.

f. In Central Animal Facilities, acts on directions from the Scientific Director, ORS on matters of space, personnel and finances as specified by Standard Operating Procedures or specifically in intraagency agreements with user ICs.

g. Shall work with the PIs and the PI's APD to ensure that refinements and/or additions to animal activities developed with investigative staff are communicated to the investigator's ACUC in a timely fashion.

8. **User Committee for Shared Animal Facilities** - Each Shared Animal Facility shall be advised by a User Committee with the following composition and responsibilities:

a. Composition - Members are appointed by the Scientific Director of user ICs and include at least the following:

(1) Senior intramural scientist from each user IC;

(2) Administrative personnel from each user IC with delegated authority to obligate the ICs on matters of finance, personnel, space and other issues which may arise; and

(3) IC Animal Program Director(s), or their designees, from the user ICs.

Representation by each IC, including the Chair, and the number of members from each IC and the disciplines represented, shall be delineated in the Intraagency Agreement. The veterinarian serving as the Facility Veterinarian shall be a non-voting ex officio member.

A quorum of the Committee shall be defined as a majority of the Committee and a majority of the user ICs represented. Issues on which a vote is called shall require a majority of the quorum for passage.

b. Responsibilities -

(1) Advises the Facility Veterinarian and Scientific Director of the Lead IC on matters of space, personnel and finance, or other matters, specified in the Intraagency Agreement required to support research in the facility and to ensure compliance with this policy, the Guide, the PHS Policy, and the Animal Welfare Act regulations.

(2) Submits, in writing, issues on which a minority opinion is filed to the Lead IC Scientific Director. The Scientific Director of the Lead IC, in

consultation with the Scientific Directors of the other user ICs and the Director, OACU, will provide written resolution of the issue to the DDIR within 30 calendar days.

9. **The Animal Program Directors Committee shall have the following composition and responsibilities:**

   a. Composition - The Committee shall consist of the Animal Program Director in each IC. The Chair shall be elected from the membership.

   b. Responsibilities -

      (1) The Committee shall meet monthly and provide advice and guidance to the Director, Office of Animal Care and Use.

      (2) The Committee shall be responsible for reviewing veterinary operational issues which affect the overall NIH Animal Care and Use (ACU) program.

      (3) Recommendations from this Committee shall be presented to the NIH-ARAC and/or the DDIR, as appropriate, for action.

10. **The Animal Program Advisory Committee (APAC),** a subcommittee of the Animal Program Directors Committee, shall have the following composition and responsibilities:

   a. Composition - The Committee shall consist of facility veterinarians and facility managers from the ICs and ORS and other NIH central service providers. The APAC shall be chaired by the Deputy Director, OACU.

   b. Responsibilities -

      (1) The Committee shall meet at least quarterly and provide advice and guidance to the Animal Program Directors Committee and the Director, Office of Animal Care and Use.

      (2) The Committee shall be responsible for reviewing facility operational issues which affect the overall NIH Animal Care and Use (ACU) program.

11. **Each IC that uses research animals in its intramural program shall maintain an Animal Care and Use Committee (IC-ACUC)** with the following composition and responsibilities:

a. Composition - Not more than three members shall be from the same office, laboratory or branch of the facility (IC). The Chair and members are appointed by the IC Scientific Director, per the authority delegated from the Director, NIH. Each IC-ACUC is composed of at least five individuals and includes at least:

(1) One Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program authority and responsibility for activities involving animals within the IC;

(2) One practicing scientist experienced in research involving animals;

(3) One member whose primary concerns are in a nonscientific area (for example, ethicist, lawyer, member of the clergy);

(4) One individual who is not affiliated with the Federal government and not affiliated with the NIH, in any way other than as a member of the IC-ACUC, and is not a member of the immediate family of a person who is affiliated with the Institution. This person will provide representation for general community interests in the proper care and treatment of animals; and

(5) The ombudsman, see paragraph F.12.a.(6), shall serve as an ex- officio member of all ACUCs. The ombudsman is not obligated to attend all meetings, and is not counted in determining if a quorum is present.

b. Responsibilities - The IC-ACUCs shall:

(1) Review animal care and use programs and inspect all IC facilities (including satellite facilities and animal study areas) at least semiannually using the Guide and the Animal Welfare Act regulations as a basis for evaluation. The Lead IC-ACUC shall be responsible for the semiannual evaluation of Shared Animal Facilities. The ORS-ACUC shall be responsible for semiannual evaluations of Central Animal Facilities. At least two members of the ACUC of each IC housing animals in Shared or Central Animal Facilities shall review the animals and the animal activities of its investigators in those facilities at least semiannually.

(2) Prepare written reports of the IC-ACUC semiannual evaluations conducted as required by the PHS Policy and the Animal Welfare Act regulations and submit the reports to the DDIR/OACU in April and

October, with a copy to the Scientific Director. The reports must contain a description of the nature and extent of each IC's adherence to the Guide, the PHS Policy, and the Animal Welfare Act regulations, must identify specifically any departures from the provisions of the Guide, the PHS Policy, and the Animal Welfare Act regulations; and must state reasons for each departure. In accordance with the PHS Policy and the Animal Welfare Act regulations, the reports must distinguish significant deficiencies from minor deficiencies and contain a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one which, in the judgement of the IC-ACUC, and Scientific Director, and/or the DDIR/OACU is or may be a threat to the health or safety of the animals. Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IC-ACUC, through the Director, OACU, to the DDIR. The DDIR shall report such instances to OPRR.

No Committee member wishing to participate in any evaluation may be excluded except for reasons of conflict of interest. The IC-ACUC may use subcommittees composed of at least two Committee members and may invite ad hoc consultants to assist in conducting the evaluations. The reports shall be reviewed and signed by a majority of the IC-ACUC members and must include any minority views.

The Lead IC-ACUC shall be responsible for the written report of the semiannual evaluation of the Animal Care and Use (ACU) program and facilities in Shared Animal Facilities. A copy of that portion of a Lead IC's written report describing the semiannual evaluation of the Shared Animal Facilities shall be submitted to the Scientific Directors of all user ICs.

The ORS-ACUC shall be responsible for the written report of the semiannual evaluation of the ACU program and facilities of the Central Animal Facilities.

(3) Review all IC Animal Study Proposals related to the care and use of animals (to include requests for the use of satellite facilities) to ensure adherence to the humane and ethical principles for use of animals as outlined in the Guide and the Animal Welfare Act regulations. The Animal Study Proposal is to be used for this purpose. Animal Study Proposal numbers are to be recorded in the minutes of the IC-ACUC, together with significant aspects of the review and disposition. Meeting minutes and reports are subject to Freedom of Information Act requests.

(4) In April and October, submit to the Director, OACU, a listing of currently active approved Animal Study Proposals with the following information: Proposal No., Title, Principal Investigator, and Date Approved.

(5) Notify the investigators and the institution, i.e., the Scientific Director, in writing, of decisions to approve or withhold approval of those sections of Animal Study Proposals related to the care and use of animals, or of modifications required to secure IC-ACUC approval as set forth in the PHS Policy and the Animal Welfare Act regulations. Copies of approved Animal Study Proposals and all approved modifications to existing Animal Study Proposals shall be provided to the Facility Veterinarian prior to initiation of the study in the facility(ies) where the animals included in such studies will be housed and/or used.

(6) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities as set forth in the PHS Policy and the Animal Welfare Act regulations.

(7) Be authorized to suspend an activity involving animals that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act regulations, the Guide, the Institution's Assurance, or the PHS Policy. The IC-ACUC may suspend an activity only after a review of the matter at a convened meeting of a quorum of the IC-ACUC and with the suspension vote of a majority of the quorum present. If the IC-ACUC suspends an activity involving animals, the IC Scientific Director in consultation with the IC-ACUC, shall review the reasons for suspension, and recommend appropriate action to the DDIR for implementation. The DDIR will review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OPRR as required by thePHS Policy.

(8) Review all proposed methods of euthanasia and consider waivers for those not recommended by the American Veterinary Medical Association (AVMA) Panel on Euthanasia as required by the PHS Policy and the Animal Welfare Act regulations. Waivers from the AVMA recommendations are authorized by the ACUC only for

scientific reasons. They are issued in writing and filed with the ACUC Chair, either separately or as a part of the Animal Study Proposal.

(9) Advise investigators regarding animal care and use as requested by IC investigators, required by the Scientific Director or Institutional Official, or as recommended by the NIH-ARAC. This shall include ensuring that all ACU program activities under their purview are performed with consideration of current ARAC Guidelines.

(10) Remain cognizant of animal care and use practices of IC investigators and advise the Scientific Director and the Institutional Official of significant changes from those described in their most recent project review. Considering the recommendations contained in the NIH-ARAC Guidelines, this is to include the practices conducted in shared, central and satellite facilities.

(11) Advise the NIH-ARAC and the OACU of unresolved deficiencies in any aspect of the IC program of animal care and use. ORS and Lead ICs shall similarly advise of unresolved deficiencies in Central or Shared Animal Facilities respectively. These deficiencies will, in turn, be reported to the Institutional Official (DDIR). Any unresolved significant deficiencies shall be reported to OPRR, as required by the PHS Policy.

(12) Hold meetings monthly or as needed to fulfill its responsibilities, in which a majority of the IC-ACUC members attend. The Chair ensures that all members are notified of these meetings in a timely fashion, provides copies of minutes to the Scientific Director and the OACU, and maintains a file of all minutes, memoranda, waivers, and project review documents that will be disposed of in accordance with approved records disposal schedules. Minutes, records of attendance and project reviews will be maintained in accordance with the NIH Manual 1743, Keeping and Destroying Records, Appendix 1, 1100-H-2 following termination of the research.

(13) Prepare the IC's "Annual Report of Research Facility" as required by the United States Department of Agriculture (USDA) and submit it to the OACU in conjunction with the November NIH-ARAC meeting. The OACU will prepare the composite NIH report and submit it to the USDA. For further information contact the OACU, OD, NIH, at 496-5424.

(14) Identify training needs for intramural staff who work with laboratory animals, communicate those needs to the Training Coordinator,

Laboratory Animal Care and Use, OACU, and assist the Coordinator with the development of the appropriate courses.

(15) Ensure new ACUC members complete ACUC Member training provided by OACU.

(16) Advise the Scientific Director regarding the training of professional and technical staff in animal care and use.

(17) Advise the Scientific Director concerning newly proposed or enacted legislation, policies, and guidelines regarding laboratory animals, including recommending responses to proposals, and implementing enacted procedures.

(18) Review, and, if warranted, investigate concerns involving the care and use of animals within the research facility (IC) resulting from complaints received and from reports of noncompliance received from laboratory or research facility personnel, employees, or the public. All instances of noncompliance shall be reported to DDIR/OACU to effect appropriate Institutional communications with OPRR.

(19) Conduct continuing reviews of activities covered by the PHS Policy and the Animal Welfare Act regulations (including exemptions to plans for exercise for dogs and environmental enrichment for nonhuman primates) at appropriate intervals, but not less than annually.

12. **The NIH Animal Research Advisory Committee (NIH- ARAC)** is established by the DDIR, who appoints its Chair, Executive Secretary, veterinarian, non-scientist, ombudsman, and the non-affiliated member. The Executive Secretary and staff support are provided by the Office of Animal Care and Use, OD, NIH.

    a. Composition - The NIH-ARAC is composed of full-time Federal Government employees and includes at least:

        (1) The Chair from each IC-ACUC. The APD shall serve as the alternate member from each IC. The Vice Chair shall serve as the alternate member from each IC. APDs shall not serve as the alternate member from each IC but should attend the meetings.

        (2) One Doctor of Veterinary Medicine with training or experience in laboratory animal science and medicine who has delegated oversight responsibility for compliance of activities involving animals at NIH.

(3) One practicing scientist experienced in research involving animals.

(4) One member whose primary concerns are in a non-scientific area.

(5) One individual who is not affiliated with NIH, in any way other than as a member of the NIH-ARAC, and is not a member of the immediate family of a person who is affiliated with NIH. This person will provide representation for general community interests in the proper care and treatment of animals.

(6) An ombudsman, appointed by the DDIR, to receive, review, and assure an appropriate response to complaints concerning the care and use of animals in the intramural program. The duties and responsibilities of the ombudsman are detailed in the NIH Animal Research Advisory Committee (NIH-ARAC) Guidelines.

b. Responsibilities - The NIH-ARAC:

(1) Meets at monthly intervals or as needed to advise the DDIR on the Institution's program for humane care and use of animals and to support the Institution's conformance to Guide recommendations and this policy. The Chair ensures that all members are notified of these meetings in a timely fashion and provides copies of minutes to the DDIR. The Executive Secretary maintains file copies of all meetings, minutes and attendance, memoranda, and activities of the Committee.

(2) Reviews IC and/or trans-NIH concerns involving the care and use of animals at NIH following investigation, deliberation, and closure by the IC ACUC(s).

(3) Makes written recommendations to the DDIR, NIH, regarding any aspect of the Intramural Animal Care and Use program, facilities, or personnel training which needs improvement or change.

(4) Serves in an advisory role to the NIH Director and the DDIR in all matters involving animal care and research use.

(5) Identifies trans-NIH training needs for intramural staff who work with laboratory animals, and assists the Training Coordinator, Laboratory Animal Care and Use, with the development of the appropriate courses.

(6) Provides copies of its minutes to the DDIR and maintains minutes and records of attendance, in accordance with the NIH Manual 1743, Keeping and Destroying Records, Appendix 1, 1100-H-2.

G. Transportation of Animals:

Transportation of experimental animals on NIH property, either between or within buildings or facilities, to or from commercial carriers, or in any other manner shall be in accordance with NIH-ARAC Guidelines. If a vehicle is used, it must be properly designed for the transportation of animals.

H. Transfer of Animals:

The transfer of animals for research purposes, pursuant to section 301 of the Public Health Service Act, shall be in conformance with the provisions of the Animal Transfer Agreement contained in the ARAC Guidelines, or as specified in other binding agreements, such as Material Transfer Agreements or Cooperative Research and Development Agreements.

I. Records Retention and Disposal:

All records (e-mail and non-e-mail) pertaining to this manual must be retained and disposed of under the authority of NIH Manual 1743, before Keeping and Destroying Records, Appendix 1, NIH Records Control Schedule, before Items: 1100-H-2, committee records; 3000-C, VRP, ORS records; and 3000-G-2-a, biomedical research protocol records related to animal use.

NIH e-mail messages. NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted

from an individual's computer. The back-up files are subject to the same requests as the original messages.

J. Management Controls:

The purpose of this manual is to establish responsibility for humane care and use of animals within the intramural program of NIH.

(1) Office Responsible for Reviewing Management Controls Relative to this Manual: Office of Animal Care and Use and the Office of Intramural Research.

(2) Frequency of Review (in years): Ongoing; at least annually.

(3) Method of Review:

_X_Alternative Review

The Scientific Directors participate in the Biennial Intramural Self Assessment of Management Controls, through completion of a set of comprehensive checklist of questions. This process is managed by the Office of Intramural Research.

The Intramural Program must make annual reports to both the United States Department of Agriculture and the PHS Office for the Protection from Research Risks (OPRR.) These agencies have regulatory authorities over the NIH IRP Animal Care and Use program. Per the PHS Policy, instances of significant noncompliance are required to be reported to OPRR, In addition, the Association for Assessment and Accreditation of Laboratory Animal Care International performs triennial peer review site visits to all NIH components who use animals in their IRP programs.

(4) Review Reports are sent to: the Deputy Director for Intramural Research.

Animal Care and Use in the Intramural Program
Animal Study Proposal

PROPOSAL #_____

APPROVAL DATE _____

EXPIRATION DATE _____

PLEASE TYPE :

A. ADMINISTRATIVE DATA:

Institute or Center_____

Principal Investigator_____

Building/Room_____Telephone_____

FAX_____

Division, Laboratory, or
Branch_____

Project Title_____

Initial Submission [ ] Renewal [ ] or Modification [ ] of Proposal Number_____

List the names of all individuals authorized to conduct procedures involving animals under this proposal and identify key personnel (i.e., Co-investigator(s)):

B. ANIMAL REQUIREMENTS:

Species_____

Age/Weight/Size_____Sex_____

Stock or Strain_____

Source(s)_____

Holding Location(s)_____

Animal Procedure Location(s)_____

Number of Animals to Be Used:

			=	
Year 1	Year 2	Year 3		TOTAL

C. TRANSPORTATION: Transportation of animals must conform to all NIH and Facility guidelines/policies. If animals will be transported between facilities, describe the methods and containment to be utilized. If animals will be transported within the Clinical Center, also include the route and elevator(s) to be utilized.

D. STUDY OBJECTIVES: Briefly explain in non-technical terms the aim of the study and why the study is important.

E. RATIONALE FOR ANIMAL USE: 1) Explain your rationale for animal use. 2) Justify the appropriateness of the species selected. 3) Justify the number of animals to be used. (Use additional sheets if necessary.)

F. DESCRIPTION OF EXPERIMENTAL DESIGN AND ANIMAL PROCEDURES: Briefly explain the experimental design and specify all animal procedures. This description should allow the ACUC to understand the experimental course of an animal from its entry into the experiment to the endpoint of the study. Specifically address the following:

(Use additional sheets if necessary.)

- **Injections or Inoculations** (substances, e.g., infectious agents, adjuvants, etc.; dose, sites, volume, route, and schedules)
- **Blood Withdrawals** (volume, frequency, withdrawal sites, and methodology)
- **Non-Survival Surgical Procedures** (Provide details of survival surgical procedures in Section G.)
- **Radiation** (dosage and schedule)
- **Methods of Restraint** (e.g., restraint chairs, collars, vests, harnesses, slings, etc.)
- **Animal Identification Methods** (e.g., ear tags, tattoos, collar, cage card, etc.)
- **Other Procedures** (e.g., survival studies, tail biopsies, etc.)
- **Resultant Effects**, if any, the animals are expected to experience (e.g., pain or distress, ascites production, etc.)

- **Experimental Endpoint Criteria** (i.e., tumor size, percentage body weight gain or loss, inability to eat or drink, behavioral abnormalities, clinical symptomatology, or signs of toxicity) must be specified when the administration of tumor cells, biologics, infectious agents, radiation or toxic chemicals are expected to cause significant symptomatology or are potentially lethal. List the criteria to be used to determine when euthanasia is to be performed. Death as an endpoint must always be scientifically justified.

G. SURVIVAL SURGERY - If proposed, complete the following:

1. Identify and describe the surgical procedure(s) to be performed. Include the aseptic methods to be utilized. (Use additional sheets if necessary):

2. Who will perform surgery and what are their qualifications and/or experience?

3. Where will surgery be performed (Building and Room)?

4. Describe post-operative care required and identify the responsible individual:

5. Has major survival surgery been performed on any animal prior to being placed on this study? Y/N_____. If yes, please explain:

6. Will more than one major survival surgery be performed on an animal while on this study? Y/N_____. If yes, please justify:

H. PAIN OR DISTRESS CATEGORY - The ACUC is responsible for applying U.S. Government Principle IV. Contained in Appendix 3: "Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause

pain or distress in other animals." Check the appropriate category(ies) and indicate the approximate number of animals in each. Sum(s) should equal total from Section B.

IF ANIMALS ARE INDICATED IN COLUMN E, A SCIENTIFIC JUSTIFICATION IS REQUIRED TO EXPLAIN WHY THE USE OF ANESTHETICS, ANALGESICS, SEDATIVES OR TRANQUILIZERS DURING AND/OR FOLLOWING PAINFUL OR DISTRESSFUL PROCEDURES IS CONTRAINDICATED. PLEASE COMPLETE THE EXPLANATION FOR COLUMN E LISTINGS FORM AT THE END OF THIS DOCUMENT. THIS FORM WILL ACCOMPANY THE NIH ANNUAL REPORT TO THE USDA. NOTE: THIS COLUMN E FORM, AND ANY ATTACHMENTS, e.g., THE ASP, ARE SUBJECT TO THE FREEDOM OF INFORMATION ACT.

	Year 1	Year 2	Year 3
[ ] USDA Column C - Minimal, Transient, or No Pain or Distress			
[ ] USDA Column D - Pain or Distress Relieved By Appropriate Measures			
[ ] USDA Column E - Unrelieved Pain or Distress			

Describe your consideration of alternatives to procedures listed for Column D and E that may cause more than momentary or slight pain or distress to the animals, and your determination that alternatives were not available. [Note: Principal investigators must certify in paragraph N.5. that no valid alternative was identified to any described procedures which may cause more than momentary pain or distress, whether it is relieved or not.] Delineate the methods and sources used in the search below. Database references must include databases searched, the date of the search, period covered, and keywords.

I. ANESTHESIA, ANALGESIA, TRANQUILIZATION - For animals indicated in Section H, Column D, specify the anesthetics, analgesics, sedatives or tranquilizers that are to be used. Include the name of the agent(s), the dosage, route and schedule of administration.

J. METHOD OF EUTHANASIA OR DISPOSITION OF ANIMALS AT END OF STUDY: Indicate the proposed method, and if a chemical agent is used, specify the dosage and route of administration. If the method(s) of euthanasia include those not recommended by the AVMA Panel Report on Euthanasia, e.g., decapitation or cervical dislocation without anesthesia, provide scientific justification why such methods must be used. Indicate the method of carcass disposal if not as MPW.

K. HAZARDOUS AGENTS: Use of hazardous agents requires the approval of an IC safety specialist. Registration Documents for the use of recombinant DNA or potential human pathogens may be attached at the discretion of the ACUC.

	YES	NO	List Agents & Registration Document # (if applicable)
1. Radionuclides			
2. Biological Agents			
3. Hazardous Chemicals or Drugs			
4. Recombinant DNA			
Study conducted at Animal Biosafety Level:			

Describe the practices and procedures required for the safe handling and disposal of contaminated animals and material associated with this study. Also describe methods for removal of radioactive waste and, if applicable, the monitoring of radioactivity.

Additional safety considerations:

L. BIOLOGICAL MATERIAL/ANIMAL PRODUCTS FOR USE IN ANIMALS (e.g., cell lines, antiserum, etc.):

1. Specify _____

2. Source _____

Material Sterile or Attenuated _____Yes _____No

3. If derived from rodents, has the material been MAP/RAP/HAP tested?
_____Yes (Attach copy of results) _____No

4. I certify that the MAP/RAP/HAP tested materials to be used have not been passed through rodent species outside of the animal facility in question and/or the material is derived from the original MAP tested sample. To the best of my knowledge the material remains uncontaminated with rodent pathogens.

_____ Initials of Principal Investigator.

M. SPECIAL CONCERNS OR REQUIREMENTS OF THE STUDY - List any special housing, equipment, animal care (i.e., special caging, water, feed, or waste disposal, etc.).

N. PRINCIPAL INVESTIGATOR CERTIFICATIONS:

1. I certify that I have attended an approved NIH investigator training course.

Year of Course Attendance_____

Location_____

2. I certify that I have determined that the research proposed herein is not unnecessarily duplicative of previously reported research.

3. I certify that all individuals working on this proposal who have significant animal contact are participating in the NIH Animal Exposure Surveillance Program.

4. I certify that the individuals listed in Section A are authorized to conduct procedures involving animals under this proposal have attended the course "Using Animals in Intramural Research: Guidelines for Animal Users" and received training in the biology, handling, and care of this species; aseptic surgical methods and techniques (if necessary); the concept, availability, and use of research or testing methods that limit the use of animals or minimize distress; the proper use of anesthetics, analgesics, and tranquilizers (if necessary); procedures for reporting animal welfare concerns.

5. *FOR ALL COLUMN D AND COLUMN E PROPOSALS (see section H):* I certify that I have reviewed the pertinent scientific literature and the sources and/or databases as noted in paragraph H. and have found no valid alternative to any procedures described herein which may cause more than momentary pain or distress, whether it is relieved or not.

6. I will obtain approval from the ACUC before initiating any significant changes in this study.

Principal Investigator:

Signature_____

Date_____

O. CONCURRENCES: PROPOSAL NUMBER _____ (LEAVE BLANK)

Laboratory/Branch Chief certification of review and approval on the basis of scientific merit. Scientific Director's signature required for proposals submitted by a Laboratory or Branch Chief.

Name _____ Signature _____ Date _____

Safety Representative certification of review and concurrence. (Required of all studies utilizing hazardous agents.)

Name _____ Signature _____ Date _____

Facility Manager certification of resource capability in the indicated facility to support the proposed study.

Facility _____ Name_____ Signature _____ Date _____

Facility _____ Name_____ Signature _____ Date _____

Facility _____ Name_____ Signature _____ Date _____

Facility _____ Name_____ Signature _____ Date _____

COMMENTS:

Facility Veterinarian certification of review.

Name _____ Signature _____ Date _____

Attending Veterinarian certification of review.

Name _____ Signature _____ Date _____

P. FINAL APPROVAL:

Certification of review and approval by the _____ Animal Care and Use Committee Chairperson.

CHAIRPERSON_____

Signature_____ Date_____

Animal Care and Use in the Intramural Program
References

For information about any of the references in this chapter contact your IC ACUC Chairperson.

A. Laws:

1. Animal Welfare Act (7 U.S.C. 2131 et. seq.).
2. The Endangered Species Act of 1973 (16 U.S.C. 1531 et. seq.).
3. The Public Health Services Act, as amended (42 U.S.C. 283e, 289d).

B. Regulations:

1. Animal Welfare, 9 CFR, Parts 1, 2, and 3.
2. Good Laboratory Practice for Nonclinical Laboratory Studies (Title 21, CFR, Part 58).
3. Procurements Involving the Use of Laboratory Animals (Federal Acquisition Regulations, Title 48 CFR, Part PHS 380.2).

C. Policies:

1. Guide for the Care and Use of Laboratory Animals, NRC 1996.
2. PHS Policy on Humane Care and Use of Laboratory Animals, September, 1986.
3. NIH Animal Research Advisory Committee Guidelines, NIH-ARAC, December 1998, or as revised.
4. Report of the AVMA Panel on Euthanasia, JAVMA 202, (2), 229-249, January 15, 1993.
5. Biosafety in Microbiological and Biomedical Laboratories, May, 1993. HHS Publication No. (CDC) 93-8395.

6. The National Institutes of Health Radiation Safety Guide, August 1996.

7. Radiation Safety for Animal Handlers, Radiation Safety Branch, Division of Safety.

8. Adequate Veterinary Care, Report of the American College of Laboratory Animal Medicine, 1996.

D. Other NIH Manual Chapters:

1. NIH Manual 1340-1 Permits for Import or Export of Biological Materials.

2. NIH Manual 26307-3, Special Clearance and Other Acquisition Procedures.

3. NIH Manual Chapters 4206 and 6380-2, Responsibility for Care and Use of Animals.

4. NIH Manual Chapter 3043-1, Introduction of Rodents and Rodent Products.

5. NIH Manual Chapter 1165, Interagency and Intraagency Agreements.

6. NIH Manual Chapter 1130, Program, General 31, NIH Intramural Animal Care and Use Program

Animal Care and Use in the Intramural Program
U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training

The development of knowledge necessary for the improvement of the health and well-being of humans as well as other animals requires in vivo experimentation with a wide variety of animal species. Whenever U.S. Government agencies develop requirements for testing, research, or training procedures involving the use of vertebrate animals, the following principles shall be considered; and whenever these agencies actually perform or sponsor such procedures, the responsible institutional official shall ensure that these principles are adhered to:

I. The transportation, care, and use of animals should be in accordance with the Animal Welfare Act (7 U.S.C. 2131 et. seq.) and other applicable Federal Laws, guidelines, and policies.

II. Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.

III. The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer stimulation, and in vitro biological systems should be considered.

IV. Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.

V. Procedures with animals that may cause more than momentary or slight pain or in distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents.

VI. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.

VII. The living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally, the housing, feeding,

and care of all animals used for biomedical purposes must be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied. In any case, veterinary care shall be provided as indicated.

VIII. Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in service training, including the proper and humane care and use of laboratory animals.

IX. Where exceptions are required in relation to the provisions of these Principles, the decisions should not rest with the investigators directly concerned but should be made, with due regard to Principle II, by an appropriate review group such as an institutional animal research committee. Such exceptions should not be made solely for the purposes of teaching or demonstration.

Published in the Federal Register, May 20, 1985, Vol. 50, No. 97, by the Office of Science and Technology Policy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

APR 2 0 2001

TO: Michael M. Gottesman, M.D.
Deputy Director for Intramural Research, NIH

Judith L. Vaitukaitis, M.D
Director, National Center for Research Resources

FROM: Deputy Director for Extramural Research, NIH

SUBJECT: Memorandum of Understanding - Alamogordo Primate Facility

This correspondence conveys the Memorandum of Understanding referenced during the March 9 meeting with Dr. Kirschtein, where the decision was reached to include the animal activities of the Alamogordo Primate Facility under the Intramural Research Program (IRP) Animal Welfare Assurance. Following approval of this memorandum, the Office of Laboratory Animal Welfare will be asked to approve the necessary amendments to the IRP Assurance.

Wendy Baldwin, Ph.D.

Attachment

cc: Ruth Kirschstein, M.D.

This Memorandum of Understanding (MOU) establishes responsibility for a group of research chimpanzees acquired recently by the National Institutes of Health (NIH) from the Coulston Foundation, Alamogordo, New Mexico. The approximately 257 chimpanzees were all exposed to real or potential human pathogenic microorganisms in experiments funded by the Public Health Service (PHS) through the NIH. Under an agreement among the Coulston Foundation, the NIH, and the United States Department of Agriculture (USDA) Animal Plant Health Inspection Service (APHIS), the NIH assumed ownership of the animals and committed to care for the chimpanzees at a particular set of facilities on the Holloman Air Force Base (HAFB), New Mexico (under contract) to be known as the Alamogordo Primate Facility (APF). The APF and all animal activities conducted therein are covered by a Use Permit between the NIH and the United States Air Force (USAF). The APF will be operated as a Government Owned - Contractor Operated (GOCO) entity.

As the funding for the APF GOCO will come from the NIH, the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) requires that the animal activities, and associated support operations and facilities, be performed under an Animal Welfare Assurance (Assurance) approved by the NIH Office of Laboratory Animal Welfare (OLAW).

This MOU establishes the specific responsibilities related to the APF among the National Center for Research Resources (NCRR), the GOCO contractor, and the Deputy Director for Intramural Research (DDIR), in his role as Institutional Official for the Intramural Research Program (IRP) Assurance. The NIH has decided to place the APF and its associated animal activities under the existing IRP Assurance, which was first filed in 1986. The NCRR provides funding and oversight for PHS-funded investigators requiring the use of nonhuman primates to support their research, and more recently developed the centralized, national NIH Chimpanzee Management Program (ChiMP). To take advantage of NCRR's management history and to minimize any real or perceived duplication of management oversight, NCRR will be responsible for the day-to-day management of the APF, its associated animal activities, and the management of the GOCO contract.

NCRR will provide all resources (funding & FTE's) necessary to maintain and oversee the health and well-being of the animals, the operation and maintenance of the APF, including any costs associated with the Use Permit with the USAF, and any costs necessary to achieve Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) accreditation of the Animal Care and Use (ACU) program at the APF. For the purposes of this agreement, NCRR's responsibility for the animals at the APF shall be restricted to no more than the 257 NIH-owned chimpanzees in residence at the APF at the time this agreement is signed. It is understood that the routine veterinary care, animal husbandry, and facility operation and maintenance shall be provided by a commercial contractor (hereinafter referred to as the Contractor) responsible to the Director, NCRR or designee.

The NCRR will provide travel funds and any extraordinary expenses required by the DDIR, or designee, associated with the inclusion, oversight and assessment of compliance of the ACU program at the APF as a component of the IRP Assurance.

For the purposes of the amended Assurance encompassing the APF, the Director, NCRR shall report to the DDIR, in his role as Institutional Official for animal activities at the APF, equivalent to the same accountabilities of the IC Directors/Scientific Directors, as set forth in NIH Policy Manual 3040-2 "Animal Care and Use in the Intramural Program" (PM 3040-2). To enable the Director, Office of Animal Care and Use (OACU) to carry out the specific responsibilities outlined in PM 3040-2, the appropriate staff members of the NCRR (and/or ChiMP) will establish and maintain open and regular communications regarding ACU activities at the APF. This will include appointing an *ex officio* member of the OACU staff as a member of the ChiMP Working Group.

The DDIR hereby delegates authority to the Director, NCRR, who may re-delegate to the Director, Comparative Medicine Program, to appoint the members of the APF Animal Care and Use Committee (ACUC). The Director, NCRR, or designee, shall further appoint or identify a senior veterinarian at the APF to serve as the Animal Program Director (APD) for the APF. The ACUC Chair and APD shall be governed by the applicable provisions of PM 3040-2.

NCRR will require, through the GOCO contract, that all ACU activities at the APF be performed in compliance with NIH Policy Manual 3040-2 and the NIH IRP Assurance. As such, all practices and procedures must comply (or be equivalent) with applicable Policy Manuals, Guidelines, and support programs referenced in the Assurance, including provision of training and occupational safety and health services. This shall include submission of semiannual ACUC reports of facility inspections and program reviews, listings of active Animal Study Proposals, and preparation of the APF "Annual Report of Research Facility" for the United States Department of Agriculture. This shall also include an explicit requirement that the ACU program at the APF seek AAALAC accreditation. Preparations for seeking accreditation should be implemented as quickly as possible and a schedule of milestones prepared between the NCRR and the Contractor. In keeping with the provisions of PM 3040-2, the Director, NCRR, or designee and the Director, OACU shall assist the Contractor to prepare for and seek AAALAC accreditation of the ACU program at the APF. Due to the geographic and operational isolation of APF ACU activities relative to the other components identified in the Assurance, it is the intent that the APF be a separately accredited component, rather than being associated with one of the existing AAALAC files.

Both the APF ACUC and the IACUC of the institution sponsoring the research must approve any research involving the animals at the APF. The Director, NCRR, or designee, and the DDIR, or designee, shall jointly develop a definition of the categories of research that may be allowed using chimpanzees at the APF.

All routine animal and support activities performed at the APF shall be conducted in accordance with Standard Operating Procedures developed by the Contractor and subsequently approved by the Director, NCRR, or designee.

Any instances of animal death or injury must be reported to the OACU within 24 hours. Those incidents in turn, will be reported to the DDIR. Any such incidents deemed to be significant deficiencies according to PHS Policy will be verbally reported to the OLAW and followed-up in writing upon completion of appropriate ACUC investigations and implementation of corrective actions.

Requests for information or inquiries/allegations regarding activities at the APF shall be first directed to the Director, NCRR, or designee. The NCRR shall promptly notify the OACU (on behalf of the DDIR) of any inquiries that may lead to or that have public, media, or congressional interest.

Judith L. Vaitukaitis, M.D.
Director
National Center for Research Resources

Michael M. Gottesman, M.D.
Deputy Director for Intramural Research

NIH POLICY MANUAL

3044-2 - PROTECTION OF NIH PERSONNEL WHO WORK WITH NONHUMAN PRIMATES

Issuing Office: OD/OIR 496-4920
Release Date: 02/09/93

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1. **Explanation of Material Transmitted:** This chapter outlines the policy for protection of National Institutes of Health (NIH) personnel who work with or around nonhuman primates. Requirements are established for training, supervision, use of personal protective equipment, medical surveillance, accident reporting, and wound care.

2. **Filing Instructions:**

   Remove: NONE
   Insert: NIH Manual Chapter 3044-2 dated: 02/09/93

3. **Distribution:** NIH Manual Mailing Keys F-401 and F-405

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.
- On-line information, enter this URL: http://www3.od.nih.gov/oma/manualchapters/
- To sign up for e-mail notification of future changes, please go to the NIH Manual Chapters LISTSERV Web page.

A. Purpose:

Established under this chapter is the NIH policy for protection of NIH personnel who work with or around nonhuman primates. The policy describes the requirements for training, supervision, compliance, personal protective equipment, medical surveillance, accident reporting, and wound care. The intent of this policy is to minimize the overall number of injuries, specifically bites and scratches, sustained by NIH employees, special volunteers, and visitors who work with nonhuman primates or enter nonhuman primate rooms. Contractors engaging in activities with nonhuman primates must have a program in place with policies and procedures equivalent to the program described herein. Project Officers for such contracts shall ensure that all contracts contain the equivalent components.

B. Policy and Procedures:

Training. Each individual regularly entering a nonhuman primate room shall have received introductory training prior to entry. Transient visitors will be supervised by someone with appropriate training. Those individuals having hands-on interaction with nonhuman primates must also have additional training in approaching and handling nonhuman primates. Certification by the first line supervisor that a basic level of performance has been achieved is required. The Training Coordinator, Office of Animal Care and Use (OACU/OD), is responsible for the development and management of the program for training intramural personnel to work safely and humanely with nonhuman primates.

Supervision and Compliance. All NIH employees, including special volunteers, guest workers, visitors, and contract personnel shall comply with procedures set forth in this policy statement. Immediate supervisors are responsible for ensuring that their employees

follow established policy. Corrective action shall be taken by the immediate supervisor for failure to comply with the provisions of this policy.

Continued failure to comply with requirements set forth in this policy shall be reported to the Scientific Director and/or Institute Director and may result in suspension of the privilege to use nonhuman primates in research protocols or other disciplinary action. The Institutional Official for Animal Welfare Assurance (i.e., Deputy Director for Intramural Research) shall be informed of such infractions and disciplinary actions taken.

Personal Protective Equipment. All individuals entering a nonhuman primate room must wear appropriate personal protective clothing and equipment which meets or exceeds the guidance established by the NIH Animal Research Advisory Committee (ARAC) (Appendix 1). Guidance on the selection and use of personal protective equipment for selected protocols will be provided upon request, by the Occupational Safety and Health Branch, Division of Safety (OSHB, DS). The NIH Institutional Biosafety Committee (NIH IBC) shall advise on appropriate protective measures, as needed, at the request of the Division of Safety. Individuals participating in protocols involving infectious disease agents must meet or exceed practices and procedures recommended in the CDC/NIH publication entitled Biosafety in Microbiological and Biomedical Laboratories and any additional stipulations placed on the protocol by the NIH IBC. Copies of THE CDC/NIH publication may be obtained by calling 496-2346. All support personnel, who have not been appropriately trained, (e.g. building engineers, pest controllers, safety and health personnel, etc.) entering nonhuman primate rooms must be accompanied by a responsible facility staff member who is knowledgeable in the behavior and handling of nonhuman primates.

Medical Surveillance. All persons having direct contact with nonhuman primates in the course of conducting research and all persons providing care must participate in the NIH Animal Exposure Surveillance Program (AESP). Transient visitors, who are required to enter a room housing nonhuman primates but do not have direct contact with the animals, are not required to participate in the AESP but are to wear single-use dust/mist masks in addition to other required protective clothing. All contractor employees having direct contact with nonhuman primates must participate in an AESP that is equivalent to that of the NIH and which shall be provided by their employer.

Accident Reporting. All accidents and injuries involving animals, animal wastes, or potentially contaminated equipment must be reported promptly to the first-line supervisor. An individual who sustains any injury must report to the Occupational Medical Service (OMS) as soon as possible. The Division of Safety will regularly review accident/injury reports and make accident information available to the Training Coordinator, OACU, who will ensure that training will address identified problem areas.

Wound Care. Each nonhuman primate facility manager or ICD veterinarian, as applicable, is responsible for maintaining an adequately stocked wound care kit. The kit includes materials for culturing a wound, inflicted by a nonhuman primate, for Herpesvirus simiae also known as Monkey B virus. The wound care kit must be located in an easily accessible area, and instructions for culturing wounds, first aid, and reporting to OMS must be prominently displayed. The facility manager or veterinarian, as applicable, is responsible for informing all research and animal care staff of the location of the wound care kit. The procedures to be followed in the event of a nonhuman primate bite or scratch are described in the NIH Animal Exposure Surveillance Program (AESP).

C. Additional Information:

For further information on this manual chapter, contact the NIH Office of Animal Care and Use (496-5424).

D. Additional Copies:

Copies of this manual chapter may be obtained by completing Form NIH 414-5 and submitting it to the P&RB, DSS, ORS, in Bldg 31, Room B4BN08.

Please see paper copy for appendix information.

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Last Updated: 12/13/99

NIH

Diet - Our preliminary assessment is that the current fruit/vegetable and monkey biscuit diet provided to the chimpanzees at the APF appears adequate from a nutritional point of view. Based on appearance, the animals appeared to be provided with adequate caloric intake and a nutritionally balanced diet. Clearly, the staff has put significant thought into supplementation of the diet with a variety of fresh fruits and vegetables. Once the contract is initiated, Dr. Lee will institute a program to assess the nutritional status of each animal and to make adjustments to each animal's diet as appropriate. In addition, the overall dietary program will be assessed to determine whether additional environmental enrichment and foraging opportunities can be provided through a range of possible dietary modifications have been developed and perfected at CRL's own facilities and in the context of chimpanzee programs familiar to Dr. Lee and [ ] Dr. Lee has also developed a diet composition that reduces morbidity and mortality in chimpanzees. As [ ] largest worldwide customer, Charles River also expects to negotiate favorable pricing consideration at the APF in the context of its proposed dietary program.

non key personnel

supplier

Sanitation - While the current staff at the APF expends considerable effort to properly sanitize the facility, several problems exist. First, many of the surfaces are not smooth and are out of repair, thus making thorough sanitization difficult or impossible. Second, the APF is chronically understaffed which affects sanitization. Thirdly, the high turnover among the animal care staff means that the training and experience level of the caretakers is not ideal and sanitization suffers. Charles River believes that it can quickly deal with the staffing level and turnover issues by provision of realistic rates of pay, a good benefit program and by establishing a stable, employee-friendly work environment. Immediate facility upgrades will be undertaken and are discussed in detail in the next section of this Proposal.

Health Care - An excellent chimpanzee healthcare program includes the proper standards of animal care and competent veterinary practices that are in line with current professional standards. Maintenance of a healthy chimpanzee colony should address complete physical and mental health with an environment that reduces exposure to pathogens and promotes psychosocial well being. Since chimpanzees have a close phylogenetic relationship to humans, they are susceptible to many human pathogens. For the same reason, they have been used as the only models for human diseases where no other animal species were suitable. In addition, there are endemic agents and subclinical infections that are prevalent in chimpanzee colonies that can be passed to naïve animals or husbandry personnel. Therefore, a good preventive medicine program addresses the health of both captive chimpanzees and their caretakers. A good veterinary care program should be multidisciplinary and use recent medical advances and a vigilant preventive medicine program to improve the health, prolong the life span, and enhance the quality of life of captive chimpanzees. This health surveillance program includes, but is not limited to, daily observations, routine physical examinations, hematological and serologic screening, tuberculin testing, and dentistry. Proper healthcare should also include investigating subclinical diseases or behavioral disorders.

As discussed earlier in this section, we have identified upgrading the quality of the veterinary clinical health care to the chimpanzee colony at the APF as one of our highest priorities. Dr. Lee is ideally suited to achieve this objective. He is recognized as one of the worlds' leading authorities on provision of veterinary health care to chimpanzees. He has published numerous papers on related subjects (See his Curriculum Vitae included in Appendix C and the "Personnel" section below). In addition, he is recognized as a leading mentor of chimpanzee veterinarians. One of his current responsibilities is to oversee the veterinary extern program at the University of Texas M.D. Anderson Cancer Center at Bastrop, where he has provided formal training in great ape medicine to 14 veterinarians (See Page 7 of his Curriculum Vitae). Dr. Lee will immediately assume personal oversight of the veterinary care program at the APF. In addition to ensuring that all of the animals receive clinical care according to the

highest current standards, he will assess the level of training and expertise of the veterinary and animal care staff and take remedial action as appropriate. Our proposed Veterinary Medicine and Animal Care Program includes each of the components outlined below. Given page constraints, the detailed Program is presented in Appendix G which we encourage the evaluators to review closely.

VETERINARY MEDICINE AND ANIMAL CARE PROGRAM

1) Disease Surveillance
   - Medical History
   - Daily Observation
   - Physical Examinations
   - Hematological Assessment
   - Serologic Testing
   - Infectious Diseases

2) Specific Diseases and Disorders
   - Respiratory Illness
   - Trauma
   - Gastrointestinal Illness
   - Prenatal Care
   - Neonatal Care
   - Tuberculosis
   - Leprosy
   - Hepatitis
   - Retroviruses
   - Herpesviruses

3) Support Services
   - Diagnostic Laboratory Services
   - Diagnostic Equipment
   - Medical Professional Consultants

4) Preventative Medicine Program
   - Quarantine
   - Vaccination
   - Anthelmentic Prophylaxis
   - Emerging Disease Monitoring
   - Experimental History

5) Treatment Guidelines
   - Professional Veterinary Judgement
   - Current Professional Standards
   - Medical Qualifications
   - Anesthetics/Sedatives
   - Analgesics
   - Records and Compliance
   - Surgical Procedures
   - Equipment

6) Euthanasia
   - Methods of Euthanasia
   - Authority to Euthanize
   - Necropsy and Histopathology
   - Clinical Pathology Services

7) Animal Care Program
   - Sanitization
   - Husbandry Protocols
   - Nutrition

8) Population Management
   - Housing Strategies
   - Breeding and Genetics
   - Contraception

9) Behavioral Management
   - Environmental Enrichment
   - Positive Reinforcement Training
   - Social Group Management

10) Administrative Responsibilities
   - Training Animal Care Staff
   - Continuing Professional Education
   - Occupational Health Program
   - Biosafety Practices

Population Management; Prevention of Breeding - We understand and concur with the Government's position that no further breeding should take place at the APF. Currently, males and females are housed separately in groups of up to six. We would propose to continue to control breeding by separation of sexes. In this way, any potential need for these animals for reproductive purposes in the future would be served. With building modifications that have been put in place over the last year, it

appears that the risk of males and females accidentally interacting is now minimal, but additional safeguards may be instituted based on a more detailed facilities assessment. A possible exception to the separation of sexes might arise if any of the males prove unsuitable for housing in all-male groups. Rather than to condemning such males to a life of solitary housing, we would recommend that they be vasectomized and housed with compatible females.

Environmental Enrichment - An innovative, proactive, professional and extensive enrichment program at the APF is critical for the well-being of the chimpanzees housed there and is an excellent public relations tool. Based on our several decades of experience, the presence of a model enrichment program has proven more effective than all other public relations initiatives in effectively blunting criticisms and concerns of the local animal protection groups who monitor Charles River facilities. It provides irrefutable and observable proof that we place animal welfare at the forefront. At a bare minimum, chimpanzees need to be housed in groups. Many additional enhancements are desirable. The current construct at the APF which allows animals to be socially housed outdoors when weather permits is excellent. Likewise the regular provision of toys, swings, and foraging opportunities is good. Following initiation of the contract we will evaluate the entire program to determine if it can practically be enhanced. [monkey personnel] are already providing an excellent enrichment program at the APF and Charles River has obtained her Letter of Commitment. [bio - monkey personnel

3. Dr. Lee and his colleagues led the environmental enrichment program at the University of Texas M.D. Anderson Cancer Center at Bastrop (and currently holds a patent on a widely-used containment and enrichment structure: Primadomes designed for group housed and infected chimpanzees). In addition, [subcontractor] has an excellent enrichment program where the needs of each animal are assessed and addressed individually. This program has served in several instances as a training example for groups of USDA veterinary inspectors. Enrichment personnel from [ ] will be made available to the contract, as needed, to share their expertise at no incremental cost to the contract.

Sub contractor

Information Technology - More than in any other animal care program, provision of excellent medical records in a chimpanzee colony is a necessity. Because these animals can live more than 50 years, their records tend to become voluminous and have often been kept on many different (and usually incompatible) systems over their lifetime. Also, because animals may have been used on a number of experiments in the past that could potentially affect their current health, or worse, the health of their caretakers, accurate and accessible records are essential. It will take several weeks to accurately assess the state of the records at the APF. Based on preliminary impressions derived during our site visit, the hand-kept records appear to be reasonably complete and accurate, and the staff seems dedicated to keeping them up to date. However, it did not appear that the computerized portions of the records or central archiving have been maintained. Following assumption of the contract, CRL will assess the state of each animal's record and implement a comprehensive program to bring all records up to date and to install appropriate computer security, passwords, and backup systems. This will require acquisition and installation of an appropriate LAN-based computerized record system, training of the staff in its use, and agreement with the Government on the extent that past records should be computerized (See the Facility Modernization Section below).

Charles River has extensive experience with animal record systems and, as the world's largest animal breeder, has unparalleled expertise in record computerization. Formerly (i.e., prior to 1991), all of the chimpanzees at the APF were maintained on the ISIS system using the ARKS software. We are not certain how well use of that system has been continued. We intend to re-establish full use of the ISIS and ARKS capabilities. Fortunately, [3. biographical info - monkey personnel

animal records at [Subcontractor]. [biological info - monkey personnel] She will be made available to the contract for design, training and implementation of a new system, as appropriate, and is a member of our Project Support Group.

Clinical Laboratory Access - Currently only "stat" hematology capabilities are present at the APF, but otherwise, the APF-based chimpanzee colony depends on hematology, clinical chemistry and microbiology capabilities which currently reside at the Coulston Foundation in Alamogordo. Consequently, the hematology equipment and capability may be lost at the contract transition. If the stat capability were to be lost we would recommend replacing it with equivalent equipment, since hematograms are frequently necessary for adequate emergency clinical management. We will negotiate either with the Coulston Foundation or the hospital clinical pathology laboratory in Alamogordo to provide other clinical pathology services when they are needed with less than 24-hour turn around. Where turn around of 24 hours or more is acceptable, we plan to overnight ship samples to [subcontractor] where the appropriate tests can be run. [Subcontractor] has extensive clinical pathology capabilities and can provide the highest degree of service and accuracy. The [ ] laboratory has fully automated GLP-compliant clinical chemistry, hematology, and coagulation capabilities and the required microbiology tests. [bio subcontractor] [sub contractor's name] directs the [ ] laboratory. He has many years of non-human primate experience and will be made available to the contract at no incremental cost in the event his expertise is needed to address difficult clinical cases.

We would recommend that a complete clinical pathology profile be run on each animal at the inception of the contract and thereafter at the time of the animals annual physical. This information would be valuable for purposes of detecting conditions that are not clinically apparent, to establish baseline information for each animal, and to track colony changes across time.

Necropsy - As we previously discussed, it is essential that any animal that dies on the contract be subjected to a complete necropsy by qualified personnel and that the tissues be examined by a pathologist expert in non-human primate pathology and diseases. This information is not only required to establish the cause of death, and perhaps to take needed action in a disease outbreak, but also to evaluate the quality of the ongoing veterinary care program. Given the past history at the Coulston Foundation, it also may prove to be an essential component to convincing the animal protection community that the chimpanzees housed at the APF are receiving exemplary care.

For purposes of our planning we have examined the colony age distribution and are projecting that between two and five chimpanzees will die each year of natural causes. We understand that necropsies are presently being conducted at an off-site facility by a histo-technologist under the supervision of a veterinarian. Both personnel are somewhat inexperienced. Tissues are shipped to a contract pathologist for evaluation. Results are often not available for several months. In the RFP it is suggested that carcasses could be shipped to another facility for necropsy since the off-site necropsy room will probably not be available in the future. Our pathologists advise that if local expertise at the APF is not sufficient to conduct a necropsy, it would be better to have one of our [ ] pathologists travel to the APF and to conduct an on-site necropsy, rather than to ship an animal. There are a multitude of issues associated with shipping an HIV infected carcass across state lines and we feel that this poses a number of unnecessary risks. They strongly recommend that dead animals should be refrigerated after death, and that the necropsy should ideally be performed within 24 hours (and absolutely within 48 hours) of death.

Subcontractor

After considering several options we have developed the following recommendations:

- A small necropsy room should be set up in one of the buildings included in the contract (See the Facilities Improvements Section below). We saw several small rooms that would be available and suitable for this purpose. Appropriate ventilation would need to be provided and an inexpensive necropsy table purchased. According to our biosafety personnel, it would not be efficient to move the current down-draft table into this space since it is not particularly helpful in reduction of biohazards potentially present in chimpanzees.
- For most necropsies we believe that the on-site veterinary staff will prove to be sufficiently competent. Dr. Lee has performed a number of chimpanzee necropsies and is familiar with all but the most rare gross pathological changes that would be expected. In order to provide further training and experience to Dr. Lee and his veterinary staff, we will arrange for them to separately spend time in [ ] working with the [ ] pathologists during routine non-human primate necropsies. This would also familiarize them with the standard [ ] procedures for personal protection, and collection, preservation, labeling and shipping of tissues. This training would be arranged to ensure that all staff coverage requirements are met.
- A protocol will be established for a standard set of tissues and samples of gross lesions would be collected and fixed from each chimpanzee necropsy conducted at the APF. Tissues would then be divided into at least two sets and one set provided ASAP to [ ] pathologists (the second set would be retained to protect against shipping or other loss). Tissues would be processed by the [ ] histology laboratory at [ ] and provided to one of the pathologists for interpretation. [ ] currently has six board-certified veterinary pathologists on staff. Each of them has extensive non-human primate experience and collectively they have participated in several thousand primate necropsies and microscopic histopathology evaluations. Pictures will be taken of all gross lesions and also forwarded to the pathologists.
- In the event that a complicated or controversial necropsy is expected, the on-site APF Veterinary Staff and the [ ] pathologists would confer on any unusual procedures or precautions that would need to be taken. If it were deemed advisable, one or more pathologists from [ ] would travel to the APF to participate in the necropsy. In most cases they could be there within 12 to 24 hours following notification.

Personnel – Resumes and Commitment Letters Included in <u>Appendix A</u>

<u>Director / Principal Investigator: D. Rick Lee, DVM</u>. - Dr. Lee obtained his DVM degree from Purdue in 1987 and in the thirteen (13) years since that time has worked almost exclusively with Chimpanzees. Through positions of increasing responsibility from Drs. Thomas Butler at the Southwest Foundation for Biomedical Research, and Dr. Michale Keeling at the University of Texas M.D. Anderson Cancer Center at Bastrop, he has acquired a thorough knowledge of chimpanzee medicine, behavioral management, environmental enrichment, facility management, public relations, and personnel management. He is recognized as a leading chimpanzee researcher and clinician with numerous publications and grants in these fields. In addition to the foregoing qualifications, we had four specific reasons for recruiting Dr. Lee for this position from a pool of several experienced chimpanzee veterinarians.

- First, his current responsibilities are very similar to the responsibilities associated with the operation of the APF, as envisioned by Charles River's overall colony management plan. The size of the colony and staff are approximately the same. Both facilities emphasize group housing and the climatic conditions are highly similar.

- Second, as opposed to other candidates who we evaluated, Dr. Lee's clinical and behavioral experience is current, whereas many of the other candidates considered lacked recent hands-on clinical experience; their recent experience was mainly focused on administrative areas. We are confident that Dr. Lee is capable of introducing the most modern clinical techniques to the APF.
- Third, Dr. Lee has a well-deserved reputation as a leader who instills great loyalty and dedication in those who work for him. He maintains an excellent rapport with his staff. We think this is essential at the APF because recent turmoil has reduced staff morale and his quiet leadership style will be a great asset in addressing this issue.
- Fourth, Dr. Lee is quite familiar with the current state of affairs at the APF since he was a participant in the recent AAALAC evaluations of that facility. In order to avoid "transitional trauma" it was important to us that the leadership of the Charles River effort be fully apprised of all aspects of the operation and management of the APF at the earliest stages.

Deputy Director:

Resumé

Clinical Veterinarian:

name and resume of non key personnel

Clinical Veterinarian:

Nurse/OSH Officer:

name and resume' of non-key personnel

Program Administrator: [non-key personnel resume]

Information Technologist: [non key personnel / resume]

Behaviorist: [non key personnel / resume]

Clinical Laboratory Technician: [non key personnel / resume]

Colony Manager: [non key personnel / resume]

[ ] In his position as Colony Manager, Charles River will ensure that [non-key per.]

- Provides overall supervision for the animal care staff;
- Selects and assures the proper training of new personnel;
- Observes all colony animals on a daily basis to check for signs of illness, injury, or other abnormalities;
- Routinely monitors the condition of facilities and equipment; coordinates repair and maintenance procedures with physical plant personnel;

- Assists the colony Veterinarian in performing physical exams, administers medications, performs routine preventive medical procedures, and provides surgical support;
- Monitors and records reproductive cycle data on adolescent and adult female chimpanzees;
- Assures that individual animal records are maintained in a complete, accurate, and updated manner; and
- Assures the availability of animal foods, supplies, and equipment needed for daily colony operations.

Other Proposed Professional/Technical Positions –

In addition to the positions outlined in the RFP, Charles River is proposing the inclusion of two additional Professional/Technical positions which we feel will help to better achieve the objectives of this contract effort and improve overall levels of service:

Resident Veterinarian: E

non key personnel/
resume

His proposed duties at the APF will include:

- Training in primate medicine and management;
- Interpretation of serological data;
- Provide additional veterinary care and support under the direction of the attending veterinarian; and
- Investigate diseases and disorders within the colony to improve colony health.

Number of personnel

As required by the RFP, a copy of our Proposed Organization for the Charles River APF Project Staff is included in Appendix C. For convenience of reference, a copy of Dr. Lee's Resume has been inserted immediately following our Proposed Organization.

Key Charles River Project Group -

Name and resume of monkey personnel

(b) Technical Approach to Facilities Operation, Maintenance and Modernization

Charles River currently operates and maintains nearly 2 million square feet of facilities space dedicated to the production and care of laboratory animals, including non-human primates. We are extremely familiar with the challenges inherent in the ongoing maintenance and periodic modernization of animal facilities, as well as the importance of ensuring that facilities are operated within specific environmental parameters critical to animal well-being. Because the APF is situated in a geographic area characterized by rapidly fluctuating temperatures, and taking into account the significant biosafety concerns presented by the chimpanzee colony housed at the APF, the facilities-related requirements of this project effort are elevated to a particularly high level of importance.

Charles River's approach to operating, maintaining, and modernizing the APF facilities incorporates three primary areas of focus: (1) Ongoing facility and property management; (2) Development and implementation of a CRL-Developed Comprehensive Preventative Maintenance Program; and (3) Development and implementation of a Facilities Improvement Plan that addresses any identified design or construction deficiencies and outlines a detailed long and short-term modernization plan for the APF which addresses workflow, process and design improvements to enhance workplace efficiency, and improvements in the overall quality of animal containment space.

Our approach draws on the expertise of our on-site Project Staff, as well as the experience and resources of our highly specialized Corporate Engineering Team who, as discussed above, possess a special expertise in applying their diverse range of engineering skills to the design, improvement and ongoing maintenance of animal facilities. Methods employed to achieve our three-fold objectives are as follows:

Facility and Property Management – At its most basic level, the general maintenance and upkeep of the APF facilities will be largely dependent on the conduct of the CRL staff who perform day-to-day activities within those facilities. CRL will properly manage the APF facilities to ensure that routine maintenance and sanitation duties are performed in accordance with a schedule established for each designated area. Our comprehensive training plan will also include a segment on the routine care and upkeep of facilities, including the adverse consequences of deficiencies in this area. Project personnel will also be sensitized to the importance of reporting any facilities-related problems or deficiencies so that our trained Maintenance Staff can take appropriate corrective action as soon as practicable.

This same approach will be applied to exterior areas in close proximity to the APF facilities in order to minimize the risk of vermin infestation and to maintain desired levels of biocontainment and upkeep. As it relates to property and/or improvements owned by the United States Air Force ("USAF"), CRL staff will conduct themselves in accordance with the Use Permit granted to the NIH by the Department of the Air Force.

Develop and Implementation of a Comprehensive Preventive Maintenance Program – During our January 10th site visit, one of Charles River's Corporate Engineers spent several hours making a preliminary inspection of the various buildings, mechanicals, and critical support systems at the APF. Buildings 1301 through 1304 comprise the basic chimpanzee holding buildings while Building 1300 is a mechanical support building and Building 1264 serves primarily as office space. Building 1301 and 1302 are of similar design, while Buildings 1303 and 1304 are of a slightly modified design. All of these buildings appear to be structurally sound. Based on our facilities assessment, however, it is evident that an ongoing program of preventive maintenance is lacking at the site or, if purported to be in place, is not being effectively implemented.

Building 1269, which is currently being used in large part for food storage, is unsuitable for this purpose due to a roof which is badly in need of repair and several other facilities deficiencies which raise concerns regarding biosecurity and the potential contamination/infestation of feed. In the opinion of Charles River's Engineering Team, the renovation of Building 1269 to meet desired standards would be cost prohibitive and is not a preferred option. In lieu of this, we have made arrangements with [ ] to deliver feed to the APF at regular intervals in refrigerated trailers which will be left on-site and serve as feed storage units. Because Charles River is [Subcont] single largest customer, we have leveraged on our worldwide purchase volumes to structure this arrangement so that it is highly cost-effective and provides feed to the APF at a delivered unit cost which is equal to the distributor cost currently being paid by the incumbent contractor, with no additional charge for full year-round use of refrigerated storage units **(See Section 4.0 – Additional Factors for Consideration)**.

Subcontractor

With the exception of Building 1269, Charles River would institute its proven Preventative Maintenance Program in support of all APF buildings, mechanicals and critical systems. Charles River currently owns and operates 25 highly efficient and well-maintained animal facilities. These facilities range in age from 40 years to newly-constructed facilities brought into operation just last year.

Consequently, Charles River is not only familiar with the latest animal facilities design innovations, but has first-hand experience in the long-term upkeep and modernization of facilities which have not only met, but exceeded all applicable animal welfare standards for decades and successfully passed numerous regulatory audits. Our customers demand extraordinary levels of biosecurity from Charles River and a key component of our comprehensive Biosecurity Program has made us industry experts in the ongoing inspection and upkeep of a variety of animal facilities of diverse age and design.

As part of our Corporate Support Plan, Charles River's experienced Engineering Team will conduct a thorough, multi-day inspection of the APF shortly after contract transition to more fully assess the condition of the APF facilities. Based on this assessment, the Engineering Team will develop a detailed Preventative Maintenance Program for the APF, and will modify facilities-related SOP's and guidelines currently in use at Charles River's own facilities so that they are specifically tailored to the requirements of the APF. Going forward, the APF facilities will also be included in Charles River's Facilities Inspection Program, and will be inspected regularly by a team of internal CRL auditors who visit our various sites (typically on a quarterly basis), to ensure ongoing compliance.

To the extent that CRL's on-site Maintenance Team supporting the APF requires supplemental expertise or the periodic services of our Corporate Engineering Team over the term of the contract in connection with specific maintenance projects, these services will be made available to the APF as required (with only reasonable travel and lodging costs being billed to the contract).

Based on our limited assessment of the APF buildings during CRL's recent site visit, we identified the following as top maintenance priorities and estimate of the costs associated with corrective action as indicated:

- ***Refinishing of Floors*** – A poorly applied floor covering in Buildings 1300 through 1304 can be easily peeled up by the resident chimpanzees. While the incumbent contractor has tried to address this problem through temporary measures, a more permanent solution must be found. A number of commercial floor coverings of the broad cast epoxy type are available and may provide a cost-effective solution. In all likelihood, it will be necessary for a CRL Engineer to core the floor in order to determine the nature of the floor preparation and to select a suitable covering.

  Charles River would propose refinishing the floors as holding units are recycled with a goal of 2 units per year (focusing first on those most in need of repair). The estimated refinishing cost is approximately $[cost]

- ***Temperature Control; Coolers/Chillers*** – The current system in place at the APF includes two 200-ton air-cooled chillers which service Buildings 1301 and 1302. One chiller carriers the load and the second chiller serves as a stand-by unit. The stand-by unit is currently down and is in need of repair. Currently, there is no service contract for preventative maintenance on these units.

  The total cost of repairing the unit and arranging for a service contract is estimated at $[ ] to $[ ]

  Buildings 1303 and 1304 are serviced by a "Swamp Cooler" evaporative cooling system which can only reduce ambient temperatures by 10-15 degrees at best. This could potentially result in

↑ one item ↓

the failure of these buildings to meet established parameters for temperature and humidity control.

The cost to extend chilled water cooling capacity to Buildings 1303 and 1304 would involve a significant one-time capital expenditure of approximately $[Cost] and is discussed below in the context of the Facilities Modernization Plan.

- ***Hot & Chilled Water Piping*** – The expansion joints for these systems have a history of failure and, based on our assessment, 93 joints should be replaced. The cost of replacement is estimated at $[Cost] inclusive of labor.

- ***Door & Lock Systems*** – We observed a number of problems associated with the remotely controlled doors used to regulate animal movement within the APF. The remote cable system used for exterior doors is poorly designed and constructed, making regular cable failure a distinct possibility. Correction would be difficult and expensive, since cable pathways are housed within the interiors of concrete walls. The locking mechanisms on interior doors is also faulty, posing a risk of injury and the potential for the unregulated movement of animals. Regular replacement of cables for exterior doors and the retro-fitting of interior door locking mechanisms should be undertaken.

  The estimated annual cost of cable maintenance is approximately $[Cost] while the one-time cost for retrofitting interior doors is estimated at $[Cost]

- ***Fire and Environmental Alarms*** – The fire and environmental alarms currently in place only ring locally, creating an unnecessary level of risk in relation to the relatively low cost of correction. The fire alarm system should be upgraded to ring either HASB fire control or the nearest local fire department, as appropriate. The existing DDC environmental monitoring system should be programmed for automatic dial-out to employee pagers in the event of system failure based on an established duty scheduled.

  The total cost of these modifications is estimated at approximately $[Cost]

- ***Emergency Generator*** – The service contract relating to this critical piece of equipment was apparently terminated as a cost-saving measure. Given the high level of risk associated with failure if emergency supplemental power is required, a new service contract should be put in place at an estimated cost of $[Cost] per year.

- ***Purchase of a Site Van*** – In order to allow the on-site Maintenance Staff to efficiently, safely and cost-effectively handle their ongoing facilities maintenance and support duties, we would recommend the purchase of a site van which can be used for hauling, transport and the moving of tools, supplies and equipment within the site. With proper scheduling, this van could also be used for the distribution of feed and similar tasks in support of overall operations.

  The estimated lease cost for a site van is approximately $[Cost] per year.

- ***Spare Parts and Tools*** – Currently the APF maintenance group does not maintain even a limited inventory of spare parts for critical system components and has a very limited inventory of tools. CRL recommends that a well-regulated inventory of critical motors, pumps belts, etc. be maintained, along with valve rebuild kits and a limited selection of required tools.

line items

The estimated cost for assembling an inventory of critical parts and tools is approximately $[ ]

- ***Refrigerant Recovery Unit*** – In order to allow the maintenance team to cost-effectively perform on-site repairs to the cooling system, a Refrigerant Recovery Unit should be purchased. The estimated cost of this unit is $[ ]

- ***Pest Control*** – The facility does not currently have an adequate pest control program and several areas we observed were overrun with flies and/or cockroaches. A commercial pest control company sensitive to the specific concerns of the use of pesticides in animal facilities should be engaged to evaluate the APF and to work with a local applicant or train the maintenance staff in the application of appropriate pest-control measures. Charles River currently has a long-standing contract with [ ] and would arrange for them to develop a comprehensive and chimpanzee-safe pest control plan for the APF.

  The estimated annual cost for such a program is approximately $[ ]

Clearly, a number of other ongoing maintenance items will need to be addressed following contract transition, but the preceding list details the most significant items identified to date, as well as those items where potential risks far outweigh the comparatively low cost of corrective action.

Development and Implementation of Facilities Improvement/Modernization Plan - In addition to maintaining, safeguarding and upgrading APF facilities in the course of day-to-day operations and through our proposed Preventative Maintenance Program, Charles River proposes, in cooperation with the Government, to develop a Facilities Improvement and Modernization Plan which will, over time, allow for the cost-effective upgrade of the APF facilities to improve overall efficiencies and enhance animal well-being. With the Government's involvement and approval, this Plan would be implemented in conjunction with a 3-year rolling capital budget for the APF, developed jointly following contract award.

In order to give the Government a sense of the overall scope, magnitude and cost of CRL's proposed Facilities Improvement and Modernization Plan, we have presented below the capital projects that we believe should be undertaken at the APF. Projects are listed according to priority, with those identified by CRL as the highest priorities listed first. Again, CRL's recommendations are based on an assessment made by one of our Corporate Engineers during a one-day inspection, so there is a likelihood that this list will be revised and modified based on a more thorough post-award inspection of the APF Facilities if Charles River is selected as the successful bidder.

Capital Projects identified to date and related costs include:

- ***Expansion of Chiller Capacity*** – As noted earlier in this Section, the two 200-ton air-cooled chillers on site currently have insufficient capacity to service Buildings 1303 and 1304. The evaporative cooling system supporting those buildings can only reduce ambient temperatures by 10-15 degrees at best. In order to ensure that appropriate temperature and humidity parameters be maintained throughout the year, we recommend expanding chilled water cooling capacity to service Buildings 1303 and 1304.

Assuming our own Corporate Engineers oversee this project, the estimated cost is approximately $[ ]

- In lieu of using Building 1264, either one or two modular units (i.e., portable office space) should be purchased and situated in close proximity to the 1300 series of buildings. These modular units would be used for administrative space and could also accommodate a small break area for employees (which is lacking). The relocation of office space and feed storage (see above) to an area in close proximity to Buildings 1300 through 1304 will allow for more regular interaction between the Professional Staff and Animal Caretakers, will improve overall efficiencies, and will create a distinct separation between CRL's operations and those of the Coulston Foundation. As an interim measure, Building 1264 could be utilized during the period following contract transition until modular units can be purchased and transported to the APF.

  The estimated per-unit cost of these modular units outfitted with customary office furniture and equipment (exclusive of utilities hook-up and site preparation) is approximately $[ ]

- ***Replacement of Floor coverings*** – Although this was discussed in the context of ongoing maintenance at the APF facilities (See detailed discussion above), it should be noted the replacement of floor coverings at a rate of two units per year will require a capital investment of approximately $[ ] per year and qualifies as an ongoing high-priority capital project.

- ***Necropsy Room*** – As discussed above, after considering several alternatives we recommend that a necropsy room be constructed in one of the 1300 series buildings. We observed several small rooms (e.g., sick rooms or treatment rooms) that would be available and suitable for this purpose. This room should contain a minimal amount of fixed equipment. An inexpensive necropsy table of adequate size that is easily cleaned and disinfected should be purchased. As noted above, according to our biosafety personnel it would not be efficient to move the down-draft table currently housed in the Bio-Containment Facility into this space since it is not particularly helpful in the potential reduction of biohazards present in chimpanzees. A ceiling-mounted surgical light should be placed over the table and there should be sufficient water-resistant lighting in the room to provide adequate illumination. A mixing station for Clidox or other similar disinfectants should be located in the room, as should adequate hot and cold water fixtures. Supplementary exhaust should be provided to the necropsy room through an auxiliary blower that operates during the necropsy procedure.

  A procedure room should also be constructed and used for surgeons to put on protective clothing and personal protective equipment, and for the trimming of tissues in a biological safety cabinet. A minimal amount of cabinetry should be located in the room to provide for container storage. The procedure room and the necropsy room should be linked either by a door or a pass-through.

  An adequately sized necropsy cooler maintained at refrigerator temperature should also be purchased and located in close proximity for the purposed of holding animals that have died.

  The estimated cost of constructing and outfitting a Necroposy Room and adjacent procedure room is approximately $[ ]

- ***LAN-Based Computerized Record System*** – As discussed above, accurate and efficient record-keeping is indispensable in maintaining a long-term colony of chimpanzees. Charles River proposes the acquisition and installation of a LAN-based computerized record system in order to

ensure that the medical records and health histories of the chimpanzees housed at the APF can be efficiently and accurately maintained. The installation of such system would, in all likelihood, involve the purchase of two routers, one hub, site hard-wiring and the purchase of 2-4 dedicated PC's.

The estimated cost of purchasing and installing this system is approximately $[ ]

- ***Surgical Suite Autoclave*** – One of the 1300 series buildings currently houses a surgical suite which will continue to be used for the purpose of any required surgical interventions. The autoclave presently servicing this area is inadequate, and a larger electrically-operated autoclave with sufficient capacity to hold a number of sterile packs of instruments, as well as sterile gowns and other items, should be purchased. An autoclave with a 2x2x3 chamber should meet all anticipated needs.

  The estimated cost of purchasing such an autoclave is [ ] based on a quote from [Subcontractor]

  Installation of Motion Detectors and Video Cameras – Initially, Charles River will make use of security patrols doing walk-throughs at 2-hour intervals during non-duty hours. However, we propose evaluating a number of long-term engineering and security solutions which could potentially reduce or eliminate the need for such patrols. Based on our extensive experience in this area, particularly at Sierra Biomedical, the installation of motion detectors and video cameras in targeted areas probably represents the most cost-effective approach to achieving desired ends.

  The estimated cost of installing such a system in Buildings 1301 and 1304 is approximately $[ ]

- ***Building 1304 Shower Area*** – Building 1304 has two shower areas, but they are constructed in such a way that they do not logically interface with the rest of the building and permit traffic flow patterns which present biosecurity risks. In order to address this problem, a partitioning wall could be placed across the corridor and one of two sets of double doors on the clean corridors permanently closed (except for a panic bar to permit emergency exit) to restrict the flow of traffic through the locker room in a logical fashion.

  The estimated cost of this project is $[ ]

- ***Building 1303 Entry Lock*** – The design of Building 1303 does not incorporate a true entry lock area. Renovations will be required to modify existing space to create an appropriately designed entry lock. This can probably be done most cost-effectively by utilizing the existing shower and kitchen area and, if necessary, one of the infant holding areas.

  The estimated cost for this project is $ [ ]

(c) Approach to Administrative and Reporting Requirements

Charles River has built project reporting requirements into each aspect of our technical approach to ensure that all required reports will be complete and delivered on schedule. Ongoing verbal and written communication between the Government and CRL Project Staff is essential. The Project Officer

must be kept current on any developments that could affect the quality of services provided by CRL or the ongoing management and operation of the APF. Effective verbal communication and the timely submission of all required reports will provide the Government with sufficient information to ensure that all contract requirements are being met, and that timely and accurate data are available for use by the Project Officer, Contract Officer, NCRR officials and, in some instances, the designated representative of the USAF.

The Statement of Work specifies several reports that the contractor is required to provide pertaining to the management and operation of the APF and the ongoing performance of this contract. These include monthly and annual progress reports, reports relating to occupational health and safety, equipment inventories, and staffing issues. Charles River understands the content and delivery requirements for these reports, and our approach ensures that they fulfill project needs.

All reports will be prepared by Dr. Lee, Charles River's on-site Director and Principle Investigator, or, if appropriate, another member of our on-site staff designated by Dr. Lee. All reports will be reviewed by a second member of CRL's Project Staff to ensure neatness, accuracy, and compliance with contractual requirements.

CRL will ensure timely submission of the following reports. To the extent that the Project Officer and/or Contract Officer require additional content or information, CRL will revise its reports accordingly.

Monthly Progress Report – Within ten (10) calendar days following the end of each month, Charles River will submit two (2) copies of a Monthly Progress Report to the Project Officer and Contract Officer. Dr. Lee will prepare this report, which will detail the progress of the program during the reporting period and will include the following information:

- Narrative statement of the work accomplished during the reporting period (including continuing education/training provided to Project Staff).
- Statement of current potential problem areas and proposed corrective actions.
- Discussion of activities to be undertaken during the next reporting period.

Annual Progress Report – On each anniversary date of the commencement of the contract, Charles River will submit two copies of an Annual Progress Report to the Project Officer and Contract Officer. Dr. Lee will prepare an annual summary of information requested by the Project Officer for the 12-month reporting period, which will include the following information:

- Narrative Statement of the work accomplished during the reporting period, including a summation of monthly progress reports and an overview of programmatic performance during the reporting period.
- Colony status report, including an inventory of animals at the beginning and end of the reporting period and an explanatory section regarding animal deaths (necropsy reports will be appended).
- Narrative discussion of major alterations and renovations that have occurred within the APF facilities during the 12-month reporting period and a discussion of the impact of these alterations and renovations on overall colony management.
- An overview of the success of the APF's program for the prevention of breeding.

Emergency Telephone Roster – Within ten (10) calendar days of contract implementation and, thereafter, within ten (10) calendar days of any personnel changes, CRL will submit to the Project Officer, Contract Officer, and Commander, 49th Fighter Wing a list of employees, including their home telephone numbers and pager numbers (for staff with pagers). This roster will be maintained by Dr. Lee's designee and will be resubmitted following any personnel changes.

Minimal Staffing Plan – Within thirty (30) days of contract implementation, Charles River will provide to the Project Officer and the Contract Officer written procedures detailing how CRL will maintain adequate staffing coverage during inclement weather or other periods of closure. As noted above, Charles River currently operates 25 animal facilities in a wide variety of geographic locales and we have developed a series of proven procedures which allow us to maintain required staffing levels under even the most adverse weather or other conditions. These procedures will be incorporated into our APF Staffing Plan, taking into account concerns specific to the region.

Occupational Safety and Health Training Plan – No later than sixty (60) days after contract implementation, Charles River will provide the Project Officer and Contract Officer with a detailed written program for continuing education in animal facility safety and health requirements. This Plan will ensure that all employees receive proper training in accident reporting, emergency evacuation procedures and any hazards related to their respective assignments. CRL's Plan will take into account exposure of the chimpanzees housed in the APF to HCV and/or HIV and will incorporate provisions specific to these potential hazards. Dr. Lee, working in conjunction with the on-site Nurse/OSH Officer, will ensure that all required OS&H training occurs and is appropriately documented. New employees will not begin their assignments until they have received a full OS&H orientation and been advised of potential hazards relating to their respective positions.

Included as Appendix D to this Proposal is a copy of our Occupational Health & Safety Program that will be used as a base to develop the health and safety plan specific to this project.

Initial Occupational Safety and Health Training Assurance statement – Within sixty (60) calendar days of the hire date for new personnel, Charles River will provide to the Project Officer and the Contract Officer documentation verifying that each new employee has completed the Charles River Occupational Health & Safety Training Program developed for the APF. This documentation will include an assurance statement signed and dated by the employee verifying that the employee has completed this course.

Incident and Accident Reports – Within ten (10) calendar days of any accident/occurrence, Charles River will provide to the Project Officer, Contract Officer, and Commander, 49th Fighter Wing, a detailed written report of any incident in which CRL Project Staff sustain an injury or suspected job-related illness. This report will include the date of the injury, a description of the accident or occurrence, any factors that may have led to the accident or occurrence, and a discussion of how the accident might have been prevented. If the injury could potentially involve a Worker's Compensation claim, the appropriate paperwork will be filed with our Worker's Compensation insurance carrier.

Equipment Inventory – If selected as the successful bidder, immediately following contract award Charles River will conduct an equipment inventory at the APF and will determine the condition and working order of all major and specialized equipment. Charles River will prepare a written equipment inventory noting the condition of all items and will submit this in report form to the Project

Officer and the Contract Officer within thirty (30) calendar days after contract award. Thereafter, Charles River will perform this inventory on an annual basis.

In addition to basic reporting requirements, a variety of other administrative requirements must be satisfied in support of this contract effort. Charles River's approach to meeting these requirements involves the combined utilization of on-site and off-site Corporate support capabilities. Additional types of administrative support which Charles River will provide include the following:

Payroll and Human Resources Support – Payroll management, benefits administration, handling of worker's compensation matters and similar functions will be handled by CRL's Corporate staff. Recruitment, hiring and termination of employees will be handled locally, with Corporate Human Resources support provided on a regular basis. CRL will ensure that the APF enjoys the full benefit of Charles River's expansive recruitment network for veterinarians and animal care professionals.

Accounting Support – Billing, payment of taxes, expense reimbursement, budgeting, cost analysis and similar types of accounting services will be handled by CRL's Corporate Accounting Department.

Purchasing – In some instances, purchasing will be done at the local level (e.g., the procurement of fresh fruit or disposables). However, significant purchases or large-volume ongoing purchases (e.g., feed) will be handled through CRL's Corporate Purchasing Department so that the Government can benefit from Charles River's purchase volumes and related discounts. As the world's largest producer of laboratory animals, Charles River has been able to negotiate favorable pricing with multiple vendors and will make full use of this Corporate capability to obtain volume price discounts for the benefit of this contract effort.

Quality Assurance – Quality Assurance support will be provided through the combined utilization of on-site and off-site Corporate capabilities. Shortly after commencement of the contract, Charles River's Project Staff, led by Dr. Lee, will begin to develop and write SOP's relating to animal care, reporting and administrative requirements, occupational safety and health, and a number of other areas. In developing these SOP's, on-site Project Staff will have the full support and assistance of our Corporate Quality Assurance Team, led by [ ], Director of Quality Assurance and Animal Operations. This Quality Assurance Team has successfully developed and implemented thousands of SOP's at Charles River's own animal facilities, including those housing non-human primates. In developing SOP's specifically related to occupational safety and health, the Nurse/OSH Officer on-site at APF will also have at her disposal Charles River's Corporate Occupational Health & Safety Department. This group has a long history of success in promoting workplace safety in the context of animal facilities and instituting progressive programs to enhance safety awareness.

Non-key personnel

Risk Management – Charles River's Corporate Risk Management group will procure and maintain all types of insurance required in connection with this project effort (fire and casualty, umbrella liability, worker's compensation, etc.). All policies will be maintained at appropriate levels, consistent with industry practices. Where practicable and not cost-prohibitive, Charles River will procure distinct and separate insurance coverage for this contract effort to allow for easy cost segregation. In those instances where insurance coverage is provided under more comprehensive multi-site policies, Charles River will make provisions for the separate accounting of costs.

Interaction With Outside Agencies (OLAW, USDA and AAALAC) – It is expected that a subdivision of NIH will procure and hold an Office for Laboratory Animal Welfare (OLAW) Assurance

number for the APF and may request and hold a USDA R-class Registration for the APF. It is also expected that USDA and possibly AAALAC representatives will periodically inspect the APF and issue reports to the contractor and NIH. Charles River is highly experienced in handling these types of inspections and interacts regularly with the USDA and AAALAC in the course of operating its own facilities. Charles River will assume responsibility for providing the Project Officer with a plan for bringing the APF into compliance with all required USDA standards and would recommend seeking AAALAC accreditation as soon as practicable. To the extent that a USDA inspection results in a finding of deficiencies that "must be replaced or repaired", Charles River will assume responsibility for obtaining required cost estimates and, with the Government's approval, managing any resulting facilities improvement projects through it's on-site Maintenance Staff or, if required, its Corporate Engineering Team.

To the extent that other licenses are required in support of ongoing operations (i.e., a DEA drug license), Charles River shall assume responsibility for procuring those licenses through its on-site veterinary staff.

IACUC Support – Based on information contained in the RFP, it is our understanding that, since a subdivision of NIH will, in all likelihood, hold the OLAW Assurance Number for the APF, that some subdivision of NIH will manage the site's IACUC. Charles River will make available members of its Project Staff to serve on the IACUC, as requested by the Government, and welcomes the opportunity to participate. To the extent that Charles River can appropriately assist in IACUC administration and recordkeeping, we would also welcome the opportunity to provide this additional support and to offer whatever expertise we have in this area.

(d) Training; Occupational Safety & Health

Employee Training - The disparate backgrounds, experiences, skills, and abilities of an animal care workforce necessitate an effective training program to improve team cohesiveness, to effect cross-training and broadening of skills to ensure program continuity in the absence of other team members, to enhance and develop innate skills/strengths in individuals, and to foster a sense of professionalism and personal pride in the services performed while on the job. Employees need to know what their employers expect of them, what hazards/risks exist in the workplace, what protective measures are in place, and what is expected of them to minimize workplace risks. A thorough knowledge of the mission, goals, and objectives of the project effort fosters and promotes a high performing, service-oriented program. Technician education and certification programs improve the knowledge base and skills of employees, and allow them the opportunity to grow and advance within the organization. And opportunities to achieve a college or advanced degree also improve the depth and breadth of service/skills provided to the client, and assure personal growth and satisfaction.

A further description of AALAS training methodologies is presented later in this section. An overview of CRL's proposed training program requirements is presented in Figure 3.A.

If ultimately selected as the successful bidder on this contract effort, CRL will provide an orientation training program for CRL personnel following award of the contract, with information on health and safety requirements, terminology, SOPs, handling of animals, equipment operation, and biosafety procedures. This training will be documented and placed in individual's training files by the CRL administrative staff.

CRL's approach to providing its staff with a broad-based, comprehensive program of employee training is outlined in the sections below.

CLASSIFICATION / TITLE	RECOMMENDED TRAINING
▪ **Director/Principle Investigator** **Professional Staff** **Technical Staff**	**CRL Policy & Workplace Practices Training** **SOP Review** **Technical Skills Update** **Team Building Training** **Safety & Health Orientation** **QA/QC Program Review**
▪ **Program Administrator & Administrative Assistant**	**Intro to CRL Computer System** **CRL Policy & Workplace Practices Training** **SOP Review** **Computer/DB Mgt. Training** **QA/QC Program Review**
▪ **Supervisor and Animal Caretakers**	**CRL Policy & Workplace Practices Training** **SOP Review** **Team Building Training** **Safety & Health Orientation** **QA/QC Program Review** **Crosstraining** **AALAS Training (upgrade)**

Figure 3.A. Recommended Training Programs for CRL Staff at the APF

Corporate Policies / Handbooks - An Employee Handbook will be issued to each of our new employees, and we will require that the employee sign an acknowledgment card verifying that he/she has read and understands the policies, rules, and procedures outlined in the document. To the extent required by the USAF, CRL will also provide (or make its personnel available to attend) USAF-sponsored training regarding USAF policies, guidelines and other practices/procedures regarding their conduct while on the HAFB (as discussed in greater detail below).

Ongoing and New Employee Safety and Health Orientation / Training - Coupled with employer requirements for providing a safe working environment, per federal and state laws, regulations, and guidelines, is the inherent responsibility vested in each individual to perform his or her own tasks in accordance to established SOPs, and their appropriate utilization of engineering methods or personal protective equipment (PPE) provided to safeguard their health and well-being. To assure that workers can

truly assess workplace risks (both for themselves, and as to how their actions affect the safety and well-being of co-workers) and to make truly informed decisions, a full presentation of the inherent risks, procedures and equipment available to minimize or eliminate those risks, and the laws and regulations which govern workplace health and safety issues must be provided to each employee. CRL recognizes that safety is of daily concern, and the necessity for constant vigilance is an imperative; consequently, employee health and safety training is an ongoing part of the employee's continuing education and training program.

The following subsections describe CRL's approach to providing the initial and ongoing health and safety training programs necessary to ensure regulatory compliance, improve employee recognition and avoidance/prevention of risks, and to minimize or eliminate lost time or disruption of contract services as a result of avoidable accidents or injuries, or the failure to maintain exclusionary practices for preventing animal disease transmission. In all cases, documentation of employee training in all aspects of workplace health and safety issues/practices will be assured, and will be audited to ensure compliance in CRL QA/QC inspections.

Basic Instructions/Guidelines - The CRL new employee orientation, consisting of information (both written and oral) regarding emergency procedures, accident/injury/illness procedures, safety, health, and environmental programs, and specific training/education on SOPs, safe working practices, and compliance with laws, regulations, and policies is summarized in Figure 3.B. Employees will be made aware of their rights and responsibilities, as well as the rights and responsibilities of the CRL Director/Principle Investigator. As indicated above, coverage of these topics is not a one-time event, but will be covered/reemphasized at regularly scheduled staff meetings and/or training sessions. CRL will be responsible for providing and documenting these training sessions, and will make use of its varied and multiple Corporate Training Resources, such as speakers (i.e., veterinary, safety, engineering and other subject matter professionals from CRL's corporate offices) at no additional cost to the Government.

Applicable sections of 29 CFR can be used to aid in the development of, and as a supplement to, the presentation of health and safety training programs:

Safety Program Topic	**Section of 29 CFR**
Emergency Action Plan	(1910.38)
Fire Prevention Plan	(1910.38)
Hearing Conservation Program	(1910.95)
Emergency Response Plan	(1910.120)
Respirator Program	(1910.134)
Lockout/Tagout Program	(1910.147)
Medical Surveillance Programs	(e.g., 1910.1025, 1910.1047, 1926.58)
First Aid	(1910.151, OSHA Directive CPL 2-2.53)
BBP Exposure Control Plan	(1910.1030, OSHA Directive CPL 2-2.44C)
Hazard Communication Program	(1910.1200, 1926.59)
Laboratory Chemical Hygiene Plan	(1910.1450)
Ergonomics Program	(5(a)(1))

Emergency Procedures
- emergency telephone numbers – locations and procedures
- evacuation procedures
- chemical spill response
- fire extinguisher locations
- first-aid kits – contents and location
- NHP bite/scratch first-aid kits – location
- safety eye washes/showers - location and use

Injury/Illness Procedures
- reporting to supervisor
- treatment (during/after hours)
- accident investigation
- near-miss reporting

Safety, Health & Environmental Programs
- policies
- research safety and biosafety manuals – location
- safety committees – representation
- employee rights and responsibilities
- supervisor/CRL responsibilities
- employee rights and responsibilities
- injury and illness prevention program

Education and Training
- specific workplace practices (SOPs)
- personal protective equipment requirements, location, use and maintenance
- MSDS information, interpretation, location
- proper waste disposal (normal, hazardous, radioactive, infectious)
- proper lifting techniques
- incentive programs
- potential workplace hazards, zoonotic diseases

Figure 3.B CRL New Safety, Health, and Environmental Orientation Checklist.

Zoonotic Diseases - CRL's PI/Director will instruct/train project personnel to: 1) recognize the range of zoonotic diseases (diseases transmissible from animals to people) which are present within the APF by nature of induced animal models, or by nature of animals used (e.g., HCV and HIV); 2) recognize the signs/symptoms likely to occur in animals and in humans; 3) recognize the routes of transmission of the disease (i.e., dermal, respiratory, ingestion, passage through mucous membranes), and mechanisms of transmission (i.e., trauma/dermal injury [bites, scratches, puncture wounds], aerosols, direct contact, via fomites, via vectors, by contact with experimental inoculates); 4) understand the importance of methods/procedures/equipment to minimize or eliminate the risk/possibility of transmission; 5) emergency/first aid procedures; 6) emergency medical treatment and 7) reporting requirements.

In addition to employee education, CRL recognizes that not every physician or medical group is experience in dealing with the types zoonotic illnesses present in a non-human primate colony of the type housed at the APF. Thus, education of local health care providers may be necessary as well, by: 1) providing the physician(s) with literature/reprints regarding signs symptoms of the range of diseases and established treatment protocols; 2) contacts with specialists/experts in disease recognition and identification; and 3) provide them with addresses of viral reference/testing labs capable of performing necessary serologic testing.

Non-human primates pose the greatest risk to animal care personnel. Separate and apart from HCV and HIV, some of the Zoonotic agents recovered from non-human primate urine and feces are listed in Figure 3.C. These are of concern when hoses are used to clean waste pans or caging, as aerosolized particulates are frequently generated/distributed throughout the room.

Personal Protective Equipment (PPE) - Personal protective equipment (i.e., lab coats, gowns, gloves, masks, respirators, safety glasses, goggles, face shields, scrub suits, tyvek suits, shoe covers, steel-toed safety shoes, primate catch gloves, ear plugs, hearing protectors, back supports, and hard hats) should be selected to provide each employee with the maximum protection possible to avoid exposure to: 1) hazardous chemicals; 2) aerosolized chemicals, particulates, or pathogenic organisms; 3) traumatic injuries (bites, scratches, lacerations, crushing injuries, back strain); and 4) direct contact with or fomites carrying pathogenic microorganisms. PPE use has a secondary benefit, in preventing transmission of human diseases from workers to animals, which could be disruptive to the research effort and animal well-being. Respirators need to be fit-tested prior to use by an individual, and it should be noted that beards/mustaches diminish the successful fit and therefore effectiveness of the respirator. Appropriate disinfecting, cleaning, and maintenance of reusable PPEs should be practiced as per existing or to be developed SOPs. The disposal of disposable PPEs should also be practiced as per existing or to be developed SOPs. Documentation of contract employee training in the use of PPEs will be subject to QA/QC audits conducted by Corporate staff.

Universal Precautions & Bloodborne Pathogen Standards – Training - The nature and extent of "Universal Precautions" and bloodborne pathogen standards is discussed below. These precautions are intended to prevent parenteral, mucous membrane, and non-intact skin exposures of employees to bloodborne pathogens. Employees should be made aware of the availability, types, proper use and maintenance of, and disposal of personal protective equipment, and of engineering controls (Biological Safety Cabinets) and workplace practices designed to limit/eliminate exposures.

CRL will provide its employees with the necessary training as required by OSHA, and will retain/archive documentation of training for at least three years as mandated including but not limited to the following:

- the date(s) of training;
- a listing of employees who attended/participated in the training, including their names, job titles, and signatures;
- a listing of the contents or a summary/synopsis of each training session;
- the names and qualifications of instructors providing the training.

Assurance of compliance with the training program will be a component part of the CRL Quality Assurance Program, and will be subject to periodic audit and review.

Safe Work Practices - As necessary, CRL employees will receive training about Biological Safety Cabinets and their proper use, electrical safety, fume hoods and their proper use, pressurized systems (gas cylinders), and appropriate storage of chemicals. Use of personal protective equipment, safety equipment, and safety procedures (minimizing aerosol generation, eye safety, foot safety, back safety and proper lifting, hearing safety, respiratory safety, preventing slips and falls, use of personal protective equipment) are described later in this section.

Adherence to established husbandry, technical, and safety SOPs is the fundamental key to minimizing or eliminating injury due to known risks, and worker competence, vigilance, and training completes the loop.

Hazard Communication Standard Training - Hazard Communication Standard training program include the basic concepts of the employer's hazard communication program, how it is

administered, the requirements of the standard, how to read and understand information labels on containers of hazardous chemicals and material safety data sheets (MSDS). The following topics must be covered routinely in ongoing training programs to ensure compliance with the standard:

- the physical and health effects of the hazardous chemicals which the employees may use or to which they may be exposed;
- means of detecting the presence of toxic materials in the workplace (i.e., odor, presence of a respiratory irritant, visual detection, common symptoms of exposure) and types of monitoring that can be done by lab personnel, health and safety office, or outside public or private agencies;
- means of reducing or eliminating the exposure of the employee to the risks associated with the hazardous chemicals in the workplace, including work practices (i.e., fume hoods) to reduce exposures or the use of personal protective equipment;
- actions taken by the employer to minimize exposure of employees to the chemical hazards, including engineering controls (fume hoods, biological safety cabinets, ventilation, shielding, and policies which encourage employees and supervisors to follow safe working practices, including incentives;
- emergency procedures to follow in the event of an accidental exposure to a hazardous chemical;
- procedures to warn visitors and others of potential exposures; and
- establish and maintain an MSDS file, how the employee can access the file, and how to interpret the data so that protective measures can be taken to reduce or eliminate the hazards associated with the use of those chemicals.

Radiation Safety - CRL personnel who will be administering x-rays or handling radioactive materials will be required to receive training provided by CRL's Radiation Safety group. Additionally, their appropriate use of PPE and radiation monitoring devices will be monitored by the appropriate CRL Supervisors. Personnel will also receive training on responses to and cleanup of spills of radioactive materials.

HAFB Policies & Procedures - Whenever possible/practical, it would be advantageous to have USAF personnel with responsibility for or expertise in the following areas to provide an introduction/overview of the significance of compliance with established HAFB safety and security guidelines. CRL's Principle Investigator/Director will coordinate lectures/training with the appropriate USAF contract.

CRL Animal Facility SOPs - Standard operating procedures are intended to ensure that all individuals providing animal care and technical support services perform routine and special tasks without deviation from the accepted standard, assuring that variability is minimized or eliminated, that experimental integrity is preserved, and that service continuity is preserved. Existing and newly developed SOPs will be covered during initial employee training, and reviewed periodically during ongoing weekly training sessions to assure that their intent and content are fully understood and adherence is verifiable.

CRL Health & Safety and Fire Safety Training –

Safety, Health, & Environmental Programs - the following subjects will be covered during initial and ongoing (annual refresher) Health & Safety training:

- established CRL Policies;
- location of research safety and biosafety manuals;
- the existence of and representation on safety committees;
- injury and illness prevention programs.

CRL employees will also receive training regarding any access/egress and corridor utilization policies established by CRL, to ensure that hallways, doorways, exits, and stairwell entrances are not blocked by caging, equipment, or supplies, posing a difficulty in egress during emergencies, or injury from collision during normal traffic flow in the corridors.

Emergency Procedures - the following subjects related to emergency response will be covered during initial and ongoing Health & Safety training:

- location and contact sequence for emergency telephone numbers;
- facility evacuation procedures;
- location and use of non-human primate bite/scratch first-aid kit;
- chemical spill response and location of Chemical Spill Control Centers;
- location of fire extinguishers/hoses;
- location and contents of first aid kits;
- location and use of safety eye washes/showers.

CRL/HAFB Security Procedures - Training will stress the necessity to protect the security of the APF facilities, animals, and equipment from vandalism or theft, and the impact those crimes would have on the ongoing success of this project effort. The necessity to maintain confidentiality as to ongoing operations will also be covered. Workers will be instructed on the use and safekeeping of security identification, receiving strict instructions to be vigilant for individuals in the area of the APF without appropriate security identification. Employees will be instructed to immediately notify the PI/Director if a security breach/intrusion is suspected.

Other CRL Policies –

No Smoking Policies - To the extent that portions of the HAFB are designated as Smoke Free Environments, CRL employees will comply with those restrictions.

Drug-free Workplace - CRL will establish an on-going drug awareness program during its regular training sessions. It is the policy of Charles River Laboratories (internal Company Policy #25) to prohibit the unauthorized or unlawful manufacture, distribution, dispensation, possession and/or use of alcohol and any controlled substance at any of its domestic locations or work sites. This policy establishes safeguards for the Company, its employees and property against the unauthorized possession and/or use of controlled substances, and assures compliance with the Drug-Free Workplace Act of 1988.

AALAS Training - The American Association for Laboratory Animal Science has as it primary mission the education and training of individuals who care for and use animals in research, teaching, and testing. This training aids in the program of compliance assurance, in broadening the capabilities and

skill mix of the workforce, and in instilling pride and professionalism in lab animal workers. Our intention is to provide training opportunities and encouragement to our entire staff, such that they can more effectively perform their tasks and through cross-training, allowing them opportunities for growth and professional advancement.

AALAS Certification Courses - The CRL PI/Director is ultimately responsible for establishing and coordinating AALAS training courses at the levels needed (Assistant Technician, Technician, and Technologist) based on each employee's current experience and current certification status. A listing of qualifications/requirements for the three certification levels is provided in Figure 3.E. The CRL PI/Director will assemble written and audiovisual aids for the course, and will arrange for speakers/lecturers to deliver the various sections of the course. Several pre-test review aids are available through AALAS, to assist individuals in developing the necessary test taking skills to successfully complete the certification exam. In comparison to past methods involving regional examiners made up from the ranks of certified individuals, AALAS now uses the services of regional professional testing services to administer and grade the written examinations.

Charles River has purchased and initiated use of a computerized autotutorial AALAS training program at its other animal care facilities, and has found it to be an invaluable adjunct to standard didactic presentations. Its self-paced learning modules present an non-threatening learning environment for workers who might feel "intimidated" in a classroom situation, allowing them to progress at their own pace along their own unique learning curve. Additionally, CRL has purchased laptop computers loaded with training software for each of its locations, allowing the management to make them available to employees for home study use. The computerized ALAT, LAT, and LATG Prep Exams allow staff with "test anxiety" to test themselves without fear of embarrassment, as is sometimes the case with hand-graded exams. The laptop training program provides an encapsulated synopsis of employee use of the program, and an indication of which areas of study were weak during testing. This information will be placed in each employee's training file.

One of the problems which other contract service providers have recognized is that simply paying study material and testing fees for employees is not an adequate incentive to motivate employees to adequately prepare for or pass the certification exams. Employees must be motivated by showing them the benefits (financial, personal, and professional) of certification, and making them a partner in the effort. Charles River will cover the initial costs of AALAS membership (to take advantage of reduced testing fees) for its employees, costs of manuals and testing fees. If the employee is unsuccessful in passing the certification exam, he/she is required to pay fees for subsequent examinations and is reimbursed upon passing. The availability of laptop computer study and self-testing software, coupled with the weekend training programs designed by CRL's Corporate Trainer, will further ensure that individuals are situated in a goal-oriented environment with the tools and resources necessary for them to excel to their greatest potential.

CERTIFICATION LEVEL	EDUCATIONAL BACKGROUND	LAB ANIMAL WORK EXPERIENCE
Assistant Lab Animal Technician Exam (must meet one of the three requirement categories)	▪ No high school diploma or G.E.D. ▪ H.S. diploma or G.E.D. ▪ Any college degree from programs 2 years duration	+ 2 years + 1 year +0.5 years

Lab Animal Technician Exam (must meet one of the five requirement categories)	▪ No high school diploma or G.E.D. ▪ H.S. diploma or G.E.D. ▪ Any A.A. or A.S. degree ▪ Any B.A. or B.S. degree or graduate degrees (M.A., M.S., PhD, DVM) ▪ ALAT Certification plus H.S. diploma or G.E.D. or higher	Not Eligible + 3 years + 2.5 years +2 years + 1 year (after passing ALAT exam)
Lab Animal Technologist Exam (must meet one of the five requirement categories)	▪ No high school diploma or G.E.D. ▪ H.S. diploma or G.E.D. ▪ Any A.A. or A.S. degree ▪ Any B.A. or B.S. degree or graduate degrees (M.A., M.S., Ph.D., DVM) ▪ LAT Certification plus H.S. diploma or G.E.D. or higher	Not Eligible + 5 years + 4.5 years +4 years + 1 year (after passing LAT exam)

Figure 3.E Educational and Work Experience Requirements for Certification by AALAS at the ALAT, LAT, and LATG Levels.

Attendance at Local, Branch, or National Meetings - In addition to internal training programs, CRL recognizes the myriad of benefits of membership and participation in local and regional branches for project staff, and in national AALAS involvement and attendance at annual national meetings by certain Project Staff. Those meetings provide the following opportunities: 1) speakers, seminars, and other presentations applicable to project activities and performance; 2) continuing educational opportunities through use of audiovisual tutorials in learning resource aspects of the meeting; 3) establishment of peer/professional contacts, providing a network of individuals to assist in problem solving, and 4) fostering a professional attitude which is reflected in delivery of service.

Crosstraining - Whenever possible/practical, CRL's PI/Director will assess project needs, and the breadth of capabilities of the project workforce, to determine if broader crosstraining of personnel is warranted. Crosstraining: 1) enhances individual and contractor capabilities and the depth of skill mix within the workforce; 2) reduces or minimizes overtime; assures coverage of critical tasks/duties in the event of absence of one or more project personnel; and 3) allows better handling/scheduling of peak work loads and unanticipated requests for services. Development of targeted technical skills may be accomplished in one-on-one sessions, or during group training sessions (i.e., AALAS training courses).

Quality Assurance / Quality Control Program and Procedures - Customer satisfaction and compliance assurance are two major goals CRL has set for itself if selected to manage and operate the APF. The accomplishment of those goals requires a competent, trained, experienced, service-oriented workforce, adherence to established SOPs and study protocols, compliance assurance with applicable laws, regulations, and guidelines, and the requisite documentation and records necessary to establish that appropriate animal care and husbandry was provided, and that environmental variables can be

recognized/documented and controlled. CRL's staff will be made aware of the necessity for and importance of providing Quality Assurance and Quality Control, both for the company (in maintaining its standards of performance) and for the Government, in assuring it that it is receiving efficient, cost-effective services from CRL. Personnel will be advised of the types of logs/records associated with their tasks, and appropriate methods for recording entries. Appropriate procedures for correction of transcriptional or recording errors will be covered. The types, methods, and reasons for auditing of procedures and records will be discussed, demonstrating that QA/QC oversight is not an adversarial process, but a means of verifying work done correctly/appropriately, and for remediation/rectification of problems or errors in a timely manner, before they lead to serious consequences that could negatively impact animal/colony health or experimental validity/integrity.

Degree Studies / Continuing Education - CRL recognize the benefits of post-high school education for its contract employees, opening management and professional opportunities to them, resulting in enhanced job satisfaction, personal growth, and a greater range of services/skills which can be employed in the workplace. It is CRL's policy to allocate $1000/year of corporate funds per employee for formal educational programs, and programs leading to college and advanced degrees. Employees are compensated based upon grade performance, with 100% of fees (up to $1000) compensated for an "A", 75% for a "B", and 50% for a "C". We also recognize that employees must schedule courses outside of normal work hours to assure that service/contract performance is not compromised.

Occupational Health and Safety Plan - Concerns for the safety and the health/well-being of employees in animal care facilities are embodied in federal laws, regulations, and guidelines (i.e., the Animal Welfare Act ("AWA"), the Guide for the Care and Use of Laboratory Animals ("Guide"), OSHA standards and AAALAC accreditation standards, as applicable). Programs for assessing personnel health over time help in evaluating the effectiveness/reliability of sanitization procedures and personal protective equipment. Providing effective programs to educate employees on the nature of hazards/risks and methods/equipment to prevent accidents or exposures, helps in minimizing time lost to injury or illness (and possible disruption of work schedules), and provides a greater sense of security/confidence in employees with resultant benefits from improved morale. Safety programs are also intended to prevent damage or destruction of Government furnished equipment, which could adversely affect the program of animal care. A copy of Charles River's Occupational Health and Safety Program is attached as Appendix D to this Proposal.

The general approach and basic tenets and underpinnings of our Health and Safety Plan are provided in the following subsections. Following contract award, CRL will modify and supplement this Plan to address specific operational risks and concerns present at the APF.

Employee Physical Exams & Monitoring Procedures - A thorough Animal Exposure Surveillance Program (or "AESP"), provides the basis for health assessment/evaluation and risk minimization/prevention. One component of Charles River's AESP involves physical examination and testing by a licensed physician, including pre-employment and annual physical exams. CRL will select a health care provider in the greater Alamogordo area, with requisite training, experience, and competence in recognizing, testing for, and treatment of Zoonotic diseases and other animal-contact related illnesses. Individuals with "substantial animal contact", i.e., those with direct contact with animals, unfixed tissues, body fluids, or animal environments/soiled equipment, will be included in the AESP.

Complete AESP physical exams/evaluations will include the following:

- past medical history, including significant illnesses or conditions (asthma, emphysema, immunosuppressive disorders/treatment, allergies, back or limb injuries);

- occupational history and previous exposures;
- complete physical exam, including pulmonary function test and audiogram;
- TB skin test (and subsequent observation/interpretation in 72 hours);
- follow-up thoracic radiographs with positive or suspicious TB test reaction;
- blood collection for hematological (CBC profiles), serum chemistry profile, and serum for banking/storage for later use in clinical assessment of disease;
- urinalysis;
- fecal exam (for endoparasites, occult blood).

Documentation of completion of physical exams (and pass/no pass results) will be provided to the Project Officer.

Additional components of the AESP include: 1) tetanus vaccination, with boosters post-injury/bite; and 2) hepatitis B vaccination for individuals at risk for exposure to human blood or body fluids/tissues. Tetanus vaccination should occur at least every 10 years, or following bites/exposures/injuries.

A QA/QC assessment of compliance with AESP procedures will be conducted no less than annually.

Universal Precautions / Bloodborne Pathogens Standards - Concerns for workplace safety regarding the possible transmission of HIV, Hepatitis B Virus (HBV), and other bloodborne pathogens led the NIAID to issue in 1987 (and to update in 1988 [MMWR, 37(24), June 24, 1988]) a set of standards referred to as the "Universal Precautions" for jobs/activities with occasional or regular exposure to human blood or body fluids (i.e., semen and vaginal secretions, cerebrospinal fluid, synovial fluid, peritoneal fluid, and amniotic fluid), without regard for or requirement to verify the existence of bloodbourne pathogens in those materials. Specifically excluded from coverage were feces, nasal secretions, sputum, sweat, tears, urine, and vomitus, unless they were observed to contain blood. The Occupational Safety and Health Administration (OSHA) instituted its Final Rule on Bloodborne Pathogens on March 6, 1992, and required full compliance of standard requirements by July 6, 1992. Animal care and technical staff employed on this contract may be exposed to human blood or body fluids through accidents or injuries to co-workers, through accidental exposure to inoculates intended for introduction/injection into animal models, or from direct or indirect transmission from animals infected with human pathogens. Thus, CRL must assure the Government and OSHA that it will ensure utilization of "Universal Precautions" and implementation of the Bloodborne Pathogens Standards, to minimize and eliminate risks to their employees at the APF facilities. The "Universal Precautions" recommended by CDC/OSHA are listed in Figure 3.F, and these are applicable not only for bloodborne pathogens of human origin, but also for preventing transmission of Zoonotic diseases from laboratory animals to humans, and transmission of communicable diseases from animal to animal or room to room within the animal facility.

A key component of the OSHA Final Rule for Occupational Exposure to Bloodborne Pathogens is the requirement that employers establish an Exposure Control Plan ("ECP"), identifying individuals who are at risk for occupational exposure, describing training to be provided to those individuals, providing protective equipment and training in its appropriate maintenance and use, and provision of vaccination programs (specifically, Hepatitis B vaccination). The cornerstones of the ECP necessary to ensure compliance are listed in Figure 3.G.

Handling and Storage of Chemicals - A description of employee training in recognition and handling of hazardous chemicals is presented above.

CRL employees will assure proper storage of husbandry-related chemical agents (storage temperature requirements, assurance that chemicals are not stored in areas with feed or bedding), that chemicals are handled and mixed/diluted according to SOP and/or manufacturer's recommendations, and that appropriate personal protective equipment is available for and utilized by contract employees at risk.

Storage and Records Maintenance of Controlled Drugs - Controlled drugs (i.e., anesthetic and analgesic agents) will be under the control of the CRL Veterinary Staff, and are typically kept in double lockbox containment. To meet DEA requirements, if CRL employees are involved in handling or administering controlled drugs, appropriate inventory records shall be maintained indicating: the drug name, unit size, amount received, the date of drug administration, the purpose of use, person administering, the species involved, the PI, the dose administered, the volume remaining in the container, and volume of wastage. The log will be reviewed monthly as part of CRL's QA/QC program to ensure that it is being maintained adequately, that all entries are sufficiently recorded, and that balances correspond with a visual assessment of quantities remaining in the drug vials. Any discrepancies will be reported to the PI/Director immediately. If requested, CRL staff will also conduct a yearly inventory of controlled substances/drugs.

Personal Hygiene Practices - Failure to wash hands after using the restroom, following handling of animals or equipment within holding rooms, or following handling of dirty cages and waste pans, is a primary means of disease transmission and infection. The use of gloves and thorough washing/disinfection of hands will be stressed in employee training programs. This is of critical importance for BL-3 facilities (as mandated in the CDC publication "Biosafety in Microbiological and Biomedical Laboratories"), but of equal significance in BL-1 and BL-2 facilities as well. Some activities may require shower-in and shower-out of personnel. Potentially contaminated gloves must be removed and appropriately disposed of before touching/handling door knobs or other points of egress, and must not be worn outside of the animal care facilities.

Injury Prevention / Safe Work Practices - Certain risks are inherent in animal care facilities, and recognition of their causation and measures to prevent or limit injury will also be a focus of CRL's comprehensive training program. Some significant/important risks are presented below.

Eye Safety - Injuries to the eye and adnexa can occur from: 1) penetrating trauma or scratches from animals, equipment, or other facility structures; 2) exposure to dusts or bedding; 3) exposure/contact with chemical sterilant/disinfectant/cleaning agents; 4) contusions or blunt trauma to the eye; 5) exposure to/contact with test agents or therapeutic drugs; and 6) exposure to/contact with aerosolized particulates (urine, feces, body fluids). It is estimated that 90% of eye injuries can be prevented through the use of proper protective eyewear. The use of safety glasses, goggles, and face shields helps to reduce/eliminate risks of eye injury/exposure. Eye protection devices must be properly maintained, as scratched and dirty devices reduce vision, cause glare and may contribute to accidents. CRL will provide its employees with appropriate eye protection where needed/indicated, monitoring and enforcing proper use.

Hearing Protection - Noise can be generated in animal facilities in a number of ways: 1) animal vocalizations; 2) movement of caging; 3) non-human primates banging on caging; and 4) from mechanical cage/rack washing equipment. Prolonged exposure to significant decibel levels can lead to hearing loss or deafness, posing additional productivity and safety concerns. Workplaces where noise

exposures equal or exceed 90 dBA (8-hour time-weighted average) are required to use feasible controls to reduce or eliminate hazardous noise. These may consist of engineering controls to reduce noise levels, administrative controls to limit exposure time, or personal protective equipment to reduce exposure levels. The use of ear plugs or hearing protectors will be required of certain CRL personnel in order to adequately protect workers' hearing.

Back Safety / Proper Lifting - Animal husbandry and clinical care activities involve the lifting of moderate to heavy objects (i.e., feed and bedding sacks, caging, animals), and pulling or pushing objects (racks, equipment, feed barrels). Failure to use recommended techniques for lifting (i.e., bending the knees, squatting and lifting straight up [rather than bending at the waist]; and use of back support belts/devices) may result in painful muscle pulls or injury to the spine or spinal nerves, with temporary or permanent disability occurring. CRL staff will provide QA/QC review of employee lifting techniques, correcting improper techniques/practices as they occur.

Slips and Falls - Wet floors, slippery walking surfaces, and improper footwear may result in slips or falls which might injure the employee's back. Use of safety boots, and identification of wet/slippery surfaces with plastic cones, should minimize problems. Ladders should be used as per manufacturers recommendations to avoid tipping and falls. CRL will ensure that contract personnel keep traffic lanes free of water and debris in order to reduce safety hazards.

Foot Safety - Crushing injuries, penetrating injuries, and slips/falls can be avoided through use of safety boots or shoes, preferably with steel toes.

Repetitive Motion Disorders - Tasks such as keyboard entry/typing, cleaning/stacking cages, and other repetitive activities may predispose individuals to muscle or tendon disorders (i.e., carpal tunnel syndrome). Identifying tasks at risk, and developing procedures for breaks in activity, simple exercises, and ergonomic improvements, should minimize risks/injuries to project employees.

Respiratory Safety - Dusts from feed, animal dander, boric acid, and aerosolized chemical agents or bacterial/viral aerosols (of urine or feces) pose a risk of injury to the lungs and respiratory passages of animal care personnel. The wearing of a face mask significantly reduces exposure. Cleaning/sanitization practices, such as "dry" cleaning methods, minimize aerosol generation, and routine room cleaning/sanitization schedules, coupled with an effective HVAC system and 10-15 air changes per hour, should reduce/eliminate the concentration of airborne particulates. The use of some sterilant agents (i.e., peracetic acid) requires the use of a respirator in addition to skin and eye protection. Any respirator program should stress thorough training of all participants, especially the users who need to wear the respirators. Employers must be aware that the equipment does not eliminate the hazard. If the equipment fails, overexposure will occur. To reduce the possibility of failure, equipment must fit properly and be maintained in a clean and serviceable condition. Medical examination and testing should be performed prior to an employee using respiratory protection. All respirators used under permanent or temporary assignment shall be inspected prior to each donning by the assigned employee. The employee shall be responsible for inspection of the following points: straps, cartridges; face seal; exhaust and inlet valves; air hose connections or blower; batteries; and lens. All respirators should be stored in a clean, contaminant-free environment. The respirator/face piece should be placed in a plastic bag to ensure the contaminant does not get into or onto the face piece of the respirator. Whenever possible, respiratory protection should be stored in a secured area.

Zoonotic Diseases & Prevention of Transmission/Infection - Employee training regarding the range of Zoonotic diseases likely to be encountered in operating the APF was covered above. Measures for minimization or prevention of transmission of Zoonotic diseases would include: use of

recommended/required PPE (described below); adherence to SOPs for facility/caging sanitation, disinfection, and waste disposal; monitoring for sanitization/disinfection effectiveness; appropriate animal handling techniques; maintenance of an adequate animal health surveillance and prophylaxis program; knowledge and use of appropriate first aid techniques; and elimination of vectors.

Personal Protective Equipment (PPE) - The purpose of personal protective clothing and equipment (PPE) is to shield or isolate individuals from the chemical, physical, radiological, and biological hazards that may be encountered in an research animal care facility when engineering and other controls are not feasible or cannot provide adequate protection. Careful selection and use of adequate PPE should protect the health of contract animal care employees. These items can include: surgical masks, respirators (half and full-face), safety glasses, goggles, face shields, gloves, gowns, scrub suits, tyvek suits, shoe covers, steel-toed safety shoes, ear plugs, hearing protectors, back supports, and hard hats. Employees will receive training as to the types of PPE, the reasons for their use, where they are located/obtained, how they are appropriately used, how they are serviced/maintained/disinfected, and how they are to be disposed of. No single combination of PPE is capable of protecting against all hazards. Therefore, PPE should be used in conjunction with, not in place of, other protective methods, such as engineering controls and safe work practices. The effectiveness of the PPE program should be evaluated regularly. The use of PPE can itself create significant worker hazards, such as heat stress, physical and psychological stress, impaired vision, reduced mobility, and distorted communication. In general, the higher the level of PPE protection, the greater are the risks associated with use of PPE.

Proper Waste Disposal - Wastes will be handled, processed, and disposed of according to established CRL SOPs. Of particular concern, sharps and infectious medical waste must not be disposed of in regular waste receptacles. Needles must not be sheared-off (using devices such as a "destructo-clip") as this can produce hazardous aerosols. Resheathing of needles poses a significant risk to technicians/researchers, leading to accidental needle sticks. If practical, syringes and needles should be placed in a sharps container immediately adjacent to the procedural area, or needles should be resheathed using only one hand, threading the needle into the needle cover, turning the syringe upright to allow the cover to settle down on the needle, and only then securing it with the other hand.

(e) Shipping of Animals to Other Locations

Charles River understands and acknowledges its obligation to cooperate in the shipping of chimpanzees in the event that a transferee is willing to accept chimpanzees from the APF and the ChiMP office of NCRR has approved the transfer in writing. Charles River imports, quarantines, and ultimately manages and oversees the ground transportation of hundreds of non-human primates throughout the United States each year. As a result, Charles River is highly familiar with the regulations relating to the shipping of non-human primates, as established by Title 9, Subpart A, Part 3 of the Animal Welfare Act, applicable CDC requirements and guidelines, and other applicable standards and regulations.

Dr. Lee and [redacted] are also particularly familiar with the shipping and care in transit standards applicable to chimpanzees and will ensure that the CRL Project Staff take all appropriate actions and provide all required levels of cooperation in the event that any chimpanzees are scheduled for authorized shipment.

Non-Key Personnel

(f) Schedule

As requested in the RFP, Charles River has provided in Appendix E a proposed schedule for this project effort, outlining key deliverables and projected periods of performance.

Appendix D

STANDARD OCCUPATIONAL HEALTH AND SAFETY PROGRAM

The Charles River Laboratories (CRL) defined occupational health and safety program takes every action possible to safeguard its staff from both existing or potential hazards. This program has been designed to satisfy the general industry standards of the Occupational Safety and Health Act, the health and safety standards of major professional organizations, as well as the policies and procedures set forth in appropriate NIH safety guidelines and documents.

The following sections describe the activities, responsibilities, resources, and training associated with associated health and safety activities. Sections of this program include: 1) Policy and Responsibilities, 2) Emergency Procedures, 3) Quarterly Safety Inspections, 4) Accident Reporting, 5) Safety Orientation, 6) OSHA Recordkeeping and Reporting, 7) Hazardous Waste Disposal, 8) Hazardous Communication, 9) Respiratory Protection, 10) Lock Out/Tag Out, 11) Medical Surveillance, 12) Personal Protective Equipment, 13) Chemical Hygiene Plan and Laboratory Safety Program, 14) Hearing Conservation and Noise Control, 15) Records Management, 16) Radiation Protection, 17) Hazardous Waste Operations, 18) Biological Hazards, and 19) Emergency Planning.

1.0 Organization, Staffing, and Management

Project Managers and Project Supervisors at all levels are directly responsible for the safety of their employees and for the enforcement of safety policies and procedures. All project managers and supervisors are required to be thoroughly familiar with safety practices that apply to their work and the work of employees they supervise, advise, or observe.

Providing the oversight for the development and implementation of the CRL corporate health and safety program, the Occupational Health & Safety Department 1) reviews the status of the program on an annual basis, 2) develops recommendations to mitigate issues identified during the program review, and 3) recommends assignment of adequate resources to meet the needs of the program.

The CRL Local Health & Safety Official is responsible for: developing and implementing the corporate health and safety program; assisting the project managers and project supervisors with regulatory interface and with statutory reporting; developing an audit program to ensure regulatory compliance as well as compliance with internal CRL health and safety standards; notifying the responsible Corporate Officer of any instances that involve violation of environmental health or safety statutes; supporting the development and implementation of this health and safety program, particularly with respect to ensuring the availability of adequate training; maintaining a corporate database for statistical reporting, generating loss control reports, and tracking audit recommendation status; providing an annual status report to the responsible Corporate Officer; assisting project managers and project supervisors in developing contract site-specific safety programs as requirements/hazards change; monitoring changes in state and federal environmental compliance and health & safety laws and regulations to update corporate policies and procedures; and notifying the CRL President of violations of corporate health and safety policies and procedures and participates in decisions on disciplinary actions.

The Project Manager (On-Site Supervisor) and Assistant Project Manager (Assistant On-Site Supervisor) are responsible for reporting to CRL senior management any changes in health and safety exposures as a result of new requirements or changes in the existing contract and ensuring that employees comply with provisions of the Health and Safety Program while working under his or her management. In concert with the project managers, the Local Health and Safety

Official will: 1) implement the project-specific health and safety program, 2) provide day-to-day overview of the project health and safety program, 3) conduct and document employee health and safety training, 4) interface with regulatory agencies, 5) work with CRL corporate health and safety officials to identify health and safety concerns and needs, as well as programs or actions to mitigate concerns, and 6) provide feedback to CRL senior managers concerning the status of the location's Health and Safety program.

For a health and safety program to be successful, the broad-based support and cooperation of each employee must be ensured. Each employee will be responsible for conducting their work in accordance with CRL environmental compliance and health and safety policies and procedures, as well as job instructions received. Any environmental or health and safety concerns associated with their activities as CRL employees are to be reported to their immediate supervisor, Project Manager, or Local Health and Safety Official.

2.0 Emergency Procedures

All fires, medical emergencies, and bomb threats are reported immediately to a supervisor, the Project Manager or assistant Project Manager, or the Local Health and Safety Official, as appropriate. If evacuation of the building is signaled by the CRL or local emergency notification system (alarm or public address system), project employees will vacate the building using identified evacuation routes in accordance with the Occupant Evacuation Plan. Employees will not reenter the building until an "all clear" signal is received. Emergency cards listing emergency instructions, emergency telephone numbers, and emergency signals shall be posted in all of the assigned work areas.

The Project Manager, Assistant Project Manager, and all project supervisors shall have a thorough understanding of emergency procedures. They will also be responsible for conducting or assisting in conducting employee training in emergency procedures, evacuating employees in the event of an emergency, accounting for all employees, and reporting to emergency service personnel as required. The Local Health and Safety Official will ensure that emergency information is properly completed and posted in the work areas, building diagrams are posted that identifies all exits and emergency equipment, a designated meeting area is determined in case of building evacuation, and all employees are trained in emergency procedures and the training documented.

In the event of a fire or medical emergency, employees will be trained to provide concise information to emergency service personnel that will expedite appropriate response to these conditions. This information will include clearly stating the employees name and exact location of the emergency and the nature of the emergency while remaining on the line unless immediate evacuation is necessary. If evacuation is required, employees will shut down equipment that, if allowed to run, might cause a hazard or cause damage if left unattended; close all doors to work areas, exit the building in an orderly manner by the nearest and safest evacuation route and meet at the designated meeting area; and remain in the meeting area until an "all clear" is signaled or a management decision is made to leave the area.

An employee who discovers a fire, reports or directs another employee to report the fire and exact location to local emergency services. If the fire can be safely extinguished with available extinguishers, employees can attempt this but only after appropriate emergency services have been notified. Employees not assisting in extinguishing a fire shall leave the area by the nearest and safest evacuation route in an orderly manner and gather at the designated meeting area.

If an employee receives a bomb threat, they will be trained to attempt to obtain as much information as possible recording it on a form that will be maintained by all telephones. Information to be collected will include (if possible): location of the bomb, time bomb is et to go off, what it looks like (whether concealed or in the open), how it got into the office, the sex of the caller, any accent, caller's knowledge of the building, any background noise, and other suggested data listed on "The Bomb Threat" by the local State Fire Marshall. When the call ends, the employee will notify their supervisor and the supervisor, working with the Project Manager, Project Officer, emergency service personnel, and other authorities, will determine whether to evacuate the building.

A hazardous material event occurs when a spill or activity results in the potential exposure of people directly or indirectly to hazardous material. If this takes place employees will – evacuate the immediate area, and contact the CRL Local Health & Safety Official to report the details of the event.

Training in emergency procedures is provided to all employees as a thorough understanding of reporting, actions, and evacuation procedures is required to avoid confusion during an actual emergency. Training is provided to full-time employees annually, with new-hires and temporary employees at the time of initial assignment. All training is documented. Training concentrates on: immediate action to be taken in the event of fire or medical emergency; identification of equipment in a work area that is to be shut down in an emergency, if it can be done safely; location of fire extinguishers, fire blankets, and any other emergency equipment in the employees' work areas; the method by which employees will be notified of an emergency; and identification of equipment in a work area that is to be shut down in an emergency, if it can be done safely; location of fire extinguishers, fire blankets, and any other emergency equipment in the employees' work areas; the method by which employees will be notified of an emergency; and identification of evacuation routes and designated meeting area(s).

3.0 Quarterly Safety Inspections

Mandatory quarterly inspections at each project location are provided to identify and correct unsafe conditions and/or work practices. These inspections are conducted by the Local Health & Safety Official using standardized and custom (project specific) checklists compiled by the CRL Corporate Health and Safety Official, Local Health and Safety Official, and project managers, respectively. The Local Health & Safety Official will complete the "Quarterly Safety Inspection Checklist" during the last week of each quarter. The previously completed checklist is used during the inspection to verify completion of corrective action items for deficiencies identified earlier. Recommendations will be made to the Local Health & Safety Official regarding any changes, additions, and corrections to checklists for project office areas, laboratories, and other work areas, as necessary. A copy of each completed checklist is provided to the appropriate supervisor, the Project Manager, and the CRL Responsible Corporate Officer.

The supervisor of the inspected area initiates action to correct all deficiencies found during the inspection. Actions include, but are not limited to, the preparation of a work request or safety training of employees. Corrective actions are noted on the supervisor's copy of the inspection checklist and a copy submitted to the Local Health & Safety Official and the Project Officer through the Project Manager.

4.0 Accident Reporting

Reporting of accidents or work conditions that caused or reasonably could have resulted in injury, illness, or property damage is mandatory. Only through accurate and timely reporting can the cause be identified and, if appropriate, corrective action initiated to prevent a recurrence; OSHA reporting and recordkeeping requirements be met, and insurance notification requirements must be met.

An accident is an incident or event occurring at work or while on company business that caused or reasonably could have caused injury to personnel and/or damage to equipment or facilities. All accidents, regardless of apparent degree of severity or whether employees are injured or not, must be reported to the employee's supervisor, Assistant Project Manager, or Project Manager, and the CRL Local Health & Safety Official immediately after emergency procedures have been performed. The Local Health & Safety Official will notify the Corporate Risk Manager as soon as possible as to whether any accident results in serous injury or death to a CRL employee. A serious injury is one that involves an amputation, loss of consciousness, loss of sight, or hospitalization of five or more employees.

Employees are responsible for reporting, to their supervisor, Assistant Project Manager, or Project Manager, each on-the-job injury and damage to equipment or facilities. The supervisor, Assistant Project Manager, or Project Manager will provide training to all employees in accident reporting requirements, ensure that employees report each on-the-job injury and damage to equipment or facilities, and will complete and submit a CRL "Supervisor's Accident Investigation Report" to the Local Health & Safety Official and the Project Manager within 24 hours of any incident. This report will be reviewed and a summary report subsequently provided to the Project Officer within 48 hours of the incident.

The Local Health & Safety Official and Project Manager will investigate causes to determine actions required to preclude recurrence and follows up on implementation of recommended corrective action(s). All accident investigations and reports will be maintained in a permanent file. Appropriate reports will be filed with OSHA in the event of a serious injury or death and the "OSHA Form 200" will be maintained up-to-date supported by copies of the Employer's First Report of Occupational Injury or Illness which is filed within 24 hours of first knowledge of a work-related injury or illness that requires medical attention.

5.0 Safety Orientation

All employees receive proper training in accident reporting, emergency evacuation procedures, and any hazards pertaining to their assignments. The Local Health and Safety Official, Project Manager, Assistant Project Manager, and supervisor(s) are responsible for assuring that all employees receive safety orientation and that this activity is documented. The Project Manager, Assistant Project Manager, and project supervisors ensures that no new employee begins any work assignment without first reviewing the applicable contents of the Project Health and Safety Program. The Local Health and Safety Official also reviews the applicable contents of the Program with the employee during new employee orientation. The employee must sign an acknowledgment form certifying that he/she has reviewed and understands the applicable contents of the Program. The acknowledgment form is forwarded to the Local Health and Safety Official, filed with the employees health and safety file, and a copy provided to the Project Officer within one week of the first day of employment.

6.0 OSHA Recordkeeping and Reporting

The Occupational Safety and Health Act requires employers to immediately report to the Occupational Safety and Health Administration (OSHA) any accident that involves serious injury or death and to maintain certain records regarding work-related injuries and illnesses. In addition, an OSHA Form 200, Log of Occupational Injuries and Illnesses, must be maintained at each CRL location by the Local Health and Safety Official. Each "recordable" injury or illness (as defined on the Form 200) must be recorded on the log within 6 working days after the Local H&S Official is first advised of the injury or illness. An annual summary is developed based on the information contained in the log at the conclusion of the calendar year and posted in a place where all employees are likely to see it. Posting will occur no later than February 1 and remain in place until march 1. The summary and log is retained for 5 years.

7.0 Hazard Communication and Hazardous Chemical Control

CRL's hazard Communication Program assures that consistent and uniform information is available on hazardous chemicals present at the project sites, that employees are aware of the hazardous chemicals with which they work, and that training is provided in procedures and practices necessary to control exposures to these chemicals. The program applies to chemicals known to be present in such a manner that employees may be exposed under normal conditions of use or in a foreseeable emergency.

The regulatory requirements for this program are set forth in the Hazard Communication Standard promulgated by the Occupational Safety and Health Administration in OSHA's General Industry Safety Standards at 29 CFR 1910.1200. CRL will follow the The National Institutes of Health Hazard Communication Program for this project. Elements of this program include labels and other forms of warning, Material Safety Data Sheets (MSDS's), and employee information and training programs. This program will apply not only to informing full and part-time CRL project employees but also informing any temporary employees and subcontractors that may be assigned to support this contract.

The Local Health and Safety Official and the Project Manager will:

- Obtain and review MSDS's for all chemicals used in areas where CRL project personnel are stationed.
- Ensure that updated MSDS's are provided to project personnel whenever received.
- Provide initial and periodic training to CRL employees, temporary employees, and subcontractors assigned to this contract.
- Maintain documentation of all training provided under the Hazard Communication Program.

The Project Manager, Assistant Project Manager, and supervisors will:

- Ensure containers are properly labeled with the chemical name and appropriate hazard warning(s).
- Refer all CRL employees and temporary employees who will be working with or around hazardous chemicals to the Local HS Official for training before permitting them to work with or around hazardous chemicals.
- Notify the Local HS Official of all non-routine tasks performed by employees under their supervision to insure adequate training is provided.

Employees will:

- Use approved labels identifying the chemical and containing appropriate hazard warning(s) provided by their supervisors, Assistant Project Manager, Project Manager, or Local HS Official when transferring the contents of original containers to in-plant containers (e.g., safety cans).
- Use information and training received to protect themselves and their fellow workers against undue exposures to hazardous chemicals.
- Report to their supervisors, Assistant Project Manager, Project Manager, or Local HS Officials any condition in the workplace that is felt to be unsafe.

The success of this program requires commitment from management and employees, each of whom bears a responsibility for assuring that program goals are met. Management is responsible for providing the resources necessary to assure that employees receive accurate and complete information and training to protect themselves and their fellow workers against hazardous chemicals. Employees are responsible for using the information and training to protect themselves and their fellow workers against undue exposures to hazardous chemicals and to report any condition in the workplace that is felt to be unsafe.

7.1 Labels and Other Forms of Warning

Labels on incoming containers of hazardous chemicals must contain the name of the chemical; type of hazard present; and name and address of manufacturer or supplier. Each label will reviewed by for completeness, and deficiencies will be brought to the attention of the Project Manager, Assistant Project Manager, or Local HS Official. If the label is missing or incomplete according to the above criteria, preprinted labels containing the required information for the chemical or its hazard class will be used.

In-plant containers – If the contents of the containers are to be transferred to in-plant containers, the employee performing the transfer is responsible for using preprinted labels to identify the hazardous chemical contained therein, as well as appropriate hazard warnings. The supervisor of the employee transferring the hazardous chemical is responsible for ensuring that the container is properly labeled with preprinted labels for the chemical or its specific hazard class. The Local HS Official may be contacted to select the appropriate label(s).

7.2 Material Safety Data Sheet

Material Safety Data Sheets are readily available to employees and are the basic means of communicating information about possible physical and health hazards. The Local HS Official reviews the information in the MSDS to determine if it meets acceptable standards of quality. The procedure encompasses a preliminary review for completeness and a secondary review for technical content. The Local HS Official identifies a deficient MSDS to the vendor or other party responsible for correction.

All MSDS forms received with an incoming chemical or by mail are forwarded to the NIH Division of Safety and a copy to the Local HS Official. For chemicals with an MSDS already on file, the Local HS Official determines if the MSDS received has the same date of revision. If the date differs, the latest revision will be used. The Local HS Official initiates the clerical and technical review of new MSDS received. If the information is adequate, then the MSDS is added to the site master file of MDSE.'s and copies are distributed to the appropriate project(s) or supervisor(s). If not, additional information is requested from the vendor. The

Local HS Official maintains a site master file of MSDS's in use or stored at the site and is responsible for distributing new and revised MSDS forms to the appropriate projects(s) or supervisor(s). The MSDS forms are kept in three-ring binders. Subfiles of MSDS's may be maintained as determined by specific laboratory requirement for hazardous chemicals used in that specific work area. The MSDS's are kept in three-ring binders, and they are accessible during each work day to employees when they are in the work area.

The Local HS Official provides the initial training of CRL employees who may be exposed to hazardous chemicals. Temporary employees and subcontractors with exposure to hazardous chemicals will be referred to the Local HS Official for inclusion in the training program. CRL employees and temporary employees must complete training prior to working with or around hazardous chemicals. In addition, training or information must be completed by or provided to subcontractors prior to commencement of work.

The initial training program gives employees information on:

- The CRL Hazard Communication Program;
- Operations in employee work areas where hazardous chemicals are present;
- The location and availability of this written program, including the list of hazardous chemicals and of the MSDS's in employee work areas;
- Overall health and safety procedures;
- The labeling system;
- The MSDS and how to interpret the various entries as they relate to worker health and safety;
- Physical and health hazards of the chemicals in use in employee work areas;
- Measures they can take to protect themselves from hazardous chemicals, including procedures implemented to protect them from exposure, such as safe work practices, engineering controls, and use of personal protective equipment;
- Proper procedures for responding to emergencies and for dealing with unusual operations;
- Methods and observations they may use to detect the presence or release of a hazardous chemical in their work areas, including air monitoring and visual appearance or odor of hazardous chemicals when being released.

The overall effectiveness of the Hazard Communication Program relies on active employees participation in all aspects of the effort, particularly concerning the scope and depth of training. Employees are encouraged to bring problems or questions concerning hazardous chemicals to the attention of the Local HS Official, the Project Manager, and/or their supervisor.

7.3 Periodic Training

Periodic training will be provided to appropriate employees whenever a new hazardous chemical is introduced into their work area(s) and whenever new, significant information is received about hazardous chemicals already in their work area(s). The Local HS Official will coordinate this training.

Temporary Employees/Subcontractors – The Local HS Official will provide and document introductory training for all temporary employees and subcontractors working with or around hazardous chemicals. The CRL Project Manager, supervisor, or employee responsible for a temporary employee or subcontractor's activities must refer to the Local HS Official all temporary employees and subcontractors who will be working with or around hazardous

chemicals. The CRL Project Manager, supervisor, or employee must ensure that the required training is completed prior to commencement of work.

Recordkeeping - The Local HS Official Maintains a record of all training provided to CRL employees, temporary employees, and subcontractors under the Hazard Communication Program. All training must be documented with: (1) a sheet signed by participating employees; (20 a description of topics covered; (3) the date training was given; and (4) a course outline. A copy of this record will be provided to the Project Officer.

The CRL Project Manager or supervisor gives the Local HS Official a completed "Temporary Employee Safety Training Checklist" for each temporary under his or her supervision that does not work with or around hazardous chemicals. If a temporary employee is assigned a job or task that requires work with or around hazardous chemicals, the employee is referred by his or her CRL supervisor to the Local HS Official for appropriate training.

The CRL employee responsible for a subcontractor's activities provides the Local HS Official with a completed "Subcontractor's Safety Training Checklist" for each subcontractor who works onsite but not with or around hazardous chemicals. If a contractor will be working onsite in an area(s) where hazardous chemicals are sued or stored or will be bringing hazardous chemicals onsite, he or she is referred to the Local HS Official for appropriate training.

Non-routine Tasks – The Local HS Official, Project Manager, and/or supervisor trains employees who perform non-routine tasks. Training includes discussion of the health and physical hazards that may be encountered and procedures for measuring, if appropriate, and protecting against those hazards, including the use of monitoring instruments, engineering controls, and personal protective equipment. Training on non-routine tasks is documented.

Outside Contractors – It is the responsibility of the Project Manager in coordination with the Local HS Official, to ensure that outside contractors are provided with the following information before starting work at the project site:

- Hazardous chemicals to which they or their employees may be exposed while working in our facility;
- Hazardous chemicals to which their employees may be exposed while the contractor is working;
- Precautions their employees must take to reduce the possibility of exposure to those hazardous chemicals.

The CRL employee assigned responsibility for a contractor's activities is responsible for contracting the Local HS Official to coordinate the previously described training prior to commencement of work. A signed copy of the "Safety Information for Contractors:, will be maintained by the Local HS Official for each contractor working on this project.

7.4 Inventory of Materials

A complete inventory of all hazardous chemicals onsite is a central focus of the Hazard Communication Program. The inventory documents the hazardous chemicals that employees may encounter in the workplace. The project Manager revises the inventory routinely to include new chemicals and remove others that cease to be used or stored. The inventory is thoroughly reviewed annually by the Local HS Official. The review date will be documented on the inventory.

MSDS's are filed alphabetically by the product/chemical name appearing on the site chemical inventory. The Local HS Official conducts the preliminary and technical review of project MSDS's. The purpose of this review is to assure the presence and adequacy of information. Upon receipt of a MSDS for the project, the Local HS Official reviews the MSDS to ensure that the appropriate information is provided. If this information is incomplete, the Local HS Official must contact the vendor or supplier and request the best available information. Attempts to elicit information must be documented in writing.

The MSDS must be completed in English and the following information provided:

- Product identity (must be same as on label);
- Date of preparation of MSDS or date of last revision;
- Name, address, and telephone number of the chemical manufacturer, importer, or other party responsible for preparing or distributing the MSDS forms;
- If the chemical is a single substance, its chemical and common name(s);
- If the chemical is a mixture that has been tested as a whole to determine its hazards, the technical and common name(s) of the ingredients that contribute to these know hazards and the common names(s) of the mixture itself;
- If the chemical is a mixture that has not been tested as a whole:
  - The technical and common name(s) of all ingredients that have been determined to be health hazards and that comprise 1 percent or greater of the composition, except that chemicals identified as carcinogens under hazard communication standard shall be listed if the concentrations are 0.1 percent or greater;
  - The technical and common names(s) of all ingredients that have been determined to pose a physical hazard when present in the mixture;
- Physical and chemical characteristics (such as vapor pressure or flash point) of the hazardous chemical;
- The physical hazards of the chemical, including the potential for fire, explosion, and reactivity;
- The health hazards of the chemical, including signs and symptoms of exposure, and any medical conditions generally recognized as being aggravated by exposure to the chemical;
- The routes (such as inhalation and skin absorption) of entry into the body;
- The OSHA Permissible Exposure Limit (PEL), American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV), and any other exposure limit used or recommended by the manufacturer,, importer, or distributor preparing the MSDS, where available;
- Whether the chemical is listed in the National Toxicology Program (NTP) Annual Report on Carcinogens (latest edition) or has been found to be a potential carcinogen in the International Agency for Research on Cancer (LARC) Monographs (latest editions) or by OSHA;
- Any generally applicable control measures, such as appropriate engineering controls, work practices, or personal protective equipment, known to the manufacturer, importer, or distributor preparing the MSDS;
- Emergency and spill cleanup procedures;
- First aid procedures.

8.0 Respiratory Protection Program

This program is to assure that all employees who may be exposed to harmful levels of airborne contaminants are properly trained in the selection, use, and maintenance of air-purifying respirators and are medically capable of using those respirators.

A program has been established that satisfies the requirements of the Code of Federal Regulations, Title 29, Part 1910, Section 1910.134. It is based on the recommendations of the National Institute for Occupational Safety and Health (NIOSH), Industrial Respiratory Protection, dated September 1987, and the American National Standards Institute, ANSI Z88.2-1992.

8.1 Definitions

Air-Purifying Respirator: A respirator in which ambient air is passed through an air-purifying element that removes the contaminant(s). Air is passed through the air purifying element by means of the breathing action or by a blower.

Airline Respirator: An atmosphere supplying respirator in which the respirable gas is not designed to be carried by the wearer (formerly called supplied air respirators).

Self-Contained Breathing Apparatus (SCBA): An atmosphere-supplying respirator in which the respirable gas source is designed to be carried by the wearer.

Note: This procedure addresses training in the proper selection, use, and maintenance of air-purifying respirators. Other types of respirators including airline respirators and SCBAs are described for informational purposes. Additional, specific training and guidance beyond that provided in this procedure, is required before employees can use airline respirators or SCBAs.

Engineering controls, such as local exhaust ventilation, process enclosure, and substitution with a less toxic material, are the primary means used to eliminate or reduce employee exposure to a level that respirators are not required. If engineering controls are not feasible or completely effective, personnel who are physically and psychologically capable and properly trained use appropriate respirators.

All respiratory protection equipment and procedures for use are to be approved by the Local HS Official and must meet applicable federal regulations. Only respirators jointly certified by the Mine Safety and Health Administration (MSHA) and NIOSH will be used.

Employees shall not be assigned to tasks requiring the use of respirators until they have been trained and fit-tested and until a physician has determined they are physically and psychologically able to use a respirator.

Project Manager or supervisor:

- Requests assistance of Local HS Official to evaluate operations that use or generate hazardous substances. Evaluations should be performed during planning/pilot stages.
- Assures employees are not assigned to tasks requiring respirators until they have completed required medical examination, training, and fit-testing.
- Monitors respirator use to ensure that: proper respirators are being sued; respirators are being work properly; and respirators are properly stored, cleaned, and maintained.
- Reports all problems in respirator use to the Local HS Official.

Local HS Official:

- Evaluates operations that use or generate hazardous substances to determine the need for respiratory protection and the level of protection that is required.
- Provides a copy of the "Respiratory Protection Program" to the examining physician before sending employees for medical examination.
- Maintains records of hazard assessment, training, fit-testing, and the results of "Respirator Protection Program Annual Evaluation".
- Maintains a record of medical examinations and ensures that the examining physician has determined that employees using respirators are physically and psychologically able to wear respirators.
- Educates and trains employees in the use and care of respirators, their limitations, and the content of the written respiratory protection program. Assures retraining is completed at a predetermined frequency in accordance with applicable OSHA regulations.
  Note: Some substance specific standards specify the frequency of refresher training.
- Investigates reported malfunctions of respiratory protective equipment to determine the cause and corrective action(s) necessary to prevent a recurrence.

Employees:

- Inspect their respirators before and after each use to assure they are in good repair.
- Use respiratory protection in accordance with instructions and training received.
- Clean their respirators after use and store them in plastic bags or containers provided for respirator storage to guard against damage to the respirator.
- Immediately stop work and go to an area of "clean" air should their respirators malfunction.
- Report all malfunctions, damage, or difficulties incurred because of respirator use to supervisor or the Local HS Official.
- Obtain medical examinations to confirm that they are capable of wearing respirators.
- Report to the Local HS Official any change in his/her medical status that may impact his/her ability to wear a respirator safely.

8.2 Respirator Issuance

The employee being assigned to a task requiring respiratory protection is referred by his or her supervisor to the Local HS Official. The Local HS Official will ensure that a physician has determined that employee is physically and psychologically fit to use a respirator. Negative pressure respirators will not be issued to employees with facial hair (i.e., beards and sideburns) that interferes with the facepiece-to-face seal of the respirator. The Local HS Official will select the proper NIOSH/MSHA certified respirator based on the hazard involved. After selection of the proper respirator, the employee will be fitted with the style and size that fits best. Fit-tests will be performed using qualitative or quantitative methods. The Local HS Official will instruct the employees in the need, use, and care of respirators, their limitations, how to test the fit, and content of the written respiratory protection program. An acknowledgment that respirator training was received is provided in association with the fit-test records.

Respirators are not issued to or worn by employees who are unable to obtain an acceptable fits or have not received medical approval or training. Fit testing is recommended annually and must be completed in accordance with other applicable OSHA regulations (e.g., lead and asbestos).

8.3 Training and Education

Training in the need, use, and maintenance of respirators is mandatory. The Local HS Official is responsible for providing instruction in and documentation of respirator training. Training is provided to each employee who is assigned a task that requires a respirator and the supervisor of the employee using the respirator. Retraining is provided annually.

8.4 Inspection, Maintenance, and Storage

Employees inspect their respirators before and after each use and during cleaning. They inspect and maintain their respirators as described in their respirator user training and in accordance with manufacturer's instructions. For emergency use respirators only, monthly inspections must be performed and a record of the most recent inspection (inspector's initial, date, and respirator identification number) maintained on the respirator or it's storage container.

The respirator user is responsible for storing the respirator to protect against dust, sunlight, heat, extreme cold, excessive moisture, and damaging chemicals. Plastic bags capable of being sealed, plastic containers, or cans with tight fitting lids are the measures that will be used to protect the respirator from damage during storage.

8.5 Medical Surveillance

A medical evaluation is required to determine if an individual is physically and psychologically capable of using respiratory protection. CRL requires that the individual's medical status be reviewed prior to respirator issuance and re-examined annually. The following factors are pertinent for this determination.

- Facial deformities or facial hair that would prevent a proper respirator seal.
- Use of prescription eyeglasses or contact lenses. Use of eyeglasses may restrict the type of respirator the individual may be permitted wear. contact lenses will not be permitted for respirator use, except in accordance with Federal or State regulations and guidelines.
- Ruptured ear drums. Persons with ruptured ear drums cannot weal respirators in hazardous areas where toxic materials or vapors can enter the body through the perforation.
- respiratory diseases that affect pulmonary function. Special tests shall be required when perfusion disorders are suspected. Cardiovascular diseases. Symptomatic coronary artery disease, significant arrhythmics, or a history of myocardial infarction shall disqualify a person from respirator use. The examiner shall decide if persons with premature ventricular contractions or uncontrolled hypertension and if individuals with blood pressure or on cardiovascular medications, my wear respirators.
- Endocrine disorders. If a person may suffer sudden loss of consciousness or response capability, the examiner shall determine whether a respirator may be worn.
- Neurological disabilities. The inability to perform coordinated movements or conditions affecting response and consciousness shall disqualify a person from wearing a respirator. Epilepsy, when controlled by medicine and when a person has not had a seizure within a year and shows no adverse reaction to medicine, should not be disqualifying.
- Medications. A history of excessive use or problems related to prescriptions or nonprescription drugs (including alcohol) that affect judgment, performance, or

reliability or that alter the state of awareness or consciousness may be considered disqualifying.

- Psychological conditions. A person with a condition that results in poor judgment or reliability should be disqualified. Claustrophobia or severe anxiety shall be considered in determining if an individual is fit for respirator use.

The Local HS Official is to provide a copy of this procedure and identify the types of respirators used, typical work, activities, environmental conditions, frequency and duration of use, and hazards for which respiratory protection will be worn to the examining physician.

8.6 Respirator Program Evaluation

In accordance with 29 CFR 1910.134(b)(9), the Local HS Official is responsible for annually evaluating the respiratory protection program and documenting the results and any program adjustments. This evaluation is to be provided by February 1 of each year to the Corporate HS Official and a copy will be provided to the Project Officer. The evaluation will address program administration and operations related to each task (e.g., increases or decreases in exposure concentration or the introduction of other contaminants).

9.0 Occupational Health Surveillance

The health and safety of CRL's employees is of primary importance. An important part of the corporate mandate is to encourage a preventive approach regarding health maintenance and to comply with Federal and State OSHA requirements. These requirements include monitoring the health of those CRL employees who may be exposed to biological, chemical, or physical hazards. A comprehensive health maintenance program will be instituted for covered employees and the following procedure outlines the elements included in this program.

The Local HS Official will identify employees covered by this procedure, investigate each work related injury or illness, and provide the following information to the examining physician:

- Copies of relevant OSHA standards;
- Information about employee's exposure levels (e.g., industrial hygiene data) or anticipated exposure levels;
- Description of personal protective equipment used or intended to be used;
- Information from previous medical exams that is not readily available to the physician.

The Project Manager ensures that: each employee covered by this procedure participates in the medical surveillance program, that employees report work related injuries and illness (e.g., overexposure and emergency situations), investigates all work related injuries and illnesses and filed report with the Local HS Official and the Project Officer, and sends a written request for covered medical examinations (non-emergency) to the Local HS Official and approves costs associated with the exam.

The Occupational Medicine Physician will: provide a written final determination on individual's fitness for duty, and includes an interpretation of results related to occupational exposures, recommend any work limitations on the employee or upon the use of personal protective equipment such as clothing or respirators, and performs examinations in accordance with the Animal Exposure Surveillance Program and OSHA regulations and guidelines.

The employees that are covered by this program include:

- Employees exposed to hazardous substances or health hazards (including radiation) at or above the permissible exposure limit or, if there is no permissible exposure limit, above the published exposure level (e.g., ACGIH, NIOSH) without regard to the use of respirators; and those employees who are or will be required to wear Level A, Level B, or Level C personal protective equipment at a hazardous waste site or at a clean-up operation site.
- Employees on HAZMAT teams.
- Employees who wear a respirator.
- Employees whose exposures equal or exceed an 8-hour time-weighted average of 85 decibels.
- Employees who are injured, exposed to blood or potentially infectious materials, or develop signs and symptoms indicative of possible overexposure to hazardous substances or health hazards (including radiation).
- Employees prior to and after being exposed to the following substances at or above the levels specified below.
- Employees who work with the following carcinogens:

Chemicals	CAS #	Percent
2-Acetylaminofluorene	53963	1.0
4-Aminodiphenyl	92671	0.1
bis-Chloromethyl ether	54288	10.1
Benzidine (and its salts)	92875	0.1
3,3'-Dichlorobenzidine (and its salts)	91941	1.0
4-Dimethylaminoazobenzene	60117	1.0
Ethyleneimine	151564	1.0
Methyl chloromethyl ether	107302	0.1
alpha-Naphthylamine	134327	1.0
beta-Naphthylamine	91598	0.1
4-Nitrobiphenyl	92933	0.1
N-Nitrosodimethylamine	62759	1.0
beta-Propiolactone	57578	1.0

9.1 Frequency of Medical Examinations

For all covered employees, the following examination schedule will apply:

- Initial examination prior to assignment (preplacement).
- Annually if the employee is to continue with the same type of assignments.
- At termination of employment if there has been no examination.
- At more frequent intervals if determined to be necessary by the examining physician.

In addition, employees covered who are subject to possible lead exposure, the following examination schedule will apply:

- At least monthly for each employee whose last blood sampling and analysis indicated a blood lead level at or above 40 up/100 gm of whole blood. This frequency will continue until tow consecutive blood samples and analyses indicate a blood lead level below 40 ug/100 gm of whole blood.

For employees covered who are subject to possible high noise levels, the following frequency of audiograms will be used:

- Initial audiogram (baseline) within 6 months of an employees first exposure at or above the action level (85 dBA 8-hour time-weighted average);
- Annually, if the employee will continue to be exposed above the action level.

For employees in overexposure situations, the following examination schedule will apply:

Chemical	Exposure Level Criteria for Medical Monitoring
Acrylonitrile	1 ppm, 8 hour TWA
Arsenic	5 ug/M^3, 8 hour TWA
Asbestos, actinolite, anthophyllite or tremolite	0.1 fibers/cm^3, 8 hour TWA 1.0 fibers/cm^3, 30 minute TWA
Cadmium	2.5 ug/m^3, 8 hour TWA, 30 or more days/year
Benzene	0.5 ppm, 30 or more days/year 1.0 ppm, 10 or more days/year
Ethylene Oxide	0.5 ppm 8 hour TWA
Formaldehyde	0.5 ppm 8 hour TWA 2.0 ppm, 15 minute period
Lead	30 ug/m^3 40 ug/100g blood
Methylenedianaline	5 ppb, 8 hour TWA 30 or more days/year dermal exposure 15 or more days/year
Vinyl Chloride	0.5 ppm, 8 hour TWA

- As soon as possible following the emergency incident or development of sign and symptoms;
- Future examinations at intervals determined to be necessary by the examining physician.

9.2 Medical Examination Content

Medical and work history and physical examination,
Audiogram,
Blood chemistry (SMAC24),
Blood serum (archived frozen),
CBC,
Chest X-Ray (PA & Lateral) (if required),
Drug screen,
EKG (optional),
Hepatitis B vaccination series (if required),
Pulmonary function test (Spirometry),
TB Test,
Tetanus vaccination (if required),
Urinalysis,
Visual acuity,
Other tests as directed by examining physician.

9.3 Examining Physician

The Local HS Official will designate a local, licensed physician, preferably one who is board-certified or knowledgeable in occupational medicine, to provide the necessary medical monitoring and emergency medical services. The Local HS Official will audit the medical clinic (i.e., onsite walk-through of the clinic) prior to approving. Audiometric examinations may be performed by a licensed or certified audiologist, otolaryngologist, or other physician, or by a technician certified by the Council of Accreditation in Occupational Hearing Conservation. Eye examinations may be performed by a licensed ophthalmologist.

Examination costs will be furnished by CRL without loss of pay to the employee. The examination will occur at a convenient time and place. Schedule and approval of examination will be by the Local HS Official upon approval from the Project Manager.

The Local HS Official will provide the following information to the physician:

- Description of employee's duties as they relate to employee's exposure;
- Information about employee's exposure level (e.g., industrial hygiene data) or anticipated exposure levels;
- Description of any personal protective equipment used or intended to be used;
- Information from previous medical exams that is not readily available to physician;
- Copies of the following standards required by OSHA to be sent to physician:

Title	Reference
Asbestos, Tremolite, Anthophyllite, Actinolite	29 CFR 1910.1001
Bloodborne Pathogens	29 CFR 1910.1030
Formaldehyde	29 CFR 1910.1048
Hazardous Waste Operations and HAZMAT	29 CFR 1910.120
Lead	29 CFR 1910.1025
Noise	29 CFR 1910.95

The physician will provide written examination results to the employee, including:

- Detected medical conditions that would interfere with the employee's health on the job;
- Detected medical conditions that would interfere with the employee's fitness for duty;
- Results of the complete medical examination;
- Conditions of the employee might have that require further examination or treatment, regardless of whether they are occupationally related.

The physician will provide written examination results to CRL, including:

- Statement to employer that the employee has received written results of the medical examination;
- Written final opinion on individual's fitness for duty, including any interpretation of results related to occupational exposures;
- Recommendation of any limitations on the employee or upon the use of personal protective equipment such as clothing or respirators;
- Results of complete medical examination;

- A comparison of the follow-up examination with the baseline and previous years examination results to determine if an abnormally or significant deviation exists, should this be the case the physician will notify employer.

All originals of medical files will be retained by the examining service provider or physician. Hard copies of all records will be forwarded to the Local HS Official and kept in locked or restricted files. Hard copies of dosimetry data as well as radiological, biological, and air sampling data will be stored with medical data in each employee's file.

All medical records will be maintained for each employee for the duration of employment plus 30 years, except for the following type of records:

- Health insurance claim records maintained separately from the medical program and its records;
- First aid records (OSHA Non-recordable);
- Radiation employees' medical records are to be kept for 75 years after termination exposure report (when occupational exposure is finished).

The minimum information required in the medical file includes:

- Name and social security number of the employee;
- Physician's written opinions, recommended limitations, and results of examination and tests;
- Any employee medical complaints related to exposure to hazardous substances;
- A copy of the information provided to the examining physician by the Local HS Official, with the exception of the OSHA standards and appendices.

Access to detailed medical records will be restricted to the Local HS Official, Corporate HS Manager, designated medical records personnel, and examining physicians. Supervision and administrative personnel will be given only summaries of general physical condition as they affect the employee's ability to work. All company maintained records will be kept in locked and restricted files.

Employees will have full access to their own medical files and will be given a copy upon written request. Additionally, the following individuals will also be allowed access:

- Employee's legal representative (if the employee is deceased or legally incapacitated);

- Designated representative of the employee; written permission, signed by the employee, must be presented to obtain medical records;

- Representatives of the Assistant Secretary of Labor; written permission, signed by the employee must be present to obtain medical records.

9.4 Work Related Injuries and Illnesses

In the event of a work-related injury or illness that cannot be handled with minor first-aid, the employee will be taken to a physician or hospital for treatment. The Local HS Official will be notified as soon as possible by the employees' supervisor and a report of the accident or incident will be filed with the Local HS Official and Worker's Compensation Carrier. All Worker's

Compensation First Report of Injury reports must be filed within five days and should include information on site conditions, personal protective equipment required or worn, chemical and/or physical hazards, other employees working on the site, notifications made, and unusual circumstances. The employee will return to work when released by the physician. The Project Manager will provide the Project Officer a written report of all work related injuries and illnesses within 2 days of any injury or suspected job-related illness.

10.0 Personal Protective Equipment (PPE)

Personal protective equipment includes devices and clothing designed to be worn or used for the protection or safety of an individual while in potentially hazardous areas of performing potentially hazardous operations.

To protect employees from potential hazards in the workplace, CRL will provide PPE appropriate to the task. The Local HS Official will assess the workplace to identify potential hazards which necessitate the use of PPE and advise employees on PPE required for an operation. Each project, through its Project Manager and supervisors, is responsible for obtaining the equipment and enforcing its use. Defective or damaged PPE shall not be used.

The Local HS Official evaluates operations/work areas to determine PPE requirements; ensures recommended PPE conforms to applicable standards (i.e., American National Standards Institute, National Institute for Occupational Safety and Health); maintains records of hazard assessment performed to identify PPE requirements; and provides training on PPE, requirements, use, limitations, proper care, maintenance, useful life, and disposal.

The Project Manager and supervisors ensure required PPE is readily available to employees working in areas of performing operations that require PPE for protection, enforce the mandatory use of PPE when required to protect employee health and safety, and ensure PPE is properly stored and maintained.

Employees are responsible for using, maintaining, and storing PPE in accordance with established procedure and instructions provided by the Project Manager, supervisors, or Local HS Official; reporting all problems associated with PPE (i.e., damaged, worn, or inadequate) to the supervisor or the Local HS Official; and not using damaged or defective PPE.

10.1 General Requirements for Personal Protective Equipment

OSHA regulation 29 CFR 1910.132 requires an assessment of each work place to determine if hazards are present, or are likely to be present, for which the use of personal protective equipment is needed.

Each employee who is required to use PPE is required to be trained and demonstrate the ability to use PPE properly. Training must cover when PPE is necessary, what PPE is necessary, how to don, doff, adjust, and wear PPE, limitations of the PPE, and proper care, maintenance, useful life, and disposal of the PPE. Restraining is required when changes in the workplace or types of PPE to be used render previous training obsolete, or if inadequacies in an employee's knowledge or use assigned PPE indicate that the employee has not retained the requisite understanding or skill.

CRL will provide required protective eye wear to employees working in areas which an employee could cause injury to himself or herself or to another employee (eye hazard area) or

performing tasks that present a potential for eye injury to the employee doing the task (eye hazard operations). The use of contact lenses is prohibited in any operation involving hazardous chemicals.

Eye protection equipment is used to prevent injury to the eyes from flying objects, hazardous chemicals, or injurious light rays. Such equipment includes safety glasses, chemical goggles, face shields, welding goggles, and welding face shields.

Safety glasses are prescription and non-prescription lenses and frames conforming to American National Standards Institute (ANSI) Z87.1-1989. Lenses of safety glasses are distinctly marked with the monogram of the manufacturer, and frames have an identification mark (Z87.1) on both the front and temples. CRL will provide all prescription safety glasses, as well as non-prescription safety glasses, goggles, and face shields.

The Local HS Official implements and administers the eye protection program, maintains technical data on eye protection to ensure it meets federal standards, and assists the Project Manager and supervisors in identifying eye hazard areas and operations and in selecting proper eye protection.

The Project Manager and supervisors identifies eye hazard areas and operations and solicits assistance from the Local HS Official, as necessary, to ensure selection of the property type of eye protection, enforces the use of eye protection in designated eye hazard areas and while employees perform designated eye hazard operations, ensure that employees are provided with appropriate eye protection and that eye protection is available for visitors to designated eye hazard areas, and ensures that all entrances into eye hazard areas are posted with a sign (i.e., CAUTION—Eye Hazard Area—Do Not Enter Without Eye Protection).

Full-time employees who are assigned to eye hazard areas or who as a regular part of their job perform eye hazard operations are eligible to obtain prescription safety glasses. The Project Manager and supervisors with the Local HS Official determine the need for and type of eye protection required.

10.2 Emergency Eyewash and Shower Equipment

Emergency eyewash and shower equipment meeting the requirements of ANSI Z358.1-1981 is provided in all areas where hazardous chemicals, which may be injurious to the eyes or skin, are used in such a manner that an employee's eyes or body may be exposed. This equipment will be located within the work area where it is easily accessible for emergency use.

Emergency showers and eyewashes located in CRL project areas will be tested monthly to flush the line and verify proper operation. A record of this inspection will be maintained on a card attached to the unit and will include the date and inspector's initials. The exception is self-contained eyewash equipment, which will be filled with a commercially available bacteriostatic additive; maintenance will be performed at intervals recommended by the manufacturer (e.g., every 6 months the unit will be drained and refilled).

10.3 Foot Protection

Employees performing tasks that pose a recognized foot injury hazard, such as handling equipment or working on construction, will be required to wear safety shoes. Safety shoes shall

conform to ANSI Z41-1991 with the inner lining of safety shoes stamped with the ANSI Z41 identification mark.

Safety shoes will be provided at no cost to the employee (within an established price limit) for those individuals determined to require foot protection. The Project Manager, supervisor, or Local HS Official provides information on the purchase of safety shoes. Lost or stolen safety shoes will be replaced at employee expense. Worn or damaged safety shoes will be replaced in accordance with CRL policy.

10.4 Hand Protection

Employees whose hands are exposed to hazards such as skin absorption of harmful substances, severe cuts or lacerations, severe abrasions, punctures, chemical burn, thermal burns, and harmful temperature extremes will be provided and required to wear appropriate hand protection. Appropriate protection (gloves) depends on the nature of the hazard. Available glove materials provide only limited protection against many chemicals. Before purchasing gloves, documentation should be requested from the manufacturer that show that the gloves meet appropriate test standards for the hazard(s) anticipated. For gloves used to protect against chemicals, test data for breakthrough times should be obtained to determine how long the glove can be used and if it can be reused. For use with mixtures, a glove should be selected on the basis of the chemical component with the shortest breakthrough time.

CRL will provide all disposable gloves required to protect CRL employees from potential exposure to hazards. The Project Manager and the Local HS Official will assist in identifying tasks for which hand protection is required, in selecting appropriate glove material(s) for the hazard(s) identified, and enforcing the proper use of protective gloves.

11.0 Safe Handling of Radioisotopes

CRL personnel working in areas with radioactive material and those accessing facilities where there is potential for an occupational does will comply with the requirements of the NIH Radiation And Safety Guide, even if this compliance is not mandated by regulation. It is the policy of CRL to ensure that all occupational doses are as low as reasonably achievable (ALARA) and do not exceed applicable limits. All individuals entering a restricted area will receive training on the risks of exposure to radiation consistent with their potential level of exposure.

CRL policy requires all personnel and organizations to ensure that:

- All releases of radioactive material are within applicable limits and permit requirements;
- Exposures to radiation are ALARA; and
- The generation of radioactive waste is minimized.

All CRL personnel, organizations, and subcontractors will comply with applicable environmental and emergency response regulations. This includes the implementation of the Superfund Reauthorization Act, Title 3, addressing Community Right to Know.

Proposed Project Schedule

As instructed by Article XX, Section (1)(a)(4) of the RFP, Charles River is providing a Proposed Performance Schedule for providing key contract deliverables and attaining key contract objectives during our initial year of performance. Monthly references are shown in terms of calendar months immediately following date of contract start, with "Month 1" representing the first 30-day period of performance.

Month 1

- Relocated and assemble new members of Professional and Technical staff;
- Process new-hire paperwork; administer drug testing, medical evaluations, etc. of all Project Staff;
- Conduct Orientation Training;
- Establish Advisory Committee;
- Conduct equipment inventory; Complete and submit Inventory Report;
- Initiate preparation of a Facilities Improvement and Upgrade Program and development of a related 3-year capital budget;
- Initiate modification/creation of required SOP's;
- Initiate development of an APF-specific OH&S Plan;
- Evaluate current programs for environmental enrichment and prevention of breeding;
- Initiate development of a Preventive Maintenance Program;
- Implement recommended facilities maintenance recommendations, as approved by the Government;
- Prepare and submit Emergency Telephone Roster;
- Recruit and hire Trainer;
- Effect purchase of equipment from incumbent contractor; and
- Request NIH to schedule first IACUC Meeting.

Month 2

- Prepare and submit Occupational Safety and Health Training Plan;
- Prepare and submit Initial Occupational Safety and Health Training Assurance Statement;
- Complete recommended Facilities Improvement and Upgrade Program and related Capital Budget; Submit to Project Officer for review and consideration;
- Continue modification/creation of required SOP's;
- Arrange for purchase of additional equipment upon receipt of Government approval;
- Complete evaluation of environmental enrichment and non-breeding programs; implement required modifications and document through SOP's;
- Begin full-scale implementation of Preventive Maintenance Program; and
- Undertake individual animal health assessments.

Month 3

- Begin scheduling and bid process for capital improvement projects;
- Complete modification/creation of required SOP's;

- Continue individual animal health assessments;
- Initiate first phase of Project Staff Training Program (other than previously provided OS&H and SOP-relating training);
- Arrange for quarterly Advisory Committee Meeting;
- Begin SBI-based pathology training for Professional Staff;
- Conduct first CRL QA/QC Audit; and
- Initiate Phase I of TQM Training.

Month 4

- Initiate capital improvement projects following Government approval of bid submissions;
- Assuming Government approval, effect move into modular office units;
- Begin AALAS Certification training programs for Project Staff;
- Initiate Archiving Project, assuming systems/technology transition satisfactorily completed in first 90 days of contract term;
- Complete individual animal health assessments and prepare comprehensive report; and
- Conduct CRL OS&H Audit.

Month 5

- Complete Phase I of capital improvements project;
- Continue archiving project;
- Conduct CRL Engineering/Maintenance Site Audit;
- Initiate Phase II of TQM Training; and
- Implement recommendations resulting from Month 4 OS&H Audit.

Month 6

- Complete Phase II (final phase) of capital improvements project;
- Implement recommendations resulting from Month 5 Engineering/Maintenance Site Audit;
- Complete and submit Major Alterations and Renovations Report;
- Arrange for quarterly Advisory Committee Meeting;
- Conduct second CRL QA/QC Audit;
- Continue archiving project; and
- Arrange for second [illegible] based training session.

Month 7

- Conduct semi-annual Procurement & Inventory audit to identify opportunities for cost reduction and improved inventory management;
- Complete Phase I of archiving project;
- Arrange for APF All-Hands Meeting and Employee Awards;
- Implement recommendations from Month 6 QA/QC Audit; and
- Conduct second session of AALAS Certification training programs for Project Staff.

Month 8

- Arrange for Biosecurity Audit and Site Visit;
- Begin Phase II of archiving project;
- Initiate preparation of contract Year 2 capital budget;
- Initiate Phase III of TQM Training;
- Conduct second OS&H Audit; and
- Implement recommendations resulting from Procurement & Inventory Audit.

Month 9

- Arrange for quarterly Advisory Committee Meeting;
- Complete first draft of contract Year 2 capital budget;
- Begin preparation of contract Year 2 operating budget;
- Conduct third CRL QA/QC Audit;
- Continue Phase II of archiving project;
- Identify and evaluate major equipment purchases in connection with preparation of Year 2 operating budget; and
- Begin implementation of recommendations resulting from Biosecurity Audit.

Month 10

- Implement recommendations resulting from Month 9 QA/QC Audit;
- Complete Phase II of archiving project;
- Submit proposed contract Year 2 capital budget to Project Officer for review and approval;
- Submit contract Year 2 operating budget to CRL Responsible Corporate Officer for review;
- Conduct second CRL Engineering/Maintenance Site Audit; and
- Identify new or significantly modified programmatic objectives for contract Year 2.

Month 11

- Advise Project Officer of any significant incremental cost items proposed in contract Year 2 operating budget;
- Implement recommendations resulting from Month 10 Engineering/Maintenance site audit;
- Review with Project Officer proposed programmatic objectives for contract Year 2;
- Conduct third session of AALAS Certification training programs for Project Staff; and
- Begin preparation of Annual Progress Report.

Month 12

- Arrange for quarterly Advisory Committee Meeting;
- Complete preparation of Annual Progress Report;
- Finalize programmatic objectives for contract Year 2;
- Finalize contract Year 2 operating budget; and
- Effect payments to Project Staff under established incentive programs.