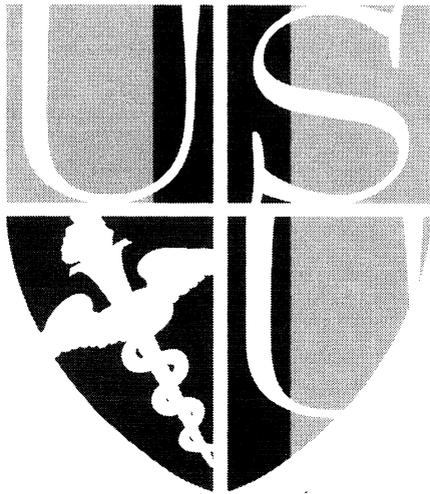


**USUHS
INSTRUCTION
3204**





UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES



SUBJECT: The Use of Animals in the Uniformed Services University of the Health Sciences

Instruction 3204

APR 29 1998

(LAM)

ABSTRACT

This Instruction implements the Department of Laboratory Animal Medicine (LAM) regulation governing the use of animals in the Uniformed Services University of the Health Sciences (USUHS). This Instruction incorporates information from the Department of Defense (DoD), the Code of Federal Regulations (CFR), and the National Institutes of Health (NIH) to provide guidance in carrying out these actions at the USUHS.

A. Reissuance and Purpose. This Instruction reissues USUHS Instruction 3204^a to:

1. Incorporate substantive procedural and administrative changes; and
2. Implement new guidelines from higher authorities and the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training"^b and the "Report of the AVMA Panel on Euthanasia"^c, which are necessary for accreditation of the USUHS animal care and use program.

B. References. *See Enclosure 1.*

C. Applicability. The contents of this Instruction apply to all members, contract employees and guests of the USUHS and its activities, as well as those individuals using animals in programs funded by the USUHS.

D. Definitions. *See Enclosure 2.*

E. Policy. It is the policy of USUHS that:

1. The "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training"^b; the "Report of the AVMA Panel on Euthanasia"^c; the Joint Regulation^d; Title 7, USC, Chapters 2131-2157^e; 9 CFR, Part 1-4^f; the "Guide for the Care and Use of Laboratory Animals"^g; the "PHS Policy on Humane Care and Use of Laboratory Animals"^h; and USUHS Instruction 6402-Mⁱ be followed in the care and use of animals at the USUHS;

2. Laboratory animals will be procured, maintained, and disposed of in compliance with this Instruction and Department of Laboratory Animal Medicine (LAM) Standard Operating Procedures (SOP);

3. All animals used within the USUHS will be housed in the USUHS Central Animal Facility or in specifically designated animal rooms. Animals will not be housed in laboratories or offices. Exceptions to this policy must be approved by the Director, LAM, with the concurrence of the USUHS Laboratory Animal Review Board (LARB);

4. All USUHS animal areas are designated "Restricted Areas" and are OFF LIMITS to unauthorized personnel. Tours of the Animal Facility must be approved, in advance, by either the Director, LAM; the Vice President, Teaching and Research Support (TRS); the Dean, School of Medicine (DEN); the President, USUHS, or their designated representative;

5. Private pets are prohibited throughout the USUHS complex, except in unusual emergency situations or for exceptional educational training purposes. These exceptions will be determined by the Director, LAM;

6. The principal point of contact within the USUHS for all matters pertaining to laboratory animals is the Director, LAM;

7. The LAM is responsible for the development and issuance of SOPs to implement provisions of this Instruction; and

8. Improper or deficient animal care and treatment will be reported by anyone observing or having knowledge of such actions. Any, or all, of the following individuals may appropriately be informed of perceived improprieties or deficiencies:

- a. supervisors within the involved administrative unit,
- b. the Director, LAM,
- c. the Chair or any member of the USUHS LARB,
- d. the Vice President, TRS,
- e. the Vice President, Research,
- f. the Dean, GSN,
- g. the DEN,
- h. the President, USUHS, or
- i. the USUHS animal advocate.

Persons receiving such information will assure anonymity of the reporting individual to the greatest extent possible. In all cases, the USUHS will ensure the individual freedom from reprisals of any type.

F. Responsibilities.

1. The Dean, School of Medicine shall:

- a. Review and approve the actions and recommendations of the LARB; and
- b. Periodically review the USUHS laboratory animal care and use program.

2. The Laboratory Animal Review Board shall:

- a. Review research and teaching protocols involving the use of laboratory animals;
- b. Recommend approval/disapproval of protocols to the DEN. In accordance with the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training"^b; Title 7, USC, Chapters 2131-2157^c; 9 CFR, Parts 1-4^f; the "Guide for the Care and Use of Laboratory Animals"^g; and the "PHS Policy on Humane Care and Use of Laboratory Animals"^h; LARB disapproval of animal use protocols may not be overridden by other USUHS officials;

- c. Conduct semiannual inspections of all animal study areas (i.e., animal holding areas, laboratories) and animal facilities, including reviews of all USUHS programs and practices relative to animal care and use;
- d. Review and make recommendations regarding a program of instruction/training in appropriate animal care and use for all investigators, research technicians, and other animal handlers; and
- e. Investigate all reported violations of United States Department of Agriculture (USDA) Regulations, in accordance with Title 7, USC, Chapters 2131-2157^e and 9 CFR, Parts 1-4^f.

3. The Chair, Laboratory Animal Review Board shall, if necessary, suspend any protocol in which procedures may violate humane treatment regulations, until a comprehensive study can be made by the LARB and DEN.

4. Department Chairs and Directors of Special Activities shall:

- a. Review and approve research and teaching protocols originating in their organization; and
- b. Coordinate all animal requirements of prospective staff members with the Director, LAM, prior to final recruitment action.

5. Principal Investigators or their Designated Representatives shall:

- a. Assure that animals are used and maintained in compliance with current regulations, to specifically include having considered non-animal alternatives and documented the non-availability or non-applicability of such alternatives;

b. Keep the number of companion animals used in research to a statistically significant minimum;

c. Directly supervise, through his/her physical presence, any painful animal procedure that must be conducted without the use of anesthetic, analgesic, or tranquilizer agents;

d. Care for and feed those laboratory animals requiring special handling or those involved in special studies with infectious, radioactive, or other known health hazard materials;

e. Ensure that casual observation of procedures being accomplished on laboratory animals in research laboratories is not possible from adjacent public areas, such as corridors;

f. Ensure that animals and animal-associated materials, such as soiled cages, are transported between research laboratories and the Central Animal Facility via the most direct route and only via one of the three freight elevators; and

g. Properly dispose of animals upon death or termination of a study, said disposition to include, but not be limited to, the following:

- (1) return animals to LAM for reuse when appropriate,
- (2) perform euthanasia in accordance with the "Report of the AVMA Panel on Euthanasia"^g,
- (3) provide LAM with the animal's cage card and/or SF Form 600, delineating method, dose, route and name of agent used for euthanasia,
- (4) return for necropsy,
- (5) render harmless, by sterilization, chemical degradation, or other USUHS approved procedure, those carcasses where potential pathogens, hazardous materials, or radiation are involved, or

(6) appropriately package carcasses, to include labeling and refrigeration, to minimize exposure of personnel responsible for further processing.

6. The Department, Laboratory Animal Medicine shall:

- a. Provide quality animals for teaching and research through proper management of animal procurement, quarantine, and maintenance programs;
- b. Maintain a professional and technical staff to administer veterinary medical care and provide consultation with regard to experimental animals used at the USUHS;
- c. Develop and implement instructional/training material and programs to advise and instruct investigators, technicians, and other personnel on procedures involving the use, treatment, handling, restraint, and care of experimental animals in accordance with all current regulatory requirements;
- d. Monitor procedures involving laboratory animals. Where procedures may violate humane treatment regulations, the Director, LAM will have the authority to suspend any procedure until reviewed by the LARB and DEN;
- e. Maintain a staff of trained animal caretaker personnel to provide routine care of all animals held at the USUHS;

f. Provide and maintain all animal care equipment (i.e., racks, cages, auxiliary supplies) and diet materials to support the animal holding requirements of approved programs;

g. Determine the number and mix of animals that may be allowed within all areas of the USUHS;

h. Assist investigators in maintaining animals in chronic experiments, excluding extensive treatment or special care required by the protocol;

i. Notify investigators when animals in chronic experiments require treatment;

j. Provide and maintain adequate surgical, clinical, laboratory, and necropsy facilities to accommodate protocol requirements and emergency needs;

k. Advise the USUHS administration on all matters of laboratory animal medicine and zoonotic disease control;

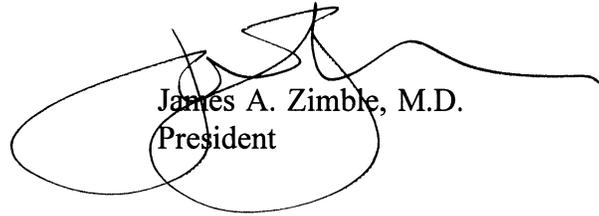
l. Assure compliance with all applicable regulations regarding the use of laboratory and exotic animals;

m. Provide or participate in training programs in the care and use of laboratory animals presented for USUHS personnel. However, it is recognized, that courses for medical or graduate students will only be accomplished through an academic department; and

G. Forms. *See Enclosure 3.*

I. Animal Use Procedures. *See Enclosure 5.*

H. Animal Use Approval. *See Enclosure 4.*



James A. Zimble, M.D.
President

Enclosures:

1. References
2. Definitions
3. Forms
4. Animal Use Approval
5. Animal Use Procedures

REFERENCES

- (a) USUHS Instruction 3204, "Supplement to Uniformed Services University of the Health Sciences (USUHS) Instruction 3203, The Use of Animals in DoD Programs," dated October 23, 1989 (hereby cancelled)
- (b) "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training," in the "Public Health Service Policy on Humane Care and Use of Laboratory Animals," dated September 1986
- (c) American Veterinary Medical Association (AVMA), "1993 Report of the AVMA Panel on Euthanasia," Journal of the American Veterinary Medical Association, Vol 202 (2): 229-249
- (d) Joint Regulation, AR 70-18, SECNAVINST 3900.38B, AFR 169-2, DARPAINST 18, DNAINST 3216.1B, USUHS Instruction 3203, "The Use of Animals in DoD Programs," dated June 1, 1984
- (e) Title 7, United States Code, Chapters 2131-2157, "Animal Welfare Act," as amended by the Food Security Act of 1985 (Public Law 99-198)
- (f) 9 Code of Federal Regulations, Parts 1-4, "Animal Welfare Regulations"
- (g) "Guide for the Care and Use of Laboratory Animals," National Academy Press, dated 1996
- (h) "Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals," dated March 1996
- (i) USUHS Instruction 6402-M, "Radiation Safety Guide," dated September 12, 1989

DEFINITIONS

Since each federal regulation has its own definition of animal, the DoD definition (approved by the Tri-Service Working Group) has been adopted for use in this Instruction and is as follows:

Laboratory animal is defined as a vertebrate animal other than human, regardless of species, used in support of biomedical research, testing, experimentation, exhibition, or teaching.

For the purpose of this Instruction, Animal handler is defined as any person who handles animals or animal tissues on a regular basis.

FORMS

The following forms can be found in Laboratory Animal Medicine:

1. USUHS Form 6053, "LAM Animal Transfer Request"
2. SF Form 600, "Chronological Record of Medical Care"

The following form can be found in Research Administration:

PHS Form 398, "PHS Grant Application Packet"

The following forms can be found in Research Administration or on the web page at **www.usuhs.mil/research/dnform.html**.

1. USUHS Form 3206, "Animal Study Form"
2. USUHS Form 3206B, "Modification to Animal Study Protocol"
3. USUHS Form 3208, "Assurance Supplement Form"

ANIMAL USE APPROVAL

A. LABORATORY ANIMAL REVIEW BOARD

1. All activities requiring the use of laboratory animals will be reviewed by the LARB. At a minimum, the Board will be composed of not less than five members appointed by the DEN, and will include the Director, LAM, or a veterinarian designated by him/her; a graduate student; a non-scientist; and at least two non-USUHS affiliated federal employees. The graduate student will be nominated by his/her Department Chair and will serve with the approval of the Chair, LARB. The graduate student has the option to refuse this committee assignment without jeopardy.

2. Problems relative to the animal care and use program may be referred to the LARB for review and adjudication. If the Board cannot work out solutions satisfactory to all parties, the problem, along with the Board's recommendations, will be referred to the DEN.

3. LAM will not house or issue laboratory animals to investigators/instructors unless a protocol for use of the animals has been approved by the LARB. Animals to be used for instructional purposes must be covered by a protocol.

4. The LARB as an agent of the USUHS shall:

a. Review, at least once every six months, the USUHS' program for humane

care and use of animals, using 9 CFR, Parts 1-4^f as a basis for evaluation;

b. Inspect, at least once every six months, all of the USUHS animal facilities, including animal study areas, using 9 CFR, Parts 1-4^f as a basis for evaluation;

c. Prepare reports of the evaluations that were conducted and submit them to the DEN and other appropriate agencies, as required (i.e., the Office for Protection from Research Risks [OPRR], NIH, and USDA);

d. Review all protocols involving animals to determine that the proposed protocols are in accordance with all applicable laws and regulations. These reviews shall be conducted not less than annually. The protocols to be reviewed include all:

(1) new protocols,
(2) animal-related contract proposals submitted to the USUHS,
(3) animal-related collaborative research efforts, and
(4) animal use training protocols;

e. Recommend approval, disapproval, or modification of each work unit or proposal to the DEN;

f. Suspend an activity that has been previously approved, if it is determined that the activity is not conducted in accordance with the description of that activity as provided by the work unit and approved by the LARB;

g. Ensure that all scientists, research technicians, animal caretakers, and

other personnel involved in animal care, treatment, and use are qualified to perform their duties through the provision of training and instruction to these personnel;

h. Maintain an official record of all LARB meetings and reports that will be signed by the LARB Chair, Executive Secretary, and appropriate members, then approved by the DEN. These records will be maintained for at least three years. All records that relate directly to an activity will be maintained for the duration of the activity and for an additional three years after completion of the activity; and

i. Investigate alleged violations of humane standards, regulations, or policies, according to the following procedures:

(1) any personnel discovering violations of humane animal treatment standards or other misuse/abuse of laboratory animals will immediately notify, verbally or in writing, the Chair, LARB or other USUHS officials. The anonymity of the reporting individual, if so desired, will be maintained. There will be no adverse action whatsoever taken or implied against the individual making the initial report,

(2) the reporting individual will provide, within 24 hours of the incident, a written report detailing the specifics of the suspected violation. This report will be furnished to the Chair, LARB and the Director, LAM,

(3) upon initial notification of the alleged violation, the Chair, LARB or the Director, LAM will immediately investigate the violation and, if indicated, terminate the procedure and institute whatever actions are necessary to ensure the welfare of the animal(s) involved,

(4) a LARB quorum will meet before the end of the next work day to

conduct an initial review of the alleged violation,

(5) additional meetings will be held as needed to complete the review and formulate recommendations to the DEN, and

(6) within seven working days from receipt of the initial report, the LARB will submit the following to the DEN:

(a) a full report describing the incident and all LARB deliberations on the case,

(b) a summary statement indicating the outcome of the investigation and a recommendation on the appropriate course of action, and

(c) a draft document for the signature of the DEN, to the principals involved, describing the outcome and course of action to be taken.

B. PROTOCOL REQUIREMENTS

The DoD standardized protocol format will be submitted for all projects using animals. In all cases, protocols must include the species and number of animals used, the rationale for involving animals, the appropriateness of the species and numbers of animals to be used, and a complete description of the proposed use of the animals. It must also address the use of anesthetics, analgesics, or tranquilizers, as appropriate, to minimize pain and discomfort of the animals, or give the rationale for not using these classes of drugs in experiments likely to cause pain or discomfort. The protocol must also provide a description of any euthanasia method used.

1. Research Protocols. All research protocols requesting NIH funding will be submitted on PHS Form 398, with

appropriate USUHS supplements (USUHS Forms 3206 and 3208). The protocol must contain detailed information on the proposed experiment, including USUHS Form 3206 and annually listing all species proposed for use during the period covered by the protocol. A sample statement that may be used for Section 1 of PHS Form 398 is provided.

2. Teaching Protocols. Protocols for teaching demonstrations and student laboratories will be prepared using USUHS Form 3206.

3. Submission of Protocols. All research protocols will initially be submitted to the Office of Research (REA). The REA will assign a USUHS control number, and forward a copy to the Director, LAM. Teaching and/or training protocols will be submitted to the Director, LAM. After assigning a USUHS control number for the training protocol, the Director, LAM will distribute copies of this protocol to LARB members for review. If a primary investigator/instructor requires an expedited protocol review, a written request to expedite that protocol must be submitted to REA for research protocols or to the Director, LAM for teaching/training protocols.

4. In conducting protocol reviews, and in accordance with the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training"^b; Joint Regulation^d; Title 7, USC, Chapters 2131-2157^e; 9 CFR, Parts 1-4^f; the "Guide for the Care and Use of Laboratory Animals"^g; and the "PHS Policy on Humane Care and

Use of Laboratory Animals"^h; the LARB will consider at a minimum whether the following requirements are met:

a. The principal investigator (PI) has provided written assurance that the activities do not unnecessarily duplicate previous experiments;

b. The information sought by the use of animals is sufficiently important to warrant their use;

c. The design of the experiment, procedure, or demonstration is adequate to provide valid scientific data;

d. The maximum amount of information consistent with good scientific research practice is obtained;

e. The minimum number of animals needed for scientific validity is used;

f. The animal model selected is the most suitable, based on consideration of the experimental design, potential alternatives, and laboratory limits;

g. The use of drugs to minimize pain or discomfort is adequate;

h. The procedures involving animals will avoid or minimize discomfort, distress, and pain to the animals. If procedures cause more than momentary or slight pain or distress, they will:

(1) be performed with appropriate sedatives, analgesics, or anesthetics, unless withholding such agents is scientifically justified in writing by the PI,

(2) involve and consult with a LAM veterinarian during their planning, and

(3) not include use of paralytic agents without general anesthesia;

i. Animals that experience severe or chronic pain or distress that cannot be

relieved will be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure;

j. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures;

k. Major survival surgical procedures conducted on nonrodent and rodent animals will:

(1) include appropriate provisions for preoperative and postoperative care of the animals in accordance with appropriate veterinary medical practices,

(2) be performed using aseptic procedures, instruments, techniques, and equipment,

(3) be conducted in facilities intended for this purpose, in the case of nonrodent animals. Surgeries performed on rodents typically require limited, contained work space, and therefore can be performed in a dedicated area of the investigator's laboratory using aseptic procedures and techniques, and

(4) not be used in more than one major survival surgical procedure from which it is allowed to recover unless:

(a) scientifically justified in writing by the PI, and

(b) required as routine veterinary procedures or to protect the health or well-being of the animals as determined by a LAM veterinarian;

l. Methods of euthanasia used are in accordance with applicable federal regulations;

m. Established policies on the care and use of animals are complied with; and

n. The number of animals, use rate, and length of stay should be stated as accurately as possible to facilitate planning of animal space requirements to LAM. All animal use protocols will be reviewed by the Director, LAM, or his designee.

5. Research protocols that do not meet the above cited requirements may be approved by the LARB contingent upon specific changes being made as recommended by the Board, or may be returned to the responsible investigator with advice on deficiencies requiring correction before resubmission.

6. In all deliberations and review of protocols, the LARB will consider the aspects of animal experimentation commonly referred to as the "Four R's": Replacement of live animals with non-sentient material; Reduction of the number of live animals used; Refinement of techniques to minimize distress and/or pain in animals; and Responsibility of all personnel involved in the use and care of animals.

7. The LARB will encourage, wherever possible, and in accordance with applicable animal welfare guidelines, re-use of animals independent of the initial investigation.

8. The LARB will provide written notification to investigators of its decision relative to approval, required modification, or disapproval of protocols involving animal use. For NIH/PHS supported animal use proposals, the Executive

Secretary, LARB will provide REA with a letter of verification that the LARB has reviewed and approved the animal care and use sections of such proposals. Suspension of PHS-funded animal activities will be reported to OPRR, along with a full explanation of the reasons for the suspension, and a review of the proceedings and corrective action taken.

9. The LARB will be responsible for approval of minor and major modifications to animal protocols. A minor modification will be submitted in written memorandum format to the Executive Secretary, LARB. Temporary approval of the minor modification may be granted to the PI pending final approval by the LARB. Major modifications are submitted through REA on USUHS Form 3206B. A listing of Protocol Modifications is attached.

10. Noncompliance with LARB decisions will be handled in the following manner:

a. Noncompliance with LARB policies, requests, and recommendations regarding animal protocols, and other LARB matters related to animal care and use, shall result in suspension of the activity in question;

b. The LARB will convene a meeting of a quorum of the LARB members to review the noncompliance. A majority vote in favor of suspension will be sufficient to stop any animal-related function of this activity; and

c. The suspension of an activity requires that the LARB notify the DEN in writing. In consultation with the DEN, the LARB will review the reasons for suspension, take appropriate corrective action and report that action with a full explanation to the appropriate federal official(s) and funding agent(s).

C. MANUSCRIPTS, ABSTRACTS, AND SPEECHES

Laboratory Animal Use Statement

Manuscripts, abstracts, or speeches reporting investigations using laboratory animals will include a footnote that will say, "The experiments reported herein were conducted according to the principles set forth in the "Guide for the Care and Use of Laboratory Animals," Institute of Laboratory Animal Resources, National Research Council, 1996." This statement will also be included as a paragraph in the cover letter (including those transmitting abstracts), when appropriate. Where there is insufficient space within the text area on abstract forms, this statement will be put on the form in some manner, such as a footnote.

Attachment:
Listing of Protocol Modifications

Protocol Modifications

Minor modifications (submitted to Executive Secretary, LARB in written memorandum) may include any one of the following changes:

- A moderate increase in the numbers of animals
- Change in personnel, such as technicians or co-investigators
- Change in euthanasia procedure
- Providing tissue from euthanized animals to others not listed in protocol
- Transfer of same animal species/strain from one investigator's approved protocol to another approved protocol of the same investigator, as long as there is no increase in the pain category
- Transfer of same animal species/strain from one investigator's approved protocol to another investigator's approved protocol, as long as there is no increase in the pain category
- Minor procedural change (i.e. additional or change in anesthetic/analgesic agent) or minor experimental design change that is similar to design already approved

Major modifications (submitted to Office of Research on USUHS Form 3206B) may include any one of the following changes:

- Change in the objectives of the original research
- Change in nonsurvival vs. survival surgery
- Change in pain category to more painful category
- Change in species or change in strain/breed of animal
- Significant procedural change
- Addition of invasive procedure
- Change in protocol PI
- Withdrawal of analgesia, anesthesia, or antibiotics

ANIMAL USE PROCEDURES

A. PROCUREMENT, REQUISITION, AND ISSUE OF ANIMALS AND EQUIPMENT

1. Animals

a. LAM will initiate procurement of all animals.

b. No animals will be brought into the USUHS facilities from any source (e.g., from another Washington area federal laboratory, a staff member's previous place of employment, or others) without prior approval from Director, LAM.

c. In-house breeding and production of animals will be kept to a minimum within the USUHS facilities. For this reason, requests for animals will be initiated as far in advance of need as possible.

d. Laboratory animals will be delivered to the requester in accordance with information entered into the computer ordering system for approval and purchase through LAM.

e. The procurement and issuance of laboratory animals will depend on the availability of adequate animal holding space, as determined by the Director, LAM.

f. Laboratory animals are Government property and may not be converted to private use. Exceptions may be made by the Director, LAM where disposal is necessary and other Government facilities do not require the animals.

2. Animal Blood or Tissue

a. Requests for fresh animal blood will be submitted to LAM on the computer

ordering system 14 days in advance of actual needs. The requester may be asked to supply blood collection equipment.

b. Requests for fresh animal tissues will be submitted to LAM on the computer ordering system as far in advance as required for procurement of the species of animal involved.

c. Requests for commercially available animal blood, tissues, and preserved specimens need not be submitted through LAM.

3. Caging and Maintenance Equipment and Supplies

a. All animal caging will be procured by LAM. Requests for animal caging and maintenance equipment will be submitted to LAM by memorandum. Requests for special cages or equipment should include detailed specifications and justifications. If requests for equipment cannot be fulfilled with in-house resources, LAM will initiate steps to request the required equipment from nearby institutes.

b. LAM will maintain and issue routine animal handling equipment (e.g., primate handler's gloves) and expendable supplies (e.g., animal feed and bedding).

B. CARE, USE, AND HOUSING OF ANIMALS

1. Feeding and Watering

All laboratory animals will have continuous access to potable water and will be fed daily on a regular schedule, according to their particular requirements,

except as dictated by experimental design or veterinary therapy.

2. Caging and Housing

a. Rooms in which animals are housed will be adequately illuminated and ventilated. The temperature will be maintained within acceptable limits for the respective species.

b. Animal rooms will not be crowded beyond the capabilities of the air conditioning or ventilation system. The use of laminar flow racks, Horsfal units, or other heat-generating equipment may limit the number of animals permitted per room.

c. The number of animals per room will be limited to permit effective sanitary maintenance and servicing.

d. Nonhuman primates will be maintained under conditions that promote their psychological well-being, in accordance with 9 CFR, Parts 1-4^f.

e. Dogs will be provided the opportunity for adequate exercise, as determined by the Director, LAM in accordance with 9 CFR, Parts 1-4^f.

f. Animal rooms will not be used as laboratories or offices. Research equipment and supplies will not be stored in rooms housing animals, unless approved by the Director, LAM.

g. Holding/restraining chairs and devices will be used only when the nature of the experiment requires such use. Restrained animals will be examined frequently throughout the experiment to ensure early detection of any problem arising from the restraints. Experiments may be suspended by the Director, LAM if it is determined that restraint equipment is being used improperly; suspension will remain in effect until such time as proper

restraint can be demonstrated to the Director, LAM.

3. Animal Records and Identification

Accurate records are critical to the efficient management of laboratory animal programs. Appropriate records will permit maximum utilization of available resources, accurate budgetary estimates, and compliance with various reporting requirements. The maintenance of detailed clinical and medical procedures for animal records and methods for identification are the responsibility of LAM. Records will be maintained three years after final disposition of animal, or three years after completion of the research protocol to which that animal was assigned, **whichever occurs last.**

4. Care of Laboratory Animals

a. Projects involving live animals must be performed by or under the direct supervision of a qualified investigator/instructor.

b. Anesthetic, analgesic, or tranquilizing drugs will be used to minimize pain and discomfort when any animal would experience pain levels above that inflicted by normal injection procedures (e.g., anytime the skin is incised). LAM will provide guidelines and consultation concerning appropriate use of these drugs. Any exceptions to the use of drugs for relief of pain or discomfort must be fully justified in an approved protocol.

c. Muscle relaxants or paralytic drugs (e.g., succinylcholine or other curariform drugs) will not be used alone for restraint or surgical procedures. Such drugs will only be used in conjunction with drugs known to produce adequate

analgesia. The criteria for monitoring the level of anesthesia must be detailed in the research proposal.

d. Experimental procedures involving induced pain or distress whereby the use of anesthetics, analgesics, or tranquilizers would defeat the purpose of the experiments require a detailed explanation paragraph in the proposal and specific approval by the LARB and must be directly supervised by the responsible investigator, or by a designated representative.

e. Major survival surgery on all nonrodent vertebrate species will be performed in accordance with acceptable aseptic hospital/surgical practices and guidelines established by LAM. Major survival surgery is defined by the USDA as any surgical intervention that penetrates and exposes a body cavity or any surgical procedure that produces a permanent impairment of physical or physiological function. Only one major survival surgery will be performed on an individual animal, unless multiple procedures are required as components of a single research project and such multiple use is specifically approved by the LARB.

f. Preoperative and postoperative care of animals is the responsibility of the PI who will request professional veterinary care, when and if appropriate. Every effort will be made to minimize discomfort to the animal during convalescence, in accordance with acceptable hospital practice.

g. Care and treatment of animals will comply with established policies, SOPs, federal regulations, and good laboratory practices (GLPs).

5. Euthanasia of Animals

a. Euthanasia of animals will be performed in a humane manner by methods that produce rapid unconsciousness and subsequent death, without visible evidence of pain or distress, or a method that utilizes anesthesia produced by an agent that causes painless loss of consciousness and subsequent death. Euthanasia methods must be in accordance with the "Report of the AVMA Panel on Euthanasia"^c and approved by the USUHS LARB.

b. LAM will provide facilities for euthanasia of animals and, by prior arrangements, will perform euthanasia on excess or used animals if no other disposition can be arranged by LAM.

6. Disposal of Animals and Animal Waste

a. Live Animals. Animals that are suitable for use in additional experiments will be returned to LAM for disposition. Per diem will be charged to the donor PI for up to 60 days or until a suitable recipient for transfer is located. All animal transfers will require a completed USUHS Form 6053 be submitted to the Director, LAM. Detailed and updated records will be returned with the animals describing the experimental procedures to which the animals were subjected.

b. Animal Carcasses. LAM will be responsible for the disposal of all animal carcasses. Investigators and instructors are responsible for returning animal carcasses to LAM for disposal. The Director, LAM has established and distributed procedures for packaging animal carcasses. All packages containing carcasses destined for necropsy will be labeled appropriately, and placed in the LAM necropsy refrigerator.

c. Unexpected Deaths. Animals found dead unexpectedly will be handled in accordance with procedures established by LAM, in cooperation with the individual investigators.

d. Animal Bedding and Waste. LAM is responsible for disposing of all animal waste and used bedding material. Individual investigators and instructors are responsible for returning the material to LAM for disposal. The Director, LAM has established procedures for packaging animal waste and used bedding material. Packages containing potentially dangerous material will be labeled with appropriate hazard labels.

7. Shipment of Animals

All shipment of animals must be coordinated through LAM. LAM will ensure that animals are transported in accordance with applicable federal, state, and military regulations, and will provide health certificates and appropriate veterinary medical health examinations.

8. Animal Charges and Per Diem Expenses

a. Actual costs of animals, including transportation charges, will be billed directly to the protocol or cost code indicated on the purchase request.

b. Payments for the purchase of animals will be made by either the USUHS or by the HMJF directly to the supplier. Transfer of funds will **not** be from any other source to the supplier.

c. Per diem fees will be charged for animals maintained at the USUHS. The fee schedule is updated annually. Copies of the current schedule may be obtained from LAM or REA.

d. Charges incurred on one protocol normally may not be charged to another protocol. However, PIs may "transfer" charges from one protocol to another, provided the following criteria are met:

- (1) The animals are to be used under the approved receiving protocol;
- (2) The "transfer" is within the scope of the animal protocols involved;
- (3) Funds are available; and
- (4) The request is made in writing, to REA outlining the details.

9. Host Facilities

a. All equipment, animal space allocations, and animal care supervision will be under the control of the host facilities supporting USUHS programs (e.g., at AFIP, AFRRRI, NIH).

b. Animal care costs will be charged in accordance with the agreement between the host facility and the USUHS.

10. USUHS Barrier Facilities

a. Only authorized personnel will be allowed into the barrier facilities.

b. Once any animal leaves the barrier facility it will not be allowed to re-enter the barrier.

c. All animal husbandry procedures performed within the barrier facility will be performed in accordance with the LAM SOPs.

C. SAFETY

1. General

a. The maintenance of high standards of personal cleanliness among persons associated with research animals is mandatory.

b. Personnel will not eat, drink, smoke, or apply make-up or lip balm in areas where animals are located, the necropsy facility, or radioactive areas.

c. All laboratory animals are potentially dangerous in some aspect or another. Larger species may inflict serious bite and scratch wounds while small rodents may cause painful although less serious wounds. All species may transmit zoonotic diseases to persons contacting the animals, their tissues and/or waste products, or contaminated bedding and caging equipment. Some of these diseases may be fatal to humans. For these reasons, persons handling research animals must take every precaution to minimize the physical and disease dangers posed by the animals while simultaneously protecting the well-being of the animals and minimizing the effect of handling on measurements taken during the study.

d. Normally, only experienced animal handlers will transfer, restrain, or handle research animals. Persons not experienced with a certain species will not handle that species. Persons being taught to handle animals may accomplish "hands-on" practice only under the direct supervision of an experienced animal handler.

e. Appropriate protective clothing will be worn by all animal handlers.

f. LAM is responsible for establishment of handling procedures for all animal species used by USUHS personnel.

g. Equipment and supplies normally will not be stored in corridors within the animal facility. The exceptions are corridors G and H, which are designated storage areas.

h. Animals will not be removed from the USUHS without the express approval of the Director, LAM. The animal tracking and accounting system used by LAM requires this for record keeping purposes.

2. Bites, Scratches, and Injuries

a. All bites, scratches, and injuries will be reported immediately to the person's supervisor and responsible Department Chair/Activity Head.

NOTE: Inanimate objects, such as cages, may transmit zoonotic diseases.

b. Emergency and follow-up treatment will be provided in accordance with appropriate procedures as specified by Environmental Health and Occupational Safety (EHS), the Division of Occupational Medicine, and LAM.

c. After arranging for treatment as described above, the Department Chair/Activity Head will notify LAM and arrange for examining and managing of the animal(s) involved.

d. LAM will notify the treating physician of any special disease hazards associated with that particular animal.

e. The Department Chair/Activity Head will then notify the Director, EHS who will investigate the circumstances involving the incident. The Director, EHS will submit a written report of the findings to the Department Chair/Activity Head, with a copy to Director, LAM.

f. All Civil Service personnel who are injured during the performance of their duties will process the necessary Accident Report forms, including CA-1 and CA-2, with Civilian Human Resources (CHR).

3. Occupational Health and Safety

a. The occupational health and safety procedures for LAM personnel and other animal handlers will be developed by EHS and LAM. Additional job-specific training will be provided where applicable.

b. Participation in the USUHS Occupational Health and Safety Program is mandatory for all personnel who have substantial animal contact.

c. Pre-placement physical exams will be given to all employees who are potential animal handlers, in accordance with current EHS operating procedures. This will include vision and hearing screening, baseline serum screening (SMAC), and chest radiograph. Women of childbearing age will have serum toxoplasmosis titer evaluation. All personnel will have serum measles and Q Fever (*Coxiella brunetti*) titer evaluation. USUHS employees' expenses will be borne by the USUHS. LAM HMJF employees costs will be borne by the HMJF. Grant Foundation employee costs will be charged against the grant; such costs will be included in the grant application.

d. An immunization schedule will be adopted. All animal care personnel will be immunized against tetanus. In addition, an opportunity for protection by preexposure immunization will be afforded to people who handle animals at substantial risk of infection with rabies virus or hepatitis B virus. A rabies titer of 1:50 is considered protective; if titers are below this level, the person will be offered immunization with human diploid vaccine.

e. Female laboratory personnel, upon learning of their pregnancy, will inform the immediate supervisor who will,

in turn, inform EHS. EHS will evaluate the employee's work environment for any potential hazards to the employee and the pregnancy. Health information concerning the effects of radiation on pregnancy are covered in USUHS Instruction 6402-Mⁱ.

f. When nonhuman primates are housed at the USUHS, occupational health exams and monitoring will be based on current Centers for Disease Control (CDC) guidelines and current federal regulations.

D. TRAINING

1. Animal Care Technicians

LAM will establish and supervise a continuous in-house training program for all animal care technicians. Teaching resources in the Washington, D.C. area may be used in this program (e.g., NIH, WRAIR). Classes and instruction may be conducted during normal duty hours.

2. Investigators, Research Technicians, and Non-LAM Animal Handlers

a. All personnel involved in the care and use of animals should be qualified to perform their duties.

b. The LARB, through LAM, should make available training and instruction to these personnel to provide guidance in the following areas:

(1) Humane methods of animal maintenance and experimentation, to include the following:

(a) the basic needs of each species of animal,

(b) proper handling and care for the various species of animals used by the facility,

(c) proper pre- and post-procedural care of animals, and

(d) aseptic surgical methods and procedures;

(2) The concept of nonanimal alternatives to limit the use of animals;

(3) Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used in the facility;

(4) Methods whereby deficiencies in animal care, use, and treatment are reported; and

(5) Utilization of services available to provide information:

(a) on appropriate methods of animal care and use,

(b) on alternatives to the use of live animals in research,

(c) that could prevent unintended and unnecessary duplication of research involving animals, and

(d) regarding the intent and requirements of Title 7, USC, Chapters 2131-2157^e.

c. Species-specific, "hands-on" training sessions will be provided by LAM.

d. Attendance at one general instructional or training session will be required of all new investigators, instructors, technicians, and other personnel

involved with the use and care of animals. Species-specific sessions will be optional, although participation by new personnel will be strongly encouraged.

3. Medical Students, Graduate Students, and Professional Staff

LAM will develop instructional material and/or programs for presentation to medical students, graduate students, or professional staff personnel on an as needed basis. Courses for medical or graduate students will only be accomplished through an academic department. Subject matter may include, but is not limited to, experimental animal techniques, laboratory animal handling and care, zoonoses, and comparative medicine. Material presented as part of an existing approved animal use training course will be reviewed by the Director, LAM and the appropriate Department Chair/Activity Head. Material prepared as a new and separate course will be submitted through the appropriate curriculum review/ approval procedures. Material to be presented in an optional "seminar" format will be reviewed by the Director, LAM.