Program Description
Animal Care and Use Program

Veterinary Medical Unit

Central Arkansas Veterans Healthcare System, Department of Veterans Affairs

Research Service
4300 W. 7th Street
Little Rock, Arkansas 72205

April 1, 2019

For
AAALAC International

Table of Contents

Appendices

Program Description

Instructions for Completing and Submitting the Program Description for the Institutional Animal Care and Use Program

Section 1. Introduction

A. State the name of the program unit and, if applicable, its parent organization. List all organizations (schools, centers, etc.) included within the program unit.

Veterinary Medical Unit, Central Arkansas Veterans Healthcare System, Little Rock, Arkansas

B. Give a brief overview of the institution, its purpose and how the animal care and use program relates to the mission of the institution.

It is a policy of the Department of Veterans Affairs to encourage and support research that holds the promise of benefiting veterans and is scientifically sound. Such research attracts bright, capable and experienced physicians and scientists to VA medical centers, thus benefiting the veteran population directly. Animal research contributes immeasurably to advancements in medical science. The use of animals in research provides hope for veterans suffering from diseases that currently lack cures or effective treatments. Yet the use of animals in research must be examined with the understanding that such research is conducted according to the highest ethical and legal standards. Animal experiments should be undertaken after consideration of their relevance for human health and the advancement of knowledge. Only research that can be translated from animals to humans and improve human health should be permitted. The fewest number of animals should be utilized to achieve the scientific goals with the least sentient species being used. The least painful procedures needed to meet the research aims should be used with reasonable measures in place to minimize pain and distress. Moreover, the best possible living conditions need to be maintained for animals kept for research. Animal care needs to be supervised by a veterinarian experienced in laboratory medicine. Housing needs to ensure that the general health of the animals is safeguarded, and that undue stress is avoided. The environment needs to be closely monitored, with attention paid to temperature, ventilation and humidity.

The personnel working with the animals need to have the appropriate training, qualifications, and experience. Without these important basic standards being met, any results from the animal experiments would be questionable. The animal care and use program at the Central Arkansas Veterans Healthcare System (CAVHS) is in place to ensure that these standards are met.

The animal care and use program provides services relating to acquisition, maintenance, and monitoring of all animal subjects and their environment. These services include providing stability and reliability before and throughout each animal model-based

investigation, physical facilities that conform with pertinent animal welfare regulations, standards, and policies to meet the scientific needs for the biomedical activities involving the animal models, the medical and surgical care for all animal subjects, and professional and technical guidance for planning and executing the design of each animal experiment.

The Veterinary Medical Unit (VMU) at CAVHS is an integral support service for basic and clinical biomedical research programs at CAVHS. The VMU has responsibility for ensuring that all animals used in the research programs are maintained in accordance with federal and institutional regulations and comply with existing standards for animal housing and health. Research at CAVHS, through the effective management of the animal care and use program and the VMU, is directed towards assuring that the most reliable, reproducible, and significant contributions may be obtained from efforts involving the use of animal models.

C. Note that AAALAC International's three primary standards are *the Guide for the Care and Use of Laboratory Animals* (*Guide*), NRC, 2011; the *Guide for the Care and Use of Agricultural Animals in Research and Teaching* (*Ag Guide*), FASS, 2010, and the European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes, Council of Europe (ETS 123). Other regulations and guidelines used (U.S. Department of Agriculture (USDA), Public Health Service (PHS) Policy, Good Laboratory Practice (GLP), Canadian Council on Animal Care (CCAC), etc.) may also apply. Describe which of the three primary standards and other regulations and guidelines are used as standards for the institutional animal care and use program and how they are applied. For example, an academic institution in the United States with an Office of Laboratory Animal Welfare (OLAW) Assurance may use the standards of the *Guide* and PHS Policy for all animals, the Animal Welfare Act regulations for covered species, and the *Ag Guide* for agricultural animals used in agricultural research and teaching (see also *Guide*, pp. 32-33). In the European Union, the standards applied might be the *Guide*, ETS 123, Directive 2010/63, and any country-specific regulations.

CAVHS is a medical facility within the United States Department of Veterans Affairs that participates in research. As such, the VA Institutional Animal Care and Use Committee (IACUC) must comply with all applicable VA regulations and policies. CAVHS has an Office of Laboratory Animal Welfare (OLAW) Assurance and uses the standards of the Guide for the Care and Use of Laboratory Animals and PHS Policy for all animals, and the Animal Welfare Act regulations for covered species.

D. Describe the organization and include an accurate, current, and detailed organizational chart or charts (see **Appendix 4**) detailing the lines of authority from the Institutional Official to the Attending Veterinarian, the Institutional Animal Care and Use Committee/Oversight Body (IACUC/OB), and the personnel providing animal care. Please include the title, name (*Note:* For individuals whose information is publically available, provide the titles and names; for individuals whose information is not publically available, you may provide titles only.), and degree (if applicable) of each individual at the level of supervisor or above. Names of animal care staff below the title of supervisor need not be included, but the titles and number of animal care personnel under each supervisor should be included. If animal care

responsibility is administratively decentralized, including the management of satellite housing areas/locations, the organizational chart or charts must include all animal care programs, indicating the relationship between each administrative unit and personnel, the Attending Veterinarian, and the Institutional Official.

The organization of CAVHS is comprised of the Medical Center Director, the Chief of Staff, Associate Chief of Staff for Research; and Service Chiefs for all other departments. The Research and Development Committee, from the Director through the Chief of Staff, is the delegated authority to approve all research at CAVHS. The Institutional Animal Care and Use Committee is a subcommittee of the Research and Development Committee. Other subcommittees of the Research and Development Committee that impact the animal research program include the Subcommittee for Research Safety (which includes Biosafety), Institutional Biosafety Committee (which includes recombinant DNA and transgenic animal protocols), and Radiation Safety Committee. The Organizational Chart is included as Appendix 1.

The lines of authority and responsibility for administering the program and ensuring compliance with this Policy are:

MEDICAL CENTER DIRECTOR
(b)(6) MD

ASSOCIATE CHIEF OF STAFF FOR RESEARCH
(b)(6) MD

DEPUTY ASSOCIATE CHIEF OF STAFF
(b)(6) PhD

RESEARCH AND DEVELOPMENT COMMITTEE
(b)(6) Chair

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE
(b)(6) MS, Chair

VETERINARY MEDICAL OFFICER
(b)(6) DVM

DIRECTOR, VETERINARY MEDICAL UNIT
(b)(6) DHSc.

SUPERVISOR, VETERINARY MEDICAL UNIT
(b)(6)

ANIMAL CARE TECHNICIANS
(b)(6)
(b)(6)

E. Identify the key institutional representatives (including, but not limited to, the Institutional Official; IACUC/OB Chairperson; Attending Veterinarian; animal program manager; individual(s) providing biosafety, chemical hazard, and radiation safety oversight; etc.); and

individuals anticipated to participate in the site visit.

Institutional representatives that are anticipated to participate in the site visit include: (b)(6) M.D., Medical Center Director; (b)(6) M.D., Chief of Staff, (b)(6) and (b)(6), Research Compliance Officers, (b)(6), M.D., Associate Chief of Staff (ACOS) for Research, (b)(6) D.V.M, Veterinary Medical Officer; (b)(6) MS, Chairman, Institutional Animal Care and Use Committee; (b)(6), Ph.D., Deputy Associate Chief of Staff for Research, (b)(6), DHSc., Veterinary Medical Unit Director, (b)(6), Veterinary Medical Unit Supervisor

F. Briefly describe the major types of research, testing, and teaching programs involving animals and note the approximate number of principal investigators and protocols involving the use of animals. As mentioned in the instructions, please complete **Appendix 5** (Animal Usage) or provide the information requested in a similar format as an Appendix.

Currently active research projects at CAVHS involve 11 principal investigators performing 20 protocols. These projects involve research in the areas of nephrology (rats and mice), geriatrics (mice and rats), antibody production (mice), drug testing (mice), biochemistry and radiation (mice and rats), cardiology and vascular disease (rats and mice), communicable disease (mice), and cancer (mice and rats).

G. Note the source(s) of research funding (grants, contracts, etc.) involving the use of animals.

1. VA appropriated funds (i.e. Merit Review Awards)
2. National Institutes of Health (i.e. National Institute of Diabetes andDigestive and Kidney Diseases; National Institutes of Neurological Disorders and Stroke; National Institutes on Aging)
3. American Heart Association
4. American Diabetes Association
5. Department of Defense
6. Various pharmaceutical industry companies
7. Biomedical Research Foundation

H. List other units (divisions, institutes, areas, departments, colleges, etc.) of your organization that house and/or use animals that are not included in this Description. If any of these are contiguous, physically or operationally (e.g., same IACUC/OB, same animal care staff), with the applicant unit, describe the association. Explain why such units are not part of this program application.
Note: Questions regarding this section should be forwarded to the AAALAC Office.

The CAVHS has no satellite facilities for housing animals. We do have a MOU with the University of Arkansas for Medical Sciences (UAMS). UAMS has their own IACUC and separate animal care staff.

I. Contract Facilities: If the institution contracts for animal care facilities or services for animals owned by the institution, the contractor and its AAALAC International accreditation status

must be identified. If a contractor's animal care and use program is not accredited by AAALAC International, a brief description, following this Program Description outline, of the relevant contractor's programs and facilities must be provided. In addition, the species and approximate average number of animals housed in the contract facilities and the approximate distance between the institution's animal facility and the contract facility must be noted. Incorporation of the contractor program into the site visit schedule will be discussed with institutional representatives. If the institution does not contract for animal care facilities or services, so note.

The care of animals housed at this facility is not a contracted service.

J. Note other relevant background that will assist reviewers of this report.

Not applicable.

Section 2. Description

I. Animal Care and Use Program

A. Program Management

1. Program Management Responsibility [*Guide*, pp. 13-15]

a. The Institutional Official [*Guide* pp. 13-14]
Describe how program needs are clearly and regularly communicated to the Institutional Official by the Attending Veterinarian, IACUC/OB, and others associated with the program.

There is a direct line of communication for the Veterinarian and the Chairperson of the IACUC to the Institutional Official (IO) of the institution. This direct line of communication is used for cases of pressing IACUC business. All other routine communications, such as the IO signature on reports, is handled through the regular chain of command.

The IACUC utilizes the following three (3) forms for conducting the semi-annual institution's program for humane care and use of animals and the institution's animal facilities with further communication to the IO:

1) VA IACUC Semi-Annual Self-Review Form
2) Table of Program and Facilities Deficiencies
3) Post-Review Documentation

The prepared reports of the IACUC evaluations are submitted to the ACOS for Research, Research and Development Committee of CAVHS, the IO, and the Chief Veterinary Medical Officer, Department of Veterans Affairs. The reports are updated at least once every six months upon completion of the semiannual facility inspection and review of the institution's program for human care and use of animals. The reports are maintained on file by the institution. Within the VA IACUC Semi-Annual Self-Review Form, there is a description of the nature and extent of the institution's adherence to the Guide and PHS Policy and states any departures from the provisions of the Guide and PHS Policy and the resultant reasons for each departure. The Table of Program and Facilities Deficiencies distinguishes between significant and minor deficiencies, with a significant deficiency being one that is or could possibly be a threat to health or safety of the animals. Also, within this table are specific plans and reasonable time frames for correction of all deficiencies. The Post-Review Documentation lists the dates of the program evaluation and facilities inspection and those who participated in such. Any minority views are discussed within this document or, if there were no minority views, a statement reflecting this is included. The final reports are signed by a majority of IACUC members and include the signatures of those who attended the facilities inspection and representatives from the Director's Office and Engineering Service.

b. Role of the Attending Veterinarian [*Guide*, p. 14]

i. Describe the institutional arrangement for providing adequate veterinary care. Although individual name(s) and qualifications will be described below, identify by title the veterinarian(s) responsible for the veterinary care program, including:

- a list of responsibilities
- a description of the veterinarian's involvement in monitoring the care and use of laboratory animals
- the percentage of time devoted to supporting the animal care and use program of the institution if full-time; or the frequency and duration of visits if employed part-time or as a consultant.

Note: If preferred, this information may be provided in a Table or additional Appendix.

(b)(6), DVM
Veterinary Medical Officer

Dr. (b)(6) reports to the ACOS for Research at CAVHS. (b)(6) is directly responsible for the implementation of the program authority and the recommendations of the Guide.

Dr. (b)(6) is responsible for veterinary care of all animals used at CAVHS. As the Veterinary Medical Officer (VMO), (b)(6) makes routine inspections of animal wards once per week for at least four (4) hours and responds to requests for assistance on all aspects of animal health and care made by the Supervisor of the VMU. (b)(6) also provides emergency and weekend veterinary care if necessary. The VMO assists research personnel in meeting established standards and in the preparation of animal use protocols. The VMO implements and maintains institutional veterinary care policies and standards that meet or exceed the requirements of regulatory and accrediting agencies. The VMO serves on the IACUC and provides veterinary and professional consultation services on the design, construction and maintenance of the animal facility. Both the VMO and the VMU Supervisor are available for emergency consultation via cellular phone or home phone. The home phone numbers and cellular numbers are posted in the VMU and recorded with CAVHS Police.

ii. List others (e.g., Principal Investigators, veterinarians serving as Principal Investigators, veterinary faculty/staff, technical staff, farm managers) who have a *direct role in the provision of veterinary care* and describe their responsibilities. The Organizational Chart(s) provided in **Appendix 4** must depict the reporting relationship between these individuals and the Attending Veterinarian.
Note: If preferred, this information may be provided in a Table or additional Appendix.

(b)(6)
VMU Supervisor
Medical Research Service, 151/LR

Central Arkansas Veterans Healthcare System

(b)(6) received training while working for four and a half years at (b)(6) in (b)(6), Arkansas. (b)(6) is ALAT certified. He received two years of college education at (b)(6) University and one year at the University of (b)(6) at (b)(6). He has been trained to perform animal handling, intraperitoneal, subcutaneous, intravenous and intramuscular injections, anesthesia, dermal application, several euthanasia procedures, blood collection, and tissue collection in multiple animal models, and oral gavage training in mice and other rodent species and is a certified VMU trainer for other employees. (b)(6) has extensive experience with retro orbital sinus blood collections in mice. (b)(6) was trained by members of Dr. (b)(6) group and VMU personnel to perform surgical intubated ventilation in mice, myocardial ischemia/reperfusion in mice, kidney ischemia/reperfusion in mice implantation of prostate and breast tumor xenografts, VisualSonics operations, transcardiac perfusion knockout colony handling, breeding and genotyping. (b)(6) is certified by VMU and has completed all of the annual training required by VA policy.

(b)(6) is the immediate supervisor of all animal care technicians within the VMU. (b)(6) monitors the daily activities of all personnel and animal health and care. As the VMU Supervisor, (b)(6) is available for emergency consultation via cellular phone or home phone. (b)(6) home phone number and cellular number are posted in the VMU and recorded with CAVHS Police. (b)(6) is the first call back on the emergency cascade of the CAVHS Police.

c. Interinstitutional Collaborations [*Guide*, p. 15]
Describe processes for assigning animal care and use responsibility, animal ownership and IACUC/OB oversight responsibilities at off-site locations for interinstitutional collaborations.

The University of Arkansas for Medical Science (UAMS) and the Central Arkansas Veterans Healthcare System (CAVHS) share a mutual concern for the appropriate and humane use of laboratory animals in research, teaching, and testing activities conducted at their respective institutions. Each institution has policy and procedures that are in compliance with the Public Health Service Policy for the humane care and use of laboratory animals. Each has on file with the Office of Laboratory Animal Welfare (OLAW) an Animal Welfare Assurance statement and OLAW has assigned compliance certification number A3063-01 to UAMS and A3509-01 to CAVHS. Each institution is accredited the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC).

The above-name institutions entered into this agreement in order to establish mutually beneficial animal use and facility review procedures. Provisions are as follows:

A. That this agreement is applicable to all research, teaching, and testing involving live vertebrate animals by collaboration between personnel in the two

institutions; and in which animals are housed or used at one institution in a study administered at the other, and/or in which animals are transported from one institution to the other for part of the study.

B. That review of animal use will be conducted by the Institutional Animal Care and Use Committee (IACUC) of the institution where the animals are primarily housed and the research is primarily performed, using the forms of that institution. In addition, as required by VA regulations, any protocol funded by the VA requires review by a VA IACUC, using the VA animal component of research protocol forms. Each institution's IACUC will receive a copy of the specific approved protocol, including any revisions and amendments, involving their animals at the other institution.

C. That the Attending Veterinarian (AV) at each institution will assure the provision of adequate veterinary care in compliance with the Animal Welfare Act (9CFR, Chapter 1, Part 2, Subpart C, Section 2.33) and the Health Research Extension Act of 1985 and its implementing regulations as put forth by the NIH Office of Laboratory Animal Welfare, for all animals housed at their institution.

D. That each institution will be responsible for all reporting requirements involving the animals housed, or primarily housed, at their facility and for whom use was approved by their IACUC.

E. That transportation of animals between institutions will be in accordance with the policies of the receiving institution.

F. That each institution will maintain accreditation by AAALAC, an updated assurance statement with OLAW, and USDA registration if applicable.

G. That a review for congruency between the grant proposal and the associated animal use protocol(s) for PHS funded activities will be conducted by the institution administering the grant.

H. That training records of the investigator and research staff for the specific protocol will be shared between institutions.

I. That Occupational Health and Safety program enrollment of the investigator and research staff for the specific protocol will be shared between institutions.

J. That each institution's IACUC will promptly notify the other of deficiencies committed by the investigator and/or research staff for the specific protocol, including noncompliance, adverse events, research misconduct, research impropriety, conflict of interest, privacy concerns, and security concerns including data security, that may affect the other institution.

K. That this agreement be invoked in the IACUC approval letter, a copy of which will be maintained by each institution.

L. That this agreement will be continuous but may be terminated by either party with reasonable written notification.

2. Personnel Management

a. Training, Education, and Continuing Educational Opportunities

Describe *how* the IACUC/OB provides *oversight* and *evaluates the effectiveness* of training programs and the assessment of personnel competencies. Describe how training is documented.

Note: Do not include details about the training program, which should be described in the following sections.

CAVHS provides mandatory training in animal care and handling/methodology for all investigators and technicians with approved research protocols using laboratory animals. This training consists of lectures and hands on simulations. Investigators who have not received this training will not be allowed to order research animals. Investigative staff that have not received this training will not be allowed access to research animals. This training applies to all persons including visiting scientists and students who will be active with the protocol using the research animals. All technical and research staff working in the CAVHS VMU must also take a Web-Based training course and pass an examination. CAVHS belongs to the Collaborative Institutional Training Initiative (CITI), which is required by the Department of Veterans Affairs. The site for this training is found as: http://www.citiprogram.org. The web-based training is also mandatory for all participants listed on the ACORP prior to the start of a new animal protocol. Recertification of training is required every three years. Specific training, which is provided by the staff of the VMU, may also be necessary on some animal protocols. No other training is accepted (i.e., from other institutions). Personnel must score at least 80% on the web site exams before they are permitted to order or use experimental animals. Personnel who have not successfully completed all phases of this training are not allowed access to the research animal.

The IACUC is responsible for oversight of the training and to ensure that all personnel listed on the ACORP have had the appropriate training, which may include specific training provided by the VMU staff. Verification of training must be provided prior to approval of any ACORP. Records of completed training are kept in the VMU.

i. Veterinary and Other Professional Staff [*Guide*, pp. 15-16]

For the Attending Veterinarian and other individuals having a direct role in providing veterinary medical care (veterinarians, other professional staff listed above, private practitioners, etc.), provide: name, credentials (including degrees), and a description of their qualifications, training, and continuing education opportunities.

Note: Please do not provide curriculum vitae of personnel; if preferred, this information may be presented in a Table or additional Appendix.

(b)(6), DVM
Veterinary Medical Officer
~~Medical Research~~ Service, 151/LR

Central Arkansas Veterans Healthcare System
4300 West 7th Street
Little Rock, AR 72205
Phone: (501) (b)(6)
Fax: (501) (b)(6)
Email: (b)(6)

(b)(6) DVM received (b)(6) degree in veterinary medicine from (b)(6) University, (b)(6) in (b)(6) . (b)(6) has been a small animal practitioner since graduation and now owns (b)(6) in (b)(6) , AR. From (b)(6) to (b)(6) (b)(6) was also the on-call veterinarian at the (b)(6) when their veterinarian was out of town. In (b)(6) (b)(6) became the Veterinary Medical Officer for the CAVHS VMU. Dr. (b)(6) is a member of the American Veterinary Medical Association, the Arkansas Veterinary Medical Association and the American Association of Laboratory Animal Science. (b)(6) was (b)(6) of the (b)(6) Veterinary Medical Association in (b)(6) .

ii. Animal Care Personnel [*Guide*, p. 16]

1) Indicate the number of animal care personnel.

There are: one (1) AALAS Registered Laboratory Animal Technologist (full time, career) with fourteen (14) years of experience in laboratory animal care and two (2) Biology Research Technicians (animal), full time- term appointment.

2) Summarize their training, certification level and type, experience, and continuing education opportunities provided.
Note: If preferred, this information may be provided in a Table or additional Appendix.

All technicians are encouraged to join the local branch of the American Association for Laboratory Animal Science (AALAS). This Facility maintains an Institutional Membership with National AALAS and has provided all full-time technicians with National AALAS membership. A computer-generated Laboratory Animal Training Program is available to all personnel. All animal care technicians are encouraged to continue their education via the certification program offered by AALAS. CAVHS pays for the study guides as well as three rounds of testing per certification grade.

All full-time animal care technicians are given the opportunity to attend AALAS National Meetings annually, and all are given yearly funded opportunities to attend a workshop or meeting relating to laboratory animal care. Workshops will include Biology & Care of Laboratory Mice, Comparative Management and Lab Animal Care, Basic Genetics and Management of Breeding Colonies, and Observing Clinical Signs of Illness in Laboratory Rodents.

iii. The Research Team [*Guide*, pp. 16-17; 115-116; 122; 124]

1) Describe the *general mechanisms* by which the institution or IACUC/OB ensures that research personnel have the necessary knowledge and expertise in the animal procedures proposed and the species used.

This institution provides mandatory training in animal care and handling/ methodology for all investigators and technicians with approved research protocols using laboratory animals. Investigators who have not received this training will not be allowed to order research animals. Investigative staff that have not received this training will not be allowed access to research animals. This training applies to all persons including visiting scientists and students who will be active with the protocol using the research animals.

a) Briefly describe the content of any required training.

CAVHS belongs to the Collaborative Institutional Training Initiative (CITI). The mandatory courses include "Working with the VA IACUC", "Working with Mice in Research Settings", "Working with Rats in Research Settings", "Working with Guinea Pigs in Research Settings", and "Post-Procedural Care of Rodents" based on the particular protocol.

Lectures are provided to animal care personnel and all members of the research team for initial orientation to the Veterinary Medical Unit. Covered in these lectures are the policies and procedures of the VMU, security procedures, and correct usage of the animal ward logbook and cage cards, the AVMA Panel on Euthanasia report, and the Animal Component of Research Protocol (ACORP).

Specialized lectures are available for good surgical technique, anesthesia delivery, alleviation of pain, euthanasia, and specific experimental procedures. Prior to performing a procedure, all personnel responsible for that procedure must pass a proficiency test overseen by the VMU supervisor.

b) Describe the timing of training requirements relative to the commencement of work.

All required training, including specialized training, must be finished prior to the beginning of any protocol. All study personnel who have not received required training will not be allowed to order research animals nor access to research animals. In the case of new techniques added to an existing ACORP that require specialized training, all study personnel must complete the specialized training prior to the initiation of the modification.

c) Describe continuing education opportunities offered.

Lectures are provided two times a year on new technologies, animal welfare laws, animal techniques, surgical techniques, guidelines for selection and proper use of analgesics and anesthetics, security procedures, and rules and regulations of the VMU. Individual training, including techniques, specific to a protocol occurs prior to start of that protocol.

2) Describe the process(es) to ensure surgical and related procedures are performed by qualified and trained personnel, including:

- who determines that personnel are qualified and trained for surgical procedures
- the roles that the Attending Veterinarian and IACUC/OB have in this determination [*Guide*, pp. 115-116]

Investigations requiring surgical procedures are performed using standard, species-specific, veterinary procedures with appropriate use of anesthetics, analgesics, and other post- operative care. Researchers conducting the surgical procedures are appropriately trained prior to implementation of any procedure. All training for surgery is overseen by the VMU Supervisor. Competency tests are performed by the research investigator before procedures are allowed to be done on experimental animals. A standing report is presented monthly to the IACUC on the status of competency and training.

The content of the training program provides for aseptic surgical guidelines to be followed. The specific surgical training of individual investigators is reviewed by the IACUC during the review of a given project. All individuals performing surgery on laboratory animals must have experience either with animal or human surgery. This experience is reflected in the research protocol that must be approved by the IACUC before the research project may begin. Surgery on laboratory animals is always performed under the direct supervision of the VMU staff.

3) Describe the training and experience required to perform anesthesia. [*Guide*, p. 122]

Training for the selection and use of anesthesia and analgesia is done prior to the initiation of any protocol and following the addition of any new procedures requiring either anesthesia or analgesia. This training is done by either the VMU Supervisor or the VMO. The VMO will also consult with the PI in the pre-review stages of the ACORP submission process on the choice and use of anesthesia and analgesia. Lectures are also provided to all research personnel on anesthesia delivery and alleviation of pain.

Before the initiation of surgical procedures, the investigative staff meets with

the VMU Director and/or the VMU Supervisor. The investigative staff is given the opportunity to review equipment, supplies and surgical support areas.

Equipment or supplies not found in the VMU inventory that are necessary to the project are procured by either the investigative staff or the VMU before initiation of the project.

The investigative staff meets with the VMU Director or the VMU Supervisor to make certain that all guidelines are followed for that particular species pertaining to pre-operative care (i.e. withhold water, food; pre-anesthetic drugs, surgical site preparation) and post-operative care (i.e. maintaining animal in a controlled environment recovery unit; administering post-operative drugs; observation of animal for signs of distress and return of reflexes). After the appropriate anesthetic is selected, it is then determined who will administer anesthesia. Surgeons who have expertise in their field, but no experience with laboratory animals, must seek the training needed to adapt to variations in anatomy, physiology, anesthetics, analgesics and post-operative requirements of the species of animal that is selected for their project.

4) Describe how the proficiency of personnel conducting euthanasia is ensured (especially physical methods of euthanasia). [*Guide*, p. 124]

All guidelines established by the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia (2013) are followed. For rodents these are as follows: carbon dioxide inhalation, sedation with carbon dioxide followed by cervical dislocation, exsanguination while under general anesthesia, and sodium pentobarbital overdose.

Only investigators or their technicians who have undergone specific training may perform euthanasia on laboratory animals. All VMU technicians have undergone this training. With few exceptions all euthanasia on animals on the phylogenetic scale higher than rodents is performed by the VMU staff. The training in lab animal euthanasia is conducted by the VMO and/or the VMU Supervisor.

b. Occupational Health and Safety of Personnel [*Guide*, pp. 17-23]

i. Institutional Oversight [*Guide*, pp. 17-19]

1) List the institutional entities (units, departments, personnel, *etc.*) that are involved in the planning, oversight, and operation of the institutional occupational health and safety program related to animal care and use (e.g., office(s) of environmental health, institutional health services or clinics (*including contracted health services*), industrial hygienists, Institutional Biosafety Committee(s) and/or Officer(s), Radiation Safety Committee(s) and/or Officer(s).

- Include a brief description of their responsibilities and qualifications.
- If contracted services are used, also include their location (e.g.,remote offices to which personnel must report).

An occupational health program is essential for personnel who work in laboratory animal facilities, or, through their work, come in contact with animals. These type of animal contacts potentially expose personnel to physical demands, allergens, and hazardous agents including infectious diseases, radioactive materials, and toxic substances. Infectious diseases may be experimental in origin or naturally occurring zoonotic diseases for a given animal species. Human allergies to animals are common and may become serious enough to constitute an important health consideration. The IACUC in consultation with the Occupational Health and Safety Division within Engineering Service is responsible for implementation of the occupational health program related to the use of animals in research. The Occupational Health and Safety Division in Engineering Service is responsible for the overall management and monitoring of the occupational health program at the Central Arkansas Veterans Healthcare System.

All individuals that care for and use laboratory animals at the facility are required to participate in an occupational health program. Facility service individuals, including Engineering Service, Environmental Management Service and Police Service, must enroll in the occupational health program at CAVHS. If the employee is a WOC and they are not enrolled in the CAVHS occupational health program, they must provide verification of participation in a comparable program which is confirmed by the IACUC coordinator. Employees are provided information and training, if necessary, on precautions to be taken in the event of pregnancy, illness, and decreased immunocompetence, by CAVHS employee health. The CAVHS employee health clinic consists of 2 APNs (advanced practical nurse) and a physician consultant.

2) Describe methods to identify work-related hazards and the processes used to evaluate the significance of those hazards in the context of duties and tasks. Describe both common approaches and differences, if applicable, for categories of personnel such as, but not limited to, researchers, veterinarians, husbandry staff, cage-washing staff, students, housekeeping, physical plant staff, security personnel, IACUC/OB members (including non-affiliated members), contractors, visitors, etc. [*Guide*, pp. 18-19; see also Chapters 2 and 3 in Occupational Health and Safety in the Care and Use of Research Animals, NRC 1997.].

There is no formal biohazard training program for investigators, research technicians or animal care technicians. It is the responsibility of the Principal Investigator to provide training to his/her staff in the administration of, use of and protection against hazardous agent(s) approved in his/her protocol. The Subcommittee for Research Safety (SRS) provides information and guidance

to these investigators. The SRS also reviews all protocols submitted that include the use of hazardous agents and give their approval before the protocol may be initiated.

Periodic updates from the Infection Control Practitioner are presented to all Medical Research personnel. Standard Operating Procedures (SOP's) have been developed for the VMU technicians that include: radioisotopes, carcinogens and pathogens. Material Safety Data Sheets are on file in the office of the Supervisor of the VMU, the main research conference room (b)(6) (b)(6) and on the door of each respective animal ward housing animals involved with a specific hazard.

The Research Safety Officer, in conjunction with CAVHS's Industrial Hygienist, provides yearly training to all hospital personnel concerning hazardous agents. The Research Health Science Officer, along with experts in the specific relevant field (i.e. Radiation Safety Officer), does annual risk assessments for each laboratory with VA personnel. If the approved study has animals, the risk assessments include working with animals and the dangers posed by such.

The VMU provides information concerning the dangers associated with the use of hazardous biologic, chemical, or physical agents and safeguards with periodic SOP review. VMU personnel directly involved with animals exposed to hazardous agents are given special counsel and training appropriate to the hazardous biologic, chemical, or physical agent being used.

3) Describe methods and frequency of reassessing work-related hazards.

Periodic updates from the Infection Control Practitioner are presented to all Medical Research personnel. Standard Operating Procedures (SOP's) have been developed for the VMU technicians that include: radioisotopes, carcinogens and pathogens. Material Safety Data Sheets are on file in the office of the Supervisor of the VMU, the main research conference room (b)(6) (b)(6) and on the door of each respective animal ward housing animals involved with a specific hazard.

The Research Safety Officer, in conjunction with CAVHS's Industrial Hygienist, provides yearly training to all hospital personnel concerning hazardous agents. The Research Health Science Officer, along with experts in the specific relevant field (i.e. Radiation Safety Officer), does annual risk assessments for each laboratory with VA personnel. If the approved study has animals, the risk assessments include working with animals and the dangers posed by such.

The VMU provides information concerning the dangers associated with the use of hazardous biologic, chemical, or physical agents and safeguards with periodic SOP review. VMU personnel directly involved with animals exposed to hazardous agents are given special counsel and training appropriate to the hazardous biologic, chemical, or physical agent being used.

4) Describe institutional programs or methods used to track and evaluate safety-related workplace incidents, including injuries, exposures, accidents, etc. Include the frequency of such assessments. [*Guide*, pp. 18-19]

Information concerning the hazards of chemicals used in the workplace will be communicated to employees by way of a comprehensive Hazard Communication Program that includes container labeling and other forms of warning, material safety data sheets (MSDSs), and employee training. Training and information will be given at the time of an employee's initial assignment, annually thereafter, and whenever a new hazardous chemical is introduced into the work area.

If employees are exposed to less than five (5) chemicals, training may be covered on particular hazards of each one. Where there are more than five chemicals, the training regarding hazards could be done on categories (e.g., flammable liquids, carcinogens, etc.), with employees being referred to substance-specific information on the labels and MSDS. This training is done by the Research Safety Officer, Health Science Officer, Industrial Hygienist, or Principle Investigator.

It is the policy of CAVHS to promote a safe and healthful work environment and implement effective practices to reduce work- related injuries/illnesses as well as compensation claims/costs. The Accident Review Board (ARB) establishes and implements plans, processes, and activities related to its defined purposes and charges. The ARB outlines procedures for reviewing incidents of occupational injury and illness cases that meet thresholds established by the committee. The committee will review individual lost time accidents to identify trends related to accidents or occupational injury/disease and present recommendations for facility accident and injury prevention.

The ARB investigates hazardous conditions and work practices, as well as deficiencies in policy and training that may contribute to unsafe working conditions. All findings of the ARB will be used to identify processes in need of correction and/or improvements. The ARB is a multi-disciplinary team, created as a fair and impartial sub-committee to review, investigate, and implement corrective measures for incidents of occupational injury or illness that result in: medical expense, job transfers, restrictions, days away from work, or in lost time beyond the day of incident. The ARB proceedings will be conducted in a manner that is non-adversarial, and findings of the ARB will not be used to penalize injured workers.

ii. Standard Working Conditions and Baseline Precautions

The following section pertains to the Occupational Health and Safety Program for all personnel associated with the animal care and use program. Specific information regarding the use of hazardous agents is included in ***subsection iii*** below.

1) **Medical Evaluation and Preventive Medicine for Personnel** [*Guide*, pp. 22-23] *Note:* Include blank forms used for individual health assessment as **Appendix 6.**

a) Describe who (e.g., personnel assigned to job/task categories in I.A.2.b.i.2) above) receives personal medical evaluation as a component of individual risk assessment. Describe who are ***not*** included and/or exempted from personal medical evaluation. *Note:* Do not include the names of personnel.

All individuals that care for and use laboratory animals at the facility are required to participate in an occupational health program. Facility service individuals, including Engineering Service, Environmental Management Service and Police Service, must enroll in the occupational health program at CAVHS. If the employee is a WOC and they are not enrolled in the CAVHS occupational health program, they must provide verification of participation in a comparable program which is confirmed by the IACUC coordinator. Employees are provided information and training, if necessary, on precautions to be taken in the event of pregnancy, illness, and decreased immunocompetence, by CAVHS employee health.

b) Describe provisions for allowing an individual (following completion of individual health and job related risk assesments) to decline participation in all or part(s) of subsequently available medical and preventive medicine components of the institutional program, e.g., vaccinations, physical examinations, respiratory protection, as applicable. Provide an estimate (percentage) of personnel associated with the animal care and use program that have declined participation in the medical evaluation program. *Note: Do not include names of the personnel*

The Occupational Health and Safety program for full, part-time, and Without Compensation (WOC) employees of the Veterinary Medical Unit includes the following procedures that each employee must observe and participate in:

a. A pre-employment physical examination that includes a complete blood count, a urinalysis, a varicella titer, and, if the employee is above the age of 40, an electrocardiogram.

b. Determination that tetanus immunization is current. The immunization in not required but offered if needed.

c. Every twelve (12) months a PPD skin test is administered for tuberculosis monitoring usually on the Entered On Duty (EOD) date. PPD testing is performed as per Medical Center Policy. Notice for the yearly test is given by the VMU Supervisor. For known reactors, positive

reactor forms are filled out on a yearly basis.

d. Blood pressure checks are offered by the Employee Health Service.

e. An annual flu inoculation is available and required. If not administered at CAVHS, proof of inoculation must be provided.

f. Free screening and vaccine for Hepatitis B is provided by the Employee Health Service on a voluntary basis.

g. A pre-exposure questionnaire is required by this institution for all VMU employees exposed to carcinogens followed by an annual questionnaire specific to the hazard. A physical exam may be suggested based on the answers to the questionnaire. Personnel assigned to projects using cancer-causing agents (i.e., cisplatin) must follow all Standard Operating Procedures developed for that hazard.

h. All personnel working with animals exposed to radioisotopes are required to wear an X-ray film badge that is monitored on a monthly basis by this institution.

i. This facility has not housed animals with the potential to carry rabies for a number of years.

j. Preventative Medicine: Personnel must participate in the Preventative Medicine Program if they have to handle animals or handle unfixed animal tissues. Because CAVHS ensures that a safe workplace is provided, all employees involved in animal research that is conducted completely or partially at CAVHS must provide proof to the Institutional Animal Care and Use Committee (IACUC) that they have participated in the Preventative Medicine Program before they enter the Veterinary Medical Unit and before they begin work with the animals. If the employee is a WOC and they are not enrolled in the CAVHS Preventative Medicine Program, they must provide verification of participation in a comparable program which is confirmed by the IACUC coordinator. Employees are provided information and training, if necessary, on precautions to be taken in the event of pregnancy, illness, and decreased immunocompetence, by CAVHS employee health.

k. Medical Follow-up Questionnaire: An annual review in the form of an interview by a qualified medical professional can substitute for a physical exam in the Preventative Medicine Program. The following information will be obtained from the VMU personnel.

   a) Name, last four digits of their social security number, date of birth, gender, pregnancy status, hospital service, job title, and contact information.

   b) The species of laboratory animal(s) encountered

   c) The amount of contact time per week including contact time with

animal tissues, waste, body fluids, carcasses, and animal housing areas.

d) Whether human or animal pathogens are included in the employee's work.

e) History of tuberculosis testing (PPD/Quantiferon Gold).

f) Whether the employee has received immunosuppressive therapy within the past year that could increase the risk of zoonotic disease.

g) How often does the employee wear the personal protective equipment (PPE) suggested for the assigned tasks; such as gloves, mask, and protective eyewear.

h) Whether the employee smokes, eats or drinks in the animal or procedure areas.

i) How often the employee washes hands, changes clothing (if soiled), or showers after handling animals during the day.

j) Is there any history of asthma, hay fever, allergic skin problems, eczema, sinusitis, chronic respiratory infections or disease.

k) Whether any allergic symptoms occur during or after contact with a laboratory animal species, and if so, which species is involved and how frequently each symptom occurs.

l) Whether the employee has any house pets that could be responsible for the allergic symptoms or that could represent a disease transmission hazard to the employee or to the animals in the research facility.

m) In the past year, has the employee ever suffered from an inguinal or similar hernia, from back pain, or from joint problems or arthritis. If so, the severity and corrective measures need to be described.

n) Whether the employee works with chemicals or hazardous materials in the workplace and does the employee have any symptoms associated with such exposure.

o) The immunization and testing history for the employee which includes date, side effect(s), or other relevant information for each of the following: tetanus, hepatitis B, and other immunizations or tests as would be appropriate for the employees work.

p) Include the printed name, signature, and date for both the employee and interviewer.

c) Describe provisions for assuring confidentiality of medical information.

The information collected is considered privileged medical information and

subject to Federal regulations that govern the collection and use of personal information.

d) Describe safety considerations for individuals with incidental exposure to animal care and use (e.g., contractors, personnel working in open laboratories).

Everyone who enters the VMU must use required PPE such as shoe covers, lab coats, gloves, and masks when applicable. Research staff working with animals where contractors and/or personnel are working in an open lab must take precautions to minimize incidental exposure. This can be accomplished by sectioning off their workspace, scheduling to use their workspace when others will not be around, using sterile techniques, using proper PPE, and practicing proper disposal procedures.

e) Describe general features of the medical evaluation and preventive medicine programs, within the context of work duties, including:

- pre-employment/pre-assignment health evaluation,
- medical evaluations (including periodicity),
- diagnostic tests (e.g., for tuberculosis),
- precautions for working with potentially hazardous species (e.g., nonhuman primates, sheep, venomous species)
- immunization programs, and
- procedures for communicating health related issues.

The Occupational Health and Safety program for full, part-time, and Without Compensation (WOC) employees of the Veterinary Medical Unit includes the following procedures that each employee must observe and participate in:

a. A pre-employment physical examination that includes a complete blood count, a urinalysis, a varicella titer, and, if the employee is above the age of 40, an electrocardiogram.

b. Determination that tetanus immunization is current. The immunization in not required but offered if needed.

c. Every twelve (12) months a PPD skin test is administered for tuberculosis monitoring usually on the Entered On Duty (EOD) date. PPD testing is performed as per Medical Center Policy. Notice for the yearly test is given by the VMU Supervisor. For known reactors, positive reactor forms are filled out on a yearly basis.

d. Blood pressure checks are offered by the Employee Health Service.

e. An annual flu inoculation is available and required. If not administered at CAVHS, proof of inoculation must be provided.

f. Free screening and vaccine for Hepatitis B is provided by the Employee Health Service on a voluntary basis.

g. A pre-exposure questionnaire is required by this institution for all VMU employees exposed to carcinogens followed by an annual questionnaire specific to the hazard. A physical exam may be suggested based on the answers to the questionnaire. Personnel assigned to projects using cancer-causing agents (i.e., cisplatin) must follow all Standard Operating Procedures developed for that hazard.

h. All personnel working with animals exposed to radioisotopes are required to wear an X-ray film badge that is monitored on a monthly basis by this institution.

i. This facility has not housed animals with the potential to carry rabies for a number of years.

j. Preventative Medicine: Personnel must participate in the Preventative Medicine Program if they have to handle animals or handle unfixed animal tissues. Because CAVHS ensures that a safe workplace is provided, all employees involved in animal research that is conducted completely or partially at CAVHS must provide proof to the Institutional Animal Care and Use Committee (IACUC) that they have participated in the Preventative Medicine Program before they enter the Veterinary Medical Unit and before they begin work with the animals. If the employee is a WOC and they are not enrolled in the CAVHS Preventative Medicine Program, they must provide verification of participation in a comparable program which is confirmed by the IACUC coordinator. Employees are provided information and training, if necessary, on precautions to be taken in the event of pregnancy, illness, and decreased immunocompetence, by CAVHS employee health.

k. Medical Follow-up Questionnaire: An annual review in the form of an interview by a qualified medical professional can substitute for a physical exam in the Preventative Medicine Program. The following information will be obtained from the VMU personnel.

   a) Name, last four digits of their social security number, date of birth, gender, pregnancy status, hospital service, job title, and contact information.

   b) The species of laboratory animal(s) encountered

   c) The amount of contact time per week including contact time with animal tissues, waste, body fluids, carcasses, and animal housing areas.

   d) Whether human or animal pathogens are included in the employee's work.

   e) History of tuberculosis testing (PPD/Quantiferon Gold).

f) Whether the employee has received immunosuppressive therapy within the past year that could increase the risk of zoonotic disease.

g) How often does the employee wear the personal protective equipment (PPE) suggested for the assigned tasks; such as gloves, mask, and protective eyewear.

h) Whether the employee smokes, eats or drinks in the animal or procedure areas.

i) How often the employee washes hands, changes clothing (if soiled), or showers after handling animals during the day.

j) Is there any history of asthma, hay fever, allergic skin problems, eczema, sinusitis, chronic respiratory infections or disease.

k) Whether any allergic symptoms occur during or after contact with a laboratory animal species, and if so, which species is involved and how frequently each symptom occurs.

l) Whether the employee has any house pets that could be responsible for the allergic symptoms or that could represent a disease transmission hazard to the employee or to the animals in the research facility.

m) In the past year, has the employee ever suffered from an inguinal or similar hernia, from back pain, or from joint problems or arthritis. If so, the severity and corrective measures need to be described.

n) Whether the employee works with chemicals or hazardous materials in the workplace and does the employee have any symptoms associated with such exposure.

o) The immunization and testing history for the employee which includes date, side effect(s), or other relevant information for each of the following: tetanus, hepatitis B, and other immunizations or tests as would be appropriate for the employees work.

Include the printed name, signature, and date for both the employee and interviewer.

f) Describe any other entities that provide medical services (e.g., emergency care, after-hours care, special medical evaluation, contracted services). Include a brief description of their credentials and/or qualifications, and how these entities remain knowledgeable about animal- or institution-related hazards and risks.

The CAVHS employee health clinic provides medical services and consists of 2 APNs (advanced practical nurse) and a physician consultant. Employees can also go to their nearest emergency room for

care.

2) **Personnel Training Regarding Occupational Health and Safety** [*Guide*, p. 20]

Describe general educational program(s) to inform personnel about:

- allergies,
- zoonoses,
- personal hygiene,
- physical injuries in animal facilities (e.g., noisy areas, large quantities of chemicals such as disinfectants, ergonomics) or species used (e.g., nonhuman primates, agricultural animals),
- other considerations regarding occupational health and safety.

Include in the description a summary of the topics covered, including:

- Entities responsible for providing the training
- Frequency of training or refresher training

Note: Do not include special or agent-specific training for personnel exposed to experiment-related hazardous agents; this will be provided in **Section iii.3** below.

This institution provides mandatory training to both VMU and research personnel about animal care and handling/methodology, zoonoses as necessary, chemical, biologic, and physical hazards, handling of waste materials, personal hygiene, the use of PPE, and experimental considerations. This training is for all investigators and technicians with approved research protocols using laboratory animals and all VMU employees. Investigators who have not received this training will not be allowed to order research animals. Investigative staff that have not received this training will not be allowed access to research animals. This training applies to all persons including visiting scientists and students who will be active with the protocol using the research animals. The training is provided by the Research Safety Officer, the Health Science Officer, the VMU Supervisor, and the facility Industrial Hygienist. These trainings are provided on an annual basis as the Risk Assessment for each active protocol within Research Service.

3) **Personal Hygiene** [*Guide*, p. 20; *Ag Guide* pp. 4-5]

a) List routine personal protective equipment and work clothing provided and/or required for animal care personnel, research and technical staff, farm employees, etc.

Protective clothing is provided to the employees at no cost. Uniforms and

laboratory coats are laundered at the VMU facility so that clean, protective clothing is available whenever needed. Within the VMU, there are enough clean inventories for research staff and animal husbandry personnel to change into clean uniforms or coats multiple times daily. Soiled protective clothing is not taken away from the work site and soiled outer garments are not worn outside the animal research facility.

Protective equipment and clothing for animal care personnel are provided by the VMU. They include: gowns, face masks, face shield (plastic), goggles (plastic), exam gloves, surgeon's gloves, heavy rubber gloves, shoe covers, heavy rubber boots, rubber aprons, head covers, hearing protectors, scrub suits, steel toe shoes/boots, lab coats, jump suits, and lifting supports.

The noise level in the VMU may possibly reach potentially damaging levels in the cage washing areas. Ear protection is provided whenever noise levels exceed those permissible levels established by OSHA regulations or whenever requested by an employee. Protective headset-style protectors are available along with disposable foam ear plugs.

Protective eye wear is also available for employees who handle corrosive or otherwise dangerous liquids or vapors. Goggles or other devices that completely shield the face region are provided when appropriate.

b) Describe arrangements for laundering work clothing.

A clothes washer and dryer are provided by the VMU to be used exclusively for VMU protective clothing and linen. Scrub suits, jump suits and all non-disposable linen are processed by the Veterinary Medical Unit.

c) Describe provisions and expected practices for washing hands, showering, and changing clothes, including instances where work clothes may be worn outside the animal facility.

Separate men and women's restrooms, and change/shower rooms are provided for washing hands and showering. These rooms include (b)(6) (b)(6)

In addition, each animal ward is equipped with a sink and hand soap disinfectant dispenser. Support areas such as necropsy, surgery and recovery also have sinks and hand soap disinfectant dispensers. Employees are required to use the hand soap disinfectant before leaving any animal ward and wash hands with a provided anti-bacterial soap before leaving the restroom. Only clean scrub suits and lab coats are allowed outside the facility. No work clothes, except lab coats not used in animal contact, are allowed to be worn home after close of business.

d) Describe policies regarding eating, drinking, and smoking in animal facilities.

CAVHS is a non-smoking Medical Center. Smoking is to be conducted outside, in a specific designated area. Personnel who smoke wash their hands prior to smoking and then following smoking before entering animal areas. Eating, applying cosmetics, installing contact lenses, and similar procedures are prohibited within the VMU except in designated areas that are free of potentially contaminated materials.

Employee food and beverages are stored only in refrigerators and/or freezers designated exclusively for such use. Eating and drinking is permitted only in the employee lounge ([b)(6)]) and offices ([b)(6)], [b)(6)] and [b)(6)]).

4) Standard Personnel Protection [*Guide*, pp. 21-22]

a) Describe facility design features, equipment and procedures employed to reduce potential for physical injury inherent to animal facilities (e.g., noisy areas, large quantities of chemicals such as disinfectants, ergonomics) or species used (e.g., nonhuman primates, agricultural animals).

Standard Operating Procedures (SOP's) have been developed for personnel performing routine animal husbandry involving animals exposed to hazardous agents. An updated copy is distributed to each Veterinary Medical Unit animal care technician on a yearly basis. Numerous carts, specialized gloves (Nitrile, Latex Free, etc.) and disposable N95 facemasks are required and respirators are available. Protective clothing, both disposable and non-disposable, is required and made available. Ear protection is mandatory in cage washing areas and is provided. The Industrial Hygienist for CAVHS annually tests the acceptable noise level in the cage washing area.

Computer based training modules pertaining to safe and humane handling of laboratory animals is mandatory. The Industrial Hygienist for CAVHS provides annual fit testing for the N95 facemasks and the respirators.

Animal care personnel exposed to carcinogenic agents are periodically monitored for symptoms by the VMU supervisor during routine animal husbandry. Monthly Standard Operating Procedure reviews on safety with hazardous agents are required.

Employees must also follow the SOP on the proper use and disposal of syringes and needles. Needles are not to be recapped. Instead, syringes with attached uncapped needles should be dropped into puncture proof containers for disposal. Such containers are located in each animal ward and procedure rooms. Needles that are capped because they have not

been used (i.e. extra needles that were not used in an experiment) should also be disposed of within the provided sharps container. These needles should be marked on the barrel of the needle with an X using a permanent marker to demonstrate that they were not used.

Personnel must participate in the Preventative Medicine Program if they have to handle animals or handle unfixed animal tissues. Because CAVHS ensures that a safe workplace is provided, all employees involved in animal research that is conducted completely or partially at CAVHS must provide proof to the Institutional Animal Care and Use Committee (IACUC) that they have participated in the Preventative Medicine Program before they enter the Veterinary Medical Unit and before they begin work with the animals.

An annual review in the form of an interview by a qualified medical professional can substitute for a physical exam in the Preventative Medicine Program. The information collected is considered privileged medical information and subject to Federal regulations that govern the collection and use of personal information.

b) Describe likely sources of allergens and facility design features, equipment, and procedures employed to reduce the potential for developing Laboratory Animal Allergies (LAA).

Possible sources:
Animals, animal cages, bedding.

Reducing potential for developing LAA:
VMU personnel handling research animals or performing cage changes are required to wear the following protective clothing: disposable gloves, lab coat and/or scrub suit and N95 facemask or respirator.

The animal care technicians transporting the animals are trained and aware of the risks to themselves and others of exposure to allergens and to negative reactions by those who are opposed to animal use in research. Public areas are avoided when possible.

Appropriate personal protective equipment (PPE) must be used during transport to prevent crosscontamination among animals and between humans and animals (e.g. pathogenic organisms and other biological materials, chemicals, fomites, etc.).
Release of animal dander, airborne animal allergens and animal bedding into the environment is minimized. VMU personnel should ensure that filter tops or other effective covers are used on rodent cages and cages are covered during transport. Empty, soiled cages should be covered during transport.

Temperature extremes must be avoided. Special precautions must be taken to protect animals from heat or cold stress when

climatic temperatures are inappropriate for the species (e.g., below 45 F or about 85 F).

Reusable primary or secondary enclosures must be sanitized between use to prevent the spread of pathogenic microorganisms, animal wastes and allergens. When any body fluids (blood, urine, salvia, mucus), feces, or dirty bedding contacts any surface outside the enclosures, it should be removed and the area appropriately disinfected as soon as possible.

c) Describe likely sources of zoonoses and facility design features, equipment, and procedures employed to reduce potential exposure to zoonoses.

Possible sources:
Animals, animal cages, bedding.

Reducing potential exposure:
VMU personnel handling research animals or performing cage changes are required to wear the following protective clothing: disposable gloves, lab coat and/or scrub suit and N95 facemask or respirator.

The animal care technicians transporting the animals are trained and aware of the risks to themselves and others of exposure to allergens and to negative reactions by those who are opposed to animal use in research. Public areas are avoided when possible.

Appropriate personal protective equipment (PPE) must be used during transport to prevent crosscontamination among animals and between humans and animals (e.g. pathogenic organisms and other biological materials, chemicals, fomites, etc.).
Release of animal dander, airborne animal allergens and animal bedding into the environment is minimized. VMU personnel should ensure that filter tops or other effective covers are used on rodent cages and cages are covered during transport. Empty, soiled cages should be covered during transport.

Temperature extremes must be avoided. Special precautions must be taken to protect animals from heat or cold stress when climatic temperatures are inappropriate for the species (e.g., below 45 F or about 85 F).

Reusable primary or secondary enclosures must be sanitized between use to prevent the spread of pathogenic microorganisms, animal wastes and allergens. When any body fluids (blood, urine, salvia, mucus), feces, or dirty bedding contacts any surface outside the enclosures, it should be removed and the area appropriately disinfected as soon as possible.

d) Describe the procedures for the maintenance of protective equipment and how its function is periodically assessed.

The Industrial Hygienist for CAVHS and Engineering Service works with Research Service to provide the annual maintenance on safety equipment within the VMU. The Industrial Hygienist provides annual fit testing for the N95 facemasks and respirators. In conjunction with Biomedical Service, the Industrial Hygienist performs annual testing for noise levels, air flow, and monitoring of any hazardous chemicals (including disinfectants) within the VMU.

e) Respiratory Protection

i) Describe situations where respiratory protective equipment is available or required, such as cage washing facilities, feedmills, etc.

VMU personnel handling research animals or performing cage changes are required to wear the following protective clothing: disposable gloves, lab coat and/or scrub suit and N95 facemask or respirator.

ii) Describe programs of medical clearance, fit-testing, and training in the proper use and maintenance of respirators.

All VMU personnel undergo fit testing for the N95 facemask and/or respirator, done by the Industrial Hygienist, on an annual basis.

iii) Describe how such respiratory protective equipment is selected and its function periodically assessed.

The Industrial Hygienist for CAVHS and Engineering Service works with Research Service to provide the annual maintenance on safety equipment within the VMU. The Industrial Hygienist provides annual fit testing for the N95 facemasks and respirators. In conjunction with Biomedical Service, the Industrial Hygienist performs annual testing for noise levels, air flow, and monitoring of any hazardous chemicals (including disinfectants) within the VMU.

f) Heavy Equipment and Motorized Vehicles

i) Provide a general list of the types of cage-processing equipment used, such as rack/cage washers, tunnel washers, robotics, and bulk autoclaves. Describe training programs, informational signage, and other program policies designed to ensure personnel safety when working with such equipment.

Note: Details of specific equipment installed in animal facility(ies) are to be provided in **Appendix 15** (Facilities and Equipment for Sanitizing Materials).

Personnel operating chemical dispensing equipment such as cage/rack washers, and detergent/disinfectant/acid dispensing machines will exercise caution and wear appropriate personnel protective equipment during the use of this equipment. All SOPs and guidelines for the operation of such equipment will be followed. In the event a chemical splash where eye or skin contact is made, the affected area will be immediately flushed with water. Personnel who have had chemicals splashed into the eye region will immediately flush the eyes in one of the two eye washes present in the VMU and report to Employee Health Service with the VMU Supervisor as soon as possible.

Personnel with chemical burns to the skin must also report to Employee Health Service with the VMU Supervisor as soon as possible. The two eye wash stations in the VMU are tested weekly.

ii) List other heavy equipment such as scrapers, tractors, and farm machinery (manufacturer name, model numbers, etc. are not necessary). Describe training programs, informational signage, and other program policies designed to ensure personnel safety when working with such equipment.
Note: If preferred, this information may be provided in a Table or additional Appendix.

No other heavy equipment.

iii) If motorized vehicles are used for animal transport, describe how the driver is protected from exposure to hazards such as allergens or zoonoses and decontamination methods employed. Also describe instances where vehicles may be shared between animal and passenger transport.

A government van is available to the VMU for transporting animals. When transporting rodents a secondary enclosure is required (e.g., an autoclavable cloth bag or disposable shipping box).

Animals are always obscured from view by the cloth bag or the opaque secondary enclosure. Only VMU personnel are allowed to transport animals. The animal care technicians transporting the animals are trained and aware of the risks to themselves and others of exposure to allergens and to negative reactions by those who are opposed to animal use in research. Public areas are avoided when

possible.

Appropriate personal protective equipment (PPE) must be used during transport to prevent cross contamination among animals and between humans and animals (e.g. pathogenic organisms and other biological materials, chemicals, fomites, etc.).

Release of animal dander, airborne animal allergens and animal bedding into the environment is minimized. VMU personnel should ensure that filter tops or other effective covers are used on rodent cages and cages are covered during transport. Empty, soiled cages should be covered during transport.

Temperature extremes must be avoided. Special precautions must be taken to protect animals from heat or cold stress when climatic temperatures are inappropriate for the species (e.g., below 45 F or about 85 F).

Reusable primary or secondary enclosures must be sanitized between use to prevent the spread of pathogenic microorganisms, animal wastes and allergens. When any body fluids (blood, urine, salvia, mucus), feces, or dirty bedding contacts any surface outside the enclosures, it should be removed and the area appropriately disinfected as soon as possible.

g) Describe safety procedures for using medical gases and volatile anesthetics, including how waste anesthetic gases are scavenged.

All anesthesia dispensing equipment in the VMU has been modified to connect to the CAVHS supplied vacuum system or HVAC exhaust vent. All gas anesthetic wastes are scavenged into the Medical Center vacuum system or HVAC exhaust vent. The Industrial Hygienist for CAVHS monitors gas anesthetic dispensing equipment on an annual basis. All anesthesia gas dispensing equipment is annually pulled out of service by CAVHS Biomedical Repair Service and preventive maintenance is performed.

iii. Animal Experimentation Involving Hazards [*Guide*, pp. 20-21]

1) List, according to each of the categories noted below, hazardous or potentially hazardous agents currently approved to be used in animals that are or will be maintained for more than a few hours following exposure. If the hazardous agent cannot be listed by name for security/proprietary reasons, identify it by the general category of agent and level of hazard.
Note: If preferred, this information may be provided in a Table or additional Appendix.

a) Biological agents, *noting hazard level* (CDC Biohazard Level, Directive 93/88 EEC, CDC or USDA/DHHS Select Agent, etc.). Examples may include bacteria, viruses, viral vectors, parasites, human-origin tissues, etc.

1) Endotoxin. Dose: 100µg/kg. One time IP. Housed for 30 days: Biosafety Level 1
2) Human cell lines. Dose: Varies. One time subcutaneous, breast tissue, and prostate tissue. Housed up to 3 months: Biosafety Level 1

b) Chemical agents, *noting general category* of hazard (toxicant, toxin, irritant, carcinogen, etc.). Examples may include streptozotocin, BrdU, anti-neoplastic drugs, formalin, etc.

1) Cisplatin (carcinogen). Dose: 20 mg/kg. One time IP. Housed for up to 7 days
2) DMBA (carcinogen). Dose: 80 mg/kg. One time oral. Housed 90 days
3) Deferiprone (chelator). Dose: 2.5 g/L in drinking water. Housed 32 weeks
4) Tunicamycin. (toxin) Dose: 20 mg/kg, I.P., once

c) Physical agents (radiation, UV light, magnetic fields, lasers, noise, etc.).

No current protocols use physical agents.

2) Experiment-Related Hazard Use [*Guide*, pp. 18-19; See also Chapters 2 and 3 in *Occupational Health and Safety in the Care and Use of Research Animals*, NRC 1997].
Note: Written policies and standard operating procedures (SOPs) governing experimentation with hazardous biological, chemical, and physical agents should be available during the site visit.

a) Describe the process used to identify and evaluate experimental hazards. Describe or identify the institutional entity(ies) responsible for ensuring appropriate safety review prior to study initiation.

Institution safety personnel such as the Infection Control Officer, the Research Safety Officer, the Biosafety Officer, the Radiation Safety Officer, and the Subcommittee for Research Safety assess the risks associated with potential hazards and approve/disapprove the initiation of projects involving hazardous agents. The SRS also makes recommendations for safety procedures to be incorporated into the SOP and the extent which personnel can participate.

b) Describe how risks of these hazards are assessed and how procedures are developed to manage the risks. Identify the institutional entity(ies)

responsible for reviewing and implementing appropriate safety or containment procedures.

Institution safety personnel such as the Infection Control Officer, the Research Safety Officer, the Biosafety Officer, the Radiation Safety Officer, and the Subcommittee for Research Safety assess the risks associated with potential hazards and approve/disapprove the initiation of projects involving hazardous agents. The SRS also makes recommendations for safety procedures to be incorporated into the SOP and the extent which personnel can participate.

c) Describe the handling, storage, method and frequency of disposal, and final disposal location for hazardous wastes, including infectious, toxic, radioactive carcasses, bedding, cages, medical sharps, and glass.

All waste that is designated as a biohazard is packaged in plastic lined boxes or red, sealable buckets labeled appropriately and incinerated.

Contaminated carcass disposal is often similar to disposal methods for other contaminated materials, but in this case needs to reflect the nature of the hazardous agent in use. Upon completion of the necessary work with the carcass, it must be bagged, labeled, and disposed of in accordance with applicable regulations. Holding, when necessary, must be accomplished in a refrigerator or freezer reserved for carcass disposal.

Radioisotopes administered to research animals are handled in much the same manner as biohazardous material except that the Radiation Safety Officer monitors the level of radioactivity. Dead animals and bedding exposed to these isotopes are stored in a specially marked storage area and disposed of by the Radiation Safety Officer. The bedding is stored in labeled boxes and disposed of by a contracted service. The Radiation Safety Committee must first approve protocols using radioisotopes. The handling of radioisotopes is the responsibility of the Principal Investigator.

d) Describe aspects of the medical evaluation and preventive health program specifically for personnel potentially exposed to hazardous agents.

A pre-exposure questionnaire is required by this institution for all VMU employees exposed to carcinogens followed by an annual questionnaire specific to the hazard. A physical exam may be suggested based on the answers to the questionnaire. Personnel assigned to projects using cancer-causing agents (i.e., cisplatin) must follow all Standard Operating Procedures developed for that hazard.

An annual review in the form of an interview by a qualified medical

professional can substitute for a physical exam in the Preventative Medicine Program. The information collected is considered privileged medical information and subject to Federal regulations that govern the collection and use of personal information.

3) **Hazardous Agent Training for Personnel** [*Guide*, p. 20]
Describe special qualifications and training of staff involved with the use of hazardous agents in animals.

All personnel who are potentially exposed to hazardous agents must first review the Standard Operating Procedures prepared for the particular hazard, along with the investigator's protocol for safeguards. The supervisor of the Veterinary Medical Unit and the Principal Investigator conduct this review in the event there are concerns that have not been properly addressed.

The investigator must provide the Veterinary Medical Unit Supervisor with a Safety Data Sheet (SDS) pertaining to the hazardous agent used. The SDS information is available in the Veterinary Medical Unit supervisor's office, as well as posted on the animal ward door. All personnel must attend all Standard Operating Procedures reviews. The review covers potential hazards such as animal bites, allergies, and hazards due to chemical cleaning agents and zoonoses. Personnel are informed of the procedures to be taken in the event of personal injury (animal bite, chemical burn, and exposure to caustic fumes, etc.). All injuries must be reported to the supervisor and to the Employee Health Service.

Institution safety personnel such as the Infection Control Officer, the Research Safety Officer, the Biosafety Officer, the Radiation Safety Officer, and the Subcommittee for Research Safety assess the risks associated with potential hazards and approve/disapprove the initiation of projects involving hazardous agents. The SRS also makes recommendations for safety procedures to be incorporated into the SOP and the extent which personnel can participate.

4) **Facilities, Equipment and Monitoring** [*Guide*, pp. 19-20]

a) Describe locations, rooms, or facilities used to house animals exposed to hazardous agents. Identify each facility according to the hazard(s) and containment levels (if appropriate).
Note: If preferred, information may be provided in a Table or additional Appendix.

Rooms where cancer causing agents (i.e., cisplatin, DMBA) or other hazardous agents are used are labeled with a biohazard sign and the agent being used is recorded on the sign. The SDS is included on the door of the animal ward. The animal cage card is labeled with the agent being

used on an appropriate colored warning tag. VMU animal care technicians wear the appropriate Personnel Protective Equipment (PPE) and follow established SOP guidelines when entering these areas. The handling of animals, bedding, refuse, etc. exposed to hazardous materials requires VMU personnel to wear facemasks, gloves and protective clothing when in contact with these animals. For cage changes, an air- filtered change station which draws aerosols away from the caretaker, are used when soiled, contaminated bedding is removed from cages.

All waste that is designated as a biohazard is packaged in plastic lined boxes or red, sealable buckets labeled appropriately and incinerated.

Contaminated carcass disposal is often similar to disposal methods for other contaminated materials, but in this case needs to reflect the nature of the hazardous agent in use. Upon completion of the necessary work with the carcass, it must be bagged, labeled, and disposed of in accordance with applicable regulations. Holding, when necessary, must be accomplished in a refrigerator or freezer reserved for carcass disposal.

Radioisotopes administered to research animals are handled in much the same manner as biohazardous material except that the Radiation Safety Officer monitors the level of radioactivity. Dead animals and bedding exposed to these isotopes are stored in a specially marked storage area and disposed of by the Radiation Safety Officer. The bedding is stored in labeled boxes and disposed of by a contracted service. The Radiation Safety Committee must first approve protocols using radioisotopes. The handling of radioisotopes is the responsibility of the Principal Investigator.

b) Describe circumstances and conditions where animals are housed in rooms outside of dedicated containment facilities (i.e., in standard animal holding rooms). Include practices and procedures used to ensure hazard containment.

Animals are not housed in rooms outside dedicated containment facilities.

c) Describe special equipment related to hazard containment; include methods, frequency, and entity(ies) responsible for assessing proper function of such equipment.

Special flow hoods are available for working with animals exposed to hazardous agents. These hoods are inspected and certified annually.

d) Describe the husbandry practices in place to ensure personnel safety, including any additional personnel protective equipment used when work assignment involves hazardous agents.

VMU animal care technicians wear the appropriate Personnel

Protective Equipment (PPE) and follow established SOP guidelines when entering these areas. The handling of animals, bedding, refuse, etc. exposed to hazardous materials requires VMU personnel to wear facemasks, gloves and protective clothing when in contact with these animals. For cage changes, an air- filtered change station which draws aerosols away from the caretaker, are used when soiled, contaminated bedding is removed from cages.

e) Incidental Animal Contact and Patient Areas

i) List and describe facilities that may be used for both animal- and human-based research or patient areas, including the policies and procedures for human patient protection, facility decontamination, animal transport through common corridors or elevators, and other personnel protection procedures.

There are no facilities at CAVHS where animal procedures are performed in conjunction with human-based research or patient areas.

ii) Describe any *other* circumstances in which animals or caging equipment are transported in common use corridors or elevators (e.g., have the potential to come in contact with individuals not associated with the animal care and use program), and measures taken to mitigate risks associated with such use.

The VMU is located on the (b)(6) floor of the John L. McClellan Hospital of CAVHS within Research Service. Research Service has approximately 62,000 square feet of which the VMU is approximately 12,000 square feet. Research Service has an outer security periphery that includes magnetic locks and badge access control. Research Service has access to outside doors that are not common use doors for any personnel from the hospital. CAVHS does not have any satellite facilities.

B. Program Oversight

1. The Role of the IACUC/OB [*Guide*, pp. 24-40]

a. IACUC/OB Composition and Function [*Guide*, pp. 17; 24-25]
Please provide a Committee roster, indicating names, degrees, membership role, and affiliation (e.g., Department/Division) as **Appendix 7**.

i. Describe Committee membership appointment procedures.

The IACUC chairperson shall be appointed by the Medical Center Director for a term of one (1) year and may be reappointed without any lapse in time. There is no limit to how many times a chair may be reappointed. The IACUC chairperson shall not simultaneously chair the R&D Committee or another subcommittee thereof.

Members other than those who are designated ex officio may serve terms of up to 3 years, on staggered appointments. Members may be re-appointed without lapse in service to the IACUC.

ii. Describe frequency of Committee meetings. Note that **Appendix 8** should contain the last two IACUC/OB meeting minutes.

Members of the IACUC meet monthly, although the Chair may call special meetings as needed.

iii. Describe the orientation, training, and continuing education opportunities for IACUC/OB members. [*Guide*, p. 17]

New members to the IACUC are provided orientation on the VA and CAVHS specific regulations governing animal research to include CAVHS Memorandum 151-10 "Subcommittee for Animal Studies" and VHA Handbook 1200.07 "Use of Animals in Research") IACUC members must also pass the examination covering the "Essentials for IACUC Members" web course. The site for this training is found as: http://www.citiprogram.org. New members are utilized as secondary reviewers on several protocols prior to assignment as a primary reviewer.

Quarterly, at regularly scheduled IACUC meetings, members interact with discussion of the IACUC Training Scenario Series provided by the Office of Research and Development, Central Office, Department of Veterans Affairs. These training scenarios are intended to encourage discussion among the IACUC members. Research Service also encourages members of the IACUC to attend meetings and workshops and will provide travel stipends when available.

b. Protocol Review [*Guide*, pp. 25-27]
A blank copy of your institution's protocol review form should be provided as **Appendix 9**. Also include forms used for annual renewal, modifications, amendments, etc., as applicable.

i. Describe the process for reviewing and approving animal use. Include descriptions of how:

- the IACUC/OB weighs the potential adverse effects of the study against the potential benefits that may result from the use ("harm-benefit analysis"),
- protocols that have the potential to cause pain or distress to animals are reviewed and alternative methodologies reviewed,
- veterinary input is provided, and

- the use of animals and experimental group sizes are justified.

Note: Make sure you address each of the items above.

The IACUC reviews all proposals involving animal use to ensure that the principal investigator incorporates the following principles into their research: scientific reliance on live animals should be minimized, and pain, distress and other harm to laboratory animals should be reduced to the minimum necessary to obtain valid scientific data.

All protocols are first submitted to the Veterinary Medical Officer (VMO) for his review. The VMO submits his comments and suggestions in writing to the Principal Investigator (PI) of the protocol. The VMO is specifically concerned, but not limited to, procedures which may result in pain, distress or ill effects that cannot be alleviated or prevented with drugs; procedures using prolonged restraint; procedures requiring the development of a serious natural or experimental disease, especially when that disease state would be maintained for an extended period of time; and methods of euthanasia differing from those recommended by the AVMA panel on euthanasia.

The PI incorporates the changes suggested by the VMO and submits copies of the protocol along with the Budget Sheet, appropriate Material Safety Data Sheet/s (MSDS), database search strategy and appropriate ACORP appendices to the IACUC Coordinator. If applicable, a copy of the research plan from the funded grant is also submitted. The Deputy ACOS compares the grant to the ACORP for consistency.

The IACUC Coordinator notifies the IACUC Chairperson, and the Chairperson assigns the ACORP to two (2) IACUC members for full review. All new and renewal ACORPS are subjected to full review. Protocol procedures that have the potential to cause pain or distress are reviewed by the full IACUC. The Principal Investigator must address personnel qualifications, pre and post operation procedures including intra operative monitoring if surgery is involved, analgesics, post-operative monitoring and support methods. The institution has an electronic data management system to administer the protocols. All documentation associated with a submission is maintained within the electronic data management system. The IACUC Coordinator informs all IACUC members seven days in advance of the protocols to be discussed at the next convened IACUC meeting. The IACUC coordinator informs all IACUC members of the location within the data base of the meeting materials. If a quorum is not present at the monthly IACUC meeting, no votes are taken on protocols. However, if a quorum is present at the monthly IACUC meeting, the reviewers then present their comments and concerns to the committee members and the protocol is discussed by all committee members. If a member of the committee has submitted a protocol application to be discussed, that member will be excused from the meeting until the discussion and vote on the protocol has been completed. The IACUC then votes on the protocol. No member may participate in the IACUC review or approval of a research project in which the member has a conflicting interest except to provide information requested by

the IACUC.

CAVHS IACUC utilizes designated member review on animal study protocols subsequent to full committee review when modifications were needed to secure approval. All IACUC members must agree that the quorum of members present at a convened meeting may decide by unanimous vote to use designated member review subsequent to full committee review when modifications are needed to secure approval. If an IACUC member has a conflict of interest with a specific protocol, that member does not contribute to a quorum for that particular vote. Any member of the IACUC may, at any time, request to see the revised protocol and/or request full committee review of the protocol.

The vote may then result in approval of the protocol, required modifications to secure approval, or withhold approval which is decided by a majority vote of the convened IACUC members. If the vote for the protocol requires modifications to secure approval, the method of designated member review subsequent to full committee review may be used with the prior agreement of the IACUC members that this method is approved and with a unanimous vote of the convened quorum of IACUC members. If this is the case, the original two IACUC members chosen for the full review are the designated members who will perform this duty. All designated member reviewers will review identical copies of the protocol and response. The designated member review may result in approval, a requirement for modifications to secure approval or refer the ACORP back to the full committee for review. The designated reviewers must be unanimous in their decision. They cannot disapprove the protocol. If they cannot approve the protocol, it must come back for a full IACUC review. If the protocol is disapproved, a list of concerns is forwarded to the Principal Investigator from the IACUC chairperson and the protocol is resubmitted to the IACUC for full review at the next monthly meeting.

Designated member review is available for modifications to an existing protocol. The changes are described on the form "Application for Protocol Modification ". This form can only be used in making a minor change to an approved protocol. If changes to an approved protocol are substantial (i.e., change of/or additional animal species, survival surgery, change increases the potential for pain or distress in the animal, or involves a significant procedure not previously approved for these animals), a new ACORP must be submitted. A new experiment or a pilot study cannot be approved as a modification even if the same funding source is used. The changes that are considered minor by the IACUC and are allowed for designated review are: a change in the test substance, a change in the anesthesia/analgesia, animal numbers, addition or deletion of an animal strain, method of euthanasia, and addition or deletion of personnel. All proposed changes must be reviewed with the Veterinary Medical Officer before submission to the IACUC Coordinator. Once submitted, the IACUC Coordinator will inform the full committee of the location of the documentation within the electronic data management system. Any member of the IACUC has the opportunity to request full committee review of a protocol modification. If this is the case, the IACUC Chairperson will follow the procedure for full committee review. If there are no objections to designated review, the

IACUC Chairperson appoints two members of the IACUC committee for designated review. The designated reviewers have authority to approve the modifications for the ACORP or approve the modification after appropriate corrections have been made. The designated reviewers must be unanimous in their decision. No member may participate in the IACUC review or approval of a research project in which the member has a conflicting interest. The designated reviewers cannot disapprove the protocol. If they cannot approve the protocol, it must come back for a full IACUC review.

There is no form of expedited protocol review.

ii. Describe the process for reviewing and approving amendments, modifications, and revised protocols. If applicable, include a description/definition of "major" vs. "minor" amendments.
Note: If preferred, this information may be provided in a Table or additional Appendix.

Any significant changes in an approved protocol must be approved by the IACUC prior to their implementation. Examples of significant changes include, but are not limited to, changes in the objectives of a study, from non-survival surgery to survival surgery, resulting in greater discomfort or greater degree of invasiveness, in the species or in approximate number of animals used greater than 10% approved, in PI, and in the duration, frequency, or number of procedures performed on an animal.

The Principal Investigator must submit a modified ACORP with the changes identified to the VMO for his suggestions followed by a review of the IACUC. The IACUC may review the protocol or may elect to have the protocol reviewed by designated reviewers. Once the modified ACORP has been submitted, the IACUC coordinator notifies the IACUC members that document(s) are contained within the electronic data management system. If even one member of the IACUC requests full review for the modifications, the protocol will go for full review. Each IACUC member has five (5) business days to request a full committee review after notification of the amended protocol. If full committee review is not requested, the IACUC Chairperson appoints two members of the IACUC committee for designated review. The designated reviewers have the authority to approve, require modifications in (to secure approval) or request full committee review of those research projects. The designated reviewers must be unanimous in their decision. No member may participate in the IACUC review or approval of a research project in which the member has a conflicting interest. The designated reviewers cannot disapprove the protocol. If modifications are required to secure approval of the significant changes, both designated reviewers must agree to the proposed modifications. If they cannot approve the protocol, it must come back for a full IACUC review. If full committee review is requested, approval of those research projects may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present. No member may participate in the IACUC review or approval of a research project in which the member has a conflicting

interest except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum.

c. Special Considerations for IACUC/OB Review [*Guide*, pp. 5; 27-33]

i. Experimental and Humane Endpoints [*Guide*, pp. 27-28]

1) Describe the IACUC/OB's review of "humane endpoints," i.e., alternatives to experimental endpoints to prevent or in response to unrelieved animal pain and distress.

Endpoints are a part of every animal protocol and the IACUC must address the endpoint for every animal on the study. The ideal situation would be when the scientific aims and objectives of the study can be accomplished without adverse affects, pain or distress to the animal. However, this is not always possible and careful consideration must be given to the scientific requirements of the study, the expected and possible adverse effects the research animals may experience (pain, distress, illness, etc.), the most likely time course and progression of those adverse effects, and the earliest most predictive indicators of present or impending adverse effects. Where pain or distress is a necessary part of the study, a humane endpoint must always be used; thus, the IACUC approved earliest scientifically justified point at which pain or distress in an experimental animal can be prevented, terminated, or relieved, while meeting the scientific aims and objectives of the study.

The effective use of endpoints requires that properly trained and qualified individuals perform both general and study-specific observations of the research animals at appropriate time points. The assessment criteria and required response must be clearly defined, and the use of study-specific animal assessment records should be considered. Studies must be designed to minimize pain and/or distress. If pain or distress is unavoidable, then a scientific justification must be reviewed and approved by the IACUC and the earliest possible endpoint compatible with answering the scientific question must be employed. Such endpoints are preferable to death or moribundity since they minimize pain and distress.

When initiating a new set of experiments, the potential for pain and/or distress may be unknown and/or the nature and extent of resulting morbidity and/or moribundity and/or mortality cannot be anticipated. Therefore, smaller pilot studies may be useful as they can be instrumental to the development of an appropriate endpoint.

Finally, investigators performing studies that include pain or distress should throughout the studies try to refine the endpoint and the necessity for any morbidity and/or mortality.

2) For studies in which humane alternative endpoints are not available, describe the IACUC/OB's consideration of animal monitoring and other means used to minimize pain and distress (e.g., pilot studies, special monitoring, other alternatives).

The effective use of endpoints requires that properly trained and qualified individuals perform both general and study-specific observations of the research animals at appropriate time points. The assessment criteria and required response must be clearly defined, and the use of study-specific animal assessment records should be considered. Studies must be designed to minimize pain and/or distress. If pain or distress is unavoidable, then a scientific justification must be reviewed and approved by the IACUC and the earliest possible endpoint compatible with answering the scientific question must be employed. Such endpoints are preferable to death or moribundity since they minimize pain and distress.

When initiating a new set of experiments, the potential for pain and/or distress may be unknown and/or the nature and extent of resulting morbidity and/or moribundity and/or mortality cannot be anticipated. Therefore, smaller pilot studies may be useful as they can be instrumental to the development of an appropriate endpoint.

Finally, investigators performing studies that include pain or distress should throughout the studies try to refine the endpoint and the necessity for any morbidity and/or mortality.

3) Identify personnel responsible for monitoring animals for potential pain and distress and describe any mechanisms in place to ensure that the personnel have received appropriate species- and study-specific training.

The effective use of endpoints requires that properly trained and qualified individuals perform both general and study-specific observations of the research animals at appropriate time points. The assessment criteria and required response must be clearly defined, and the use of study-specific animal assessment records should be considered. Studies must be designed to minimize pain and/or distress.

All VMU staff and research staff are trained to recognize animals in pain and/or distress before they are allowed to enter the VMU. This training includes online learning components from CITI and from the VMU supervisor.

Research staff with new projects approved by the IACUC are required to meet with the VMU supervisor to discuss any potential study-specific observations.

ii. Unexpected Outcomes that Affect Animal Well-being [*Guide*, pp. 28-29]
Describe how unexpected outcomes of experimental procedures (e.g., unexpected morbidity or mortality, unanticipated phenotypes in genetically-modified animals) are identified, interpreted, and reported to the IACUC/OB.

When performing a study and an unanticipated adverse affect occurs due to the experimental manipulation (morbidity, moribundity, mortality, pain or more than momentary distress) the animals must be immediately euthanized or treated at the first overt signs of adverse affects to avoid IACUC unapproved pain and distress. If standard veterinary treatment would affect the experimental results, the animals will be euthanized unless withholding treatment for the condition(s) is specifically approved in the ACORP. An animal study proposal amendment must be submitted to obtain IACUC approval to continue the experiment on to an endpoint which will include the previously unanticipated pain or distress.

Conditions may arise in breeders or other "normal" animals during the conduct of research that are unexpected and unrelated to the research being conducted. Conditions may be specific, such as a spontaneous tumor, or may be more of a general deterioration of health/quality of life. These conditions can still have a significant impact on animal welfare and experimental results and must be addressed appropriately. Any animal found unexpectedly to be moribund or unable to obtain food or water must be euthanized. In less severe cases that may include pain or distress, the unexpected/unrelated condition should be assessed for the impact on animal welfare and experimental results. If it impacts experimental results, the animal should be euthanized. If it does not affect the experimental results (this would also be the case with a breeder or a normal untreated animal), standard veterinary treatment must be provided. If standard veterinary treatment would affect the experimental results, the animals should be euthanized unless withholding treatment for the condition(s) is specifically approved in the ACORP. If the condition worsens following treatment, the animal should be euthanized dependent on veterinary judgment and with Principal Investigator consultation.

In some animal models, such as specific phenotypes in genetically modified animals, conditions that impact animal welfare can be expected to continue or reoccur. These should be included in the ACORP as "expected resultant affects" to alert animal care staff and specify appropriate additional animal care and/or euthanasia.

iii. Physical Restraint [*Guide*, pp. 29-30]
Note: This section is to include only those protocols that require prolonged restraint. Brief restraint for the purpose of performing routine clinical or experimental procedures need not be described.

1) Briefly describe the policies for the use of physical restraint procedures or devices. Include, if applicable, the IACUC/OB definition of "prolonged."

There are currently no protocols that require the use of physical restraint

procedures or devices at CAVHS.

2) Describe animal restraint devices that are used or have been used within the last three years. For each device, briefly describe

- the duration of confinement
- acclimation procedures
- monitoring procedures
- criteria for removing animals that do not adapt or acclimate, and
- provision of veterinary care for animals with adverse clinical consequences.

Note: If preferred, this information may be provided in a Table or additional Appendix.

As stated, there are no current protocols that require the use of physical restraint procedures or devices at CAVHS. There have not been any protocols that require the use of physical restraint procedures or devices in the previous five years.

iv. Multiple Survival Surgical Procedures [*Guide*, p. 30]

Note: One survival surgical procedure followed by a non-survival procedure is not included in this category.

1) Describe the IACUC/OB's expectations regarding multiple survival surgery (major or minor) on a single animal.

The IACUC reviews all proposals involving animal use, including those protocols involving multiple survival surgery, to ensure that the principal investigator incorporates the following principles into their research: scientific reliance on live animals should be minimized, and pain, distress and other harm to laboratory animals should be reduced to the minimum necessary to obtain valid scientific data. Criteria used for review must include justification that the multiple survival surgeries are essential components of the protocol, scientific justification for the surgeries, or necessary for clinical reasons. Strong evidence must be demonstrated that multiple survival surgical procedures are necessary before the IACUC will consider or grant the request.

2) Summarize the types of protocols currently approved that involve multiple major survival surgical procedures

Note: If preferred, this information may be provided in a Table or additional Appendix.

There are currently no protocols that involve multiple major survival surgical procedures.

v. **Food and Fluid Regulation** [*Guide*, pp. 30-31]. *Note:* This does not include pre-surgical fast.

Summarize the types of protocols that require food and/or fluid regulation or restriction, including:

- justification
- species involved
- length and type of food/fluid regulation
- animal health monitoring procedures and frequency (e.g., body weight, blood urea nitrogen, urine/fecal output, food/fluid consumption)
- methods of ensuring adequate nutrition and hydration during the regulated period

Note: If preferred, this information may be provided in a Table or additional Appendix.

No studies involving food and /or fluid restriction/regulation are being conducted. Currently, only rodents are used for survival surgical procedures and do not require food/fluid restrictions prior to surgery.

vi. **Use of Non-Pharmaceutical-Grade Drugs and Other Substances** [*Guide*, p. 31]

Describe the IACUC/OB's expectations regarding the justification for using non-pharmaceutical-grade drugs or other substances, if applicable.

The IACUC expects investigators to use pharmaceutical grade drugs unless the use of non-pharmaceutical grade drugs can be justified. The IACUC follows OLAW's policy regarding the use of non-pharmaceutical grade drugs. OLAW requires that only pharmaceutical grade compounds be administered to animals unless the use of non-pharmaceutical grade compounds is justified by scientific necessity and the lack of availability of an acceptable veterinary or human pharmaceutical grade compound. Investigators must provide a detailed justification for using a non-pharmaceutical grade compound and describe how it will be ensured that the grade, purity, sterility, pH, pyrogenicity, osmolality, stability, formulation, and pharmacokinetics of the material will be suitable for use in the animals. OLAW specifically advises that cost-savings alone do not adequately justify the use of non-pharmaceutical grade compounds in animals.

Other substances may be administered to animals and are considered as hazardous and follow the guidelines described previously. The duties and responsibilities of the Subcommittee for Research Safety (SRS) includes evaluation of protocols and protocol changes for possible biohazards. This applies to infectious agents, carcinogens and toxic agents. The committee approves protocols that comply with usage standards and monitors the ongoing compliance. This committee meets on a monthly basis. The SRS advises the Institutional Animal Care and Use Committee concerning the level of containment required for each protocol and the use/disposal of the

biohazardous agents.

vii. Field Investigations [*Guide*, p. 32]

Describe any additional considerations used by the IACUC/OB when reviewing field investigations of animals (non-domesticated vertebrate species), if applicable.

No field investigations of animals are done at CAVHS.

viii. Animal Reuse [*Guide*, p. 5]

1) Describe institutional policies regarding, and oversight of, animal reuse (i.e., on multiple teaching or research protocols).

There are no protocols at CAVHS that involve the reuse of individual animals at CAVHS.

2) Briefly describe the types of activities currently approved that involve the reuse of individual animals.
Note: A list of specific protocols involving reuse of animals should be available during the site visit.

There are no protocols at CAVHS that involve the reuse of individual animals at CAVHS.

3) Describe other instances where the final disposition of animals following study does not involve euthanasia, including adoption, re-homing, rehabilitation, etc.
Note: A list of specific protocols involving reuse of animals should be available during the site visit.

There are no protocols at CAVHS that involve the reuse of individual animals at CAVHS.

2. Post-Approval Monitoring [*Guide*, pp. 33-34]

a. Describe mechanisms for IACUC/OB review of ongoing studies and periodic proposal/protocol reviews (e.g., annual, biennial, triennial, or other frequency).

The IACUC performs continuing review of each previously approved, ongoing activity covered at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy at IV.C.1-4. at least once every three years. The IACUC procedures for conducting continuing review are:

a. The IACUC will conduct a yearly continuing review of each approved ongoing protocol. This is primarily the responsibility of the VMO, the Supervisor of the VMU,

and the IACUC chairperson.

b. All protocols are initially approved for a three (3) year period and must be resubmitted as a new ACORP to the VMO near the end of the three year period, prior to the expiration date of the protocol. Normal procedures are then followed as described previously for a new ACORP submission. This includes submitting the protocol first to the Veterinary Medical Officer (VMO) for her review. The VMO submits her comments and suggestions in writing to the Principal Investigator (PI)of the protocol. All renewal ACORPS (which are considered new ACORPs) are subjected to full review by the IACUC.

c. The post approval monitoring process reviews active protocols to ensure research is being conducted in accordance with what is written and approved. The protocols are selected randomly and represent 5% of the active protocols per quarter. The animal ward/procedure room is visited by the Supervisor of the VMU often with a Research Compliance Officer or IACUC member. Procedures on the selected protocol are observed and any drift from the protocol is noted. The investigator then has the opportunity to correct any deviations by improving techniques or by submitting an amendment to the protocol. The visit is as informal as possible and is an opportunity for the investigators to request any help they may need. Findings are reported at the next IACUC meeting. The report of the visit and any follow up visits are filed in the investigators IACUC protocol file. A brief follow up visit occurs after the first to document that any deficiencies highlighted in the first visit have been rectified.

d. The electronic data management system utilized by the institution generates reminders 90, 60, and 30 days prior to the annual expiration date of an ACORP. The PI, the Deputy ACOS and the IACUC coordinator are notified of the upcoming renewal dates. The "Request for Continued Approval for Animal Use" form is found in the data management system library of forms. The Principal Investigator completes the form and returns it to the IACUC Chairperson through the electronic data management system who expedites approval as long as there are no amendments or changes to the protocol. The expedited approvals are noted in the IACUC minutes.

b. Describe the process and frequency with which the IACUC/OB reviews the program of animal care and use.

The VMU Director and Supervisor evaluates, reviews, and updates the institution's program for human care and use of animals using USDA regulations, the Guide, institutional policies, VA policies, and other relevant material in May and November of each year. The Director and Supervisor then consult with the VMO and IACUC Chair on the contents. The Review of the Program is largely an administrative evaluation of all of the policies, plans, standard procedures, and systems under which the institution fulfills its responsibilities to ensure humane animal care and use. The VA Semiannual Evaluation of the Institutional Animal Care and Use Program and Facilities is the checklist used for this evaluation.

The checklist is designed to prompt review according to regulatory requirements,

and focuses on the minimum standards that must be met. The wording in the checklist is not to be interpreted as altering the regulatory requirements in any way, but represents guidance from the office of the Chief Veterinary Medical Officer for the Department of Veterans Affairs.

The document is then distributed to each of the members of the IACUC at least two weeks prior to the monthly meeting (last Monday of the month). The document is then discussed at the monthly meeting and the document approved pending any relevant changes that are necessary.

c. Describe the process and frequency with which the IACUC/OB conducts facility and laboratory inspections.

- Describe the rationale or criteria used for exempting or varying the frequency of reviewing satellite holding facilities and/or animal use areas.
- If contract facilities or contractor-provided personnel are used, describe procedures used by the IACUC/OB to review such programs and facilities.

Note: A copy of the last report of these reviews should be included as **Appendix 10**.

The IACUC members conduct the semiannual facility inspection in May and November of each year. Included in the inspection is a representative from the Medical Center Director's Office, the Chief of Staff's Office and the Engineering Service of the institution. All IACUC members are encouraged to participate in the semiannual facility inspection. However, according to the Animal Welfare Act Regulations, at least two IACUC members, delegated by the IACUC, are required for the inspection. The inspection includes the animal facility, satellite laboratories if approved for surgery by the IACUC, and transportation records. Each area is inspected for cleanliness, proper record keeping and general condition. Freezers and refrigerators, cold rooms, the dirty and clean sides of the cage washing area, and the surgery and recovery rooms are also inspected.

The IACUC utilizes the following three (3) forms for conducting the semi-annual institution's program for humane care and use of animals and the institution's animal facilities:

1) VA IACUC Semi-Annual Self-Review Form
2) Table of Program and Facilities Deficiencies
3) Post-Review Documentation

d. If applicable, summarize deficiencies noted during external regulatory inspections within the past three years (e.g., funding agencies, government, or other regulatory agencies) and describe institutional responses to those deficiencies. *Note:* Copies of all such inspection reports (if available) should be available for review by the site visitors.

The prepared reports of the IACUC evaluations as set forth in the PHS Policy at IV.B.3 are submitted to (b)(6), M.D., ACOS for Research, Research and Development Committee of CAVHS, (b)(6) MD, Medical Center Director, and (b)(6), DVM, PhD, Chief Veterinary Medical Officer, Department of

Veterans Affairs. The reports are updated at least once every six months upon completion of the semiannual facility inspection and review of the institution's program for human care and use of animals. The reports are maintained on file by the institution. Within the VA IACUC Semi-Annual Self-Review Form, there is a description of the nature and extent of the institution's adherence to the Guide and PHS Policy and states any departures from the provisions of the Guide and PHS Policy and the resultant reasons for each departure. The Table of Program and Facilities Deficiencies distinguishes between significant and minor deficiencies, with a significant deficiency being one that is or could possibly be a threat to health or safety of the animals. Also, within this table are specific plans and reasonable time frames for correction of all deficiencies. The Post- Review Documentation lists the dates of the program evaluation and facilities inspection and those who participated in such. Any minority views are discussed within this document or, if there were no minority views, a statement reflecting this is included. The final reports are signed by a majority of IACUC members and include the signatures of those who attended the facilities inspection and representatives from the Director's Office and Engineering Service.

e. Describe any other monitoring mechanisms or procedures used to facilitate ongoing protocol assessment and compliance, if applicable.

Policy within the Department of Veteran Affairs includes the Research Compliance Office. The Research Compliance Office exists to evaluate the adherence of Research and Development to applicable laws, regulations, policies, and procedures in the conduct of animal research. The Research Compliance Officer uses auditing techniques to monitor and assess research compliance risks and to assist in the reduction of identified problem areas. Every animal protocol is audited at least once every three years, or once during the life of the study, if opened less than three years. The audit results are compiled into a written report.

The written report is provided to the PI, the IACUC, the Research and Development Committee, the ACOS/Research, the AO/Research, and the Medical Center Director.

3. Investigating and Reporting Animal Welfare Concerns [*Guide*, pp. 23-24]
Describe institutional methods for reporting and investigating animal welfare concerns.

CAVHS endeavors to maintain the highest possible standards for animal welfare. The VMU is committed to complying with or surpassing all applicable Federal regulations and guidelines relating to animal care and use. The responsibility for monitoring the care and use of animals for teaching and research at CAVHS is shared primarily by the IACUC and the VMU staff. These two groups are also responsible for addressing any actual or perceived efficiency in the care and use of laboratory animals at this facility. Anyone who observes mistreatment of animals or other violations of CAVHS animal care and use policies should report their concerns to one of the listed offices. Reports may be made anonymously but should be made in writing to include a detailed description of the incident (personnel involved, time, date, place, animals

involved). All internal and external allegations of improper animal care and use at CAVHS will be investigated promptly by the IACUC. A written report of the investigation should be approved by a majority of a convened IACUC quorum and sent to the Medical Center Director through the ACOS/Research.

1. VMU Supervisor: Mail route (151/LR), (b)(6)
2. IACUC Chairman: Mail Route (151/LR), (b)(6)
3. ACOS/Research: Mail Route (151/LR), (b)(6)

The Federal Animal Welfare Act prohibits the discrimination or reprisal against any person reporting a violation of animal welfare regulations or standards. The Animal Welfare Act Regulations provide that "No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulations or standards under the Act." (9 CFR § 2.32(c)(4)).

4. Disaster Planning and Emergency Preparedness [*Guide* p. 35]

Briefly describe the plan for responding to a disaster potentially impacting the animal care and use program:

- Identify those institutional components and personnel which would participate in the response.
- Briefly describe provisions for addressing animal needs and minimizing impact to animal welfare.

Note: A copy of disaster plan(s) impacting the animal care and use program must be available for review by the site visitors.

In the event of a disaster, a cascade callback system has been approved by the Medical Center emergency committee. This system outlines types of disasters, who will be called back and a plan for care or disposition of research animals. VMU personnel, Research Safety Officer, CAVHS Police, the VMO and Research Administrative staff will be involved in a response.

The Attending Veterinarian (VMO) or the designee (the VMU Supervisor) has the authority from the Institutional Official and the IACUC to treat an animal, remove an animal from an experiment, institute appropriate measures to relieve severe pain or distress, or perform euthanasia if necessary.

II. Animal Environment, Housing and Management

Note: Complete each section including, where applicable, procedures performed in farm settings, field studies, aquatic environments, etc.

A. Animal Environment

Note: Facility-specific details regarding mechanical system construction and operation is requested in Section IV.B.5. and **Appendix 11**; current (measured ***within the last 12***

months), detailed (by room) performance data must also be provided as indicated in **Appendix 11**.

1. **Temperature and Humidity** [*Guide*, pp. 43-45]

   a. Describe the methods and frequencies of assessing, monitoring, and documenting that animal room or housing area temperature and humidity is appropriate for each species.
   Note: If preferred, this information may be provided in a Table or additional Appendix.

   The HVAC system is provided by the Medical Center. Each animal ward has individual thermostats and thermometers for monitoring. Maximum and minimum temperatures for each animal ward are maintained by Engineering Service through the HVAC system, which range from 68°-79°F. Humidity is controlled in each individual animal ward through the HVAC system. Individual investigators can request a specific humidity percentage within their animal ward. If no preference is requested, the humidity will remain between 30-70%. Humidity is monitored weekly by Veterinary Medical Unit personnel. Room temperatures are monitored daily by Veterinary Medical Unit personnel and recorded in the animal ward log.

   If the temperature or relative humidity exceeds the recommended range, the animal care technician responsible for that room gives verbal notification to the VMU Supervisor. This notification includes the reason for the occurrence, if known, and the response, if any. Based on the numbers, severity, and circumstances surrounding the occurrence, work orders for repair are submitted to Engineering Service.

   b. List, by species, set-points and daily fluctuations considered acceptable for animal holding room temperature and relative humidity.
   Note: If preferred, this information may be provided in a Table or additional Appendix. [*Guide*, pp. 44 and 139-140]

   For rodents, maximum and minimum temperatures for each animal ward are maintained by Engineering Service through the HVAC system, which range from 68°-79°F. Humidity is controlled in each individual animal ward through the HVAC system. Individual investigators can request a specific humidity percentage within their animal ward. If no preference is requested, the humidity will remain between 30-70%.

   c. Temperature set-points in animal housing rooms and/or environmental conditions are often outside of the species-specific thermoneutral zone. Describe the process for enabling behavioral thermoregulation (e.g., nesting material, shelter, etc.) or other means used to ensure that animals can control their thermoregulatory environment. Include a description of IACUC/OB approved exceptions, if applicable. [*Guide*, p. 43]

   If the temperature or relative humidity exceeds or drops below the recommended

range, the animal care technician responsible for that room gives verbal notification to the VMU Supervisor. This notification includes the reason for the occurrence, if known, and the response, if any. Based on the numbers, severity, and circumstances surrounding the occurrence, work orders for repair are submitted to Engineering Service. There are no protocols at CAVHS where environmental conditions are outside the thermoneutral zone of the species.

2. **Ventilation and Air Quality** [*Guide*, pp. 45-47]

   a. Describe the methods and frequencies of assessing, monitoring, and documenting the animal room ventilation rates and pressure gradients (with respect to adjacent areas).
   Note: If preferred, this information may be provided in a Table or additional Appendix.

   The animal wards are supplied with 100% fresh filtered outside air with each ward achieving at least 15 air changes per hour. Very few problems with the animal ward ventilation rates occur. As stated, room temperatures are monitored daily and air flow/humidity is monitored weekly. Problems with airflow or temperature are reported immediately to Engineering Service. Ventilation checks are not requested unless there is a problem with airflow direction or a room becoming static.

   b. Describe ventilation aspects of any special primary enclosures using forced ventilation.

   The only forced ventilation is via animal isolation rack using a HEPA filter. Air is exhausted into the room, and is, in turn, exhausted to the outside via Medical Center HVAC.

   c. If any supply air used in a room or primary enclosure is recycled, describe the percent and source of the air and how gaseous and particulate contaminants are removed.

   No supply of air is recycled.

3. **Life Support Systems for Aquatic Species** [*Guide*, pp. 84-87]

   a. Provide a general description of institutional requirements for enclosures using water as the primary environmental medium for a species (e.g., aquatics).

   There are no protocols using water as the primary environmental medium for a species (e.g., aquatics).

   b. Provide a general description of overall system(s) design, housing densities, and water treatment, maintenance, and quality assurance that are used to ensure species appropriateness.

Note: Facility-specific tank design and parameter monitoring frequencies should be summarized in **Appendix 12** (Aquatic Systems Summary).

There are no protocols using water as the primary environmental medium for a species (e.g., aquatics).

4. **Noise and Vibration** [*Guide*, pp. 49-50]
Describe facility design features and other methods used to control, reduce, or prevent excessive noise and vibration in the animal facility.

No special methods to reduce or prevent excessive noise or vibration have been designed for this facility. All personnel working within the facility are encouraged to take precautions against excessive or loud noises (ex. yelling, dropping objects, etc.) Cage washing and cage storage areas are separated from animal wards. Hearing protection is available within the cage washing area.

B. Animal Housing (all terrestrial, flighted, and aquatic species)

1. **Primary Enclosures**
Note: A description of primary enclosures used (e.g., cages (conventional, individually-ventilated cage systems (IVCS), etc.), pens, stalls, pastures, aviaries, tanks) should be included in **Appendix 13**.

a. Describe considerations, performance criteria and guiding documents (e.g. *Guide*, *Ag Guide*, ETS 123 and/or other applicable standards) used by the IACUC/OB to verify adequacy of space provided for all research animals, including traditional laboratory animal species, agricultural animals, aquatic species, and wildlife when reviewing biomedical, field and agricultural research studies.

Rodent cages, solid bottom shoebox style, are constructed of see- through polycarbonate. All polycarbonate cages are maintained in excellent condition. When cracks or clouding occurs, the cage is discarded. Wire bottom, metabolic cages are available and used only in protocols approved by IACUC for a specific protocol aim. Rodents are routinely maintained on three types of bedding, one quarter inch corn cob bedding (Harlan Teklad) or Alpha- Dri cellulose (Shepard).

With any bedding, a nestlet is provided for environmental enrichment. All of the bedding types give the rodent opportunities for partial nesting and help maintain a more even cage temperature. The Transgenic Core uses Alpha-Dri cellulose based bedding manufactured by Shepard. Room temperature for these species is maintained between 72^0-76^0F. All rodent cages are either equipped with automatic water sipper tubes, sippy sacks, or water bottles and all have either a wall mounted feeding station constructed of stainless steel or stainless steel wire feeding slots mounted in a stainless steel wire cage cover.

Two (2) horizontal laminar flow, HEPA filtered racks for housing rodents are available. These racks have the ability for reverse air flow depending on whether

the animal is being protected (ex. athymic mice) or other animals are being protected (i.e., animals acquired with unknown health status). These units operate within animal wards and are portable.

Eight (8) Gentle Air mouse isolation racks are available. Each unit contains 144 cages and is designed to supply HEPA filtered air to each individual cage. Two (2) Modular Animal Caging System racks are available. Each unit contains 180 cages and is designed to supply HEPA filtered air to each individual cage.

Ten (10) Super Mouse 1800 Stack-A-Rack racks are available. Each rack can hold up to 64 Super Mouse 1800 cages or 128 Super Mouse 750 cages. The Super Mouse 1800 floor area per cage is greater than 180 in^2. The Super Mouse 750 floor area per cage is greater than 75 in^2. All of these racks are equipped with automatic watering. These racks eliminate the need for wire bar lids for easier observation of animals, food, and watering system.

All mice are housed four (4) per cage unless fighting or excessive "hair cropping" occurs. This allows mice social interaction and normal behavioral needs.

Breeding colony mice have nesting material placed within the cage for a more natural environment and to provide warmth to newborn pups.

The Guide for the Care and Use of Animals is used when cage replacement becomes necessary. The Guide is followed in recommendations for the number of animals allowed per square foot of cage. It is possible that during the course of an IACUC approved experiment, rats greater than 500 grams are housed two per cage.

Although this population density exceeds that of the Guide, it allows for the distinct social needs of the rats. To compensate for the increased waste products, these cages are changed twice per week.

b. Describe space exceptions to the guiding documents (*Guide*, *Ag Guide*, ETS 123, and/or applicable standards), indicating the references, considerations and performance criteria used (e.g., by the IACUC/OB) to verify adequacy of space provided for all animal species covered by the program. [*Guide*, pp. 55-63]

At this time, there are no space exceptions to the Guide. However, it is possible that during the course of an IACUC approved experiment, rats greater than 500 grams are housed two per cage. If that is the case, the exception to the Guide must be justified in the ACORP. CAVHS is investigating the use of performance standards for breeding schemes based on past breeding colony management.

2. Environmental Enrichment, Social, and Behavioral Management [*Guide*, pp. 52-55; 63-65: *Ag Guide*, Chapter 4]

a. Environmental Enrichment

i. Describe the structural elements of the environment of primary enclosures that may enhance the well-being of animals housed (e.g., resting boards, privacy areas, shelves/perches, swings, hammocks).

Most rodent cages are constructed of clear polycarbonate to allow animals to view each other. These cages are suspended on stainless steel racks or stored on an animal isolation rack. The solid polycarbonate cages help shield these species of animals from air currents, provide for social interaction and help insulate from sudden noises. All rodents are housed in solid-bottomed caging with contact bedding, which encourages digging and foraging behavior. Whenever possible, more than one animal is housed per cage. With any bedding, a nestlet is provided for environmental enrichment. All of the bedding types give the rodent opportunities for partial nesting and help maintain a more even cage temperature. Breeding colony mice have nesting material placed within the cage for a more natural environment and to provide warmth to newborn pups. Nest boxes are also available for breeding mice and rats. Mice and rats are the only species housed in this facility.

ii. Describe nonstructural provisions to encourage animals to exhibit species typical activity patterns (e.g., exercise, gnawing, access to pens, opportunity for exploration, control over environment, foraging, denning, burrowing, nesting materials, toys/manipulanda, browsing, grazing, rooting, climbing).

Whenever possible, rodents are housed socially in compatible groups.

A nestlet is provided in every mouse cage. Better nest is provided for every rat cage. All of the types of bedding used in the VMU provide the rodents opportunity for partial nesting and help maintain a more even cage temperature.

Nests are transferred to the clean cage during cage change. Additional nesting material is also added.

Nest boxes (shacks) are also available for breeding mice and rats.

Cardboard tubes, manzanita sticks or nylabones are provided for all rats housed in the VMU to enhance hiding, foraging, and gnawing. Rats weighing over 350 grams are not provided cardboard tubes, but, instead, receive either manzanita sticks or nylabones.

b. Social Environment [*Guide*, p. 64]

i. Describe institutional expectations or strategies for social housing of animals.

Whenever possible, rodents are housed socially in compatible groups. Single housing of mice or rats is the exception and must be justified based on experimental requirements or veterinary related concerns for the animal well-

being.

ii. Describe exceptions to these expectations (e.g., veterinary care, social incompatibility) and other typical justification approved by the IACUC/OB for housing animals individually.

Justification for single housed animals is based on experimental requirements or veterinary related concerns for the animal well- being.

iii. Describe steps taken with isolated or individually housed animals to compensate for the absence of other animals (interaction with humans, environmental enrichment, etc.).

When animals are housed singly, they are placed in rodent cages constructed of clear polycarbonate to allow animals to view each other. These cages are suspended on stainless steel racks or stored on an animal isolation rack. The solid polycarbonate cages allow for visual, auditory, and olfactory contact. Nestlets are also provided for animals housed singly.

c. Enrichment, Social and Behavioral Management Program Review [*Guide*, pp. 58, 69]

Describe how enrichment programs and exceptions to social housing of social species are regularly reviewed to ensure that they are beneficial to animal well-being and consistent with the goals of animal use.

The IACUC reviews the program for humane care and use of animals once every six months, using the Guide as a basis for evaluation. If a protocol requires single housing of a social species, it must be justified in the protocol submission and reviewed and approved at a fully convened IACUC meeting. The approved protocol then receives annual review.

d. Procedural Habituation and Training of Animals [*Guide*, pp. 64-65]

Describe how animals are habituated to routine husbandry or experimental procedures, when possible, to assist animals to better cope with their environment by reducing stress associated with novel procedures or people.

Cages changes are performed on a routine schedule by a specified technician. When placed in a novel environment, mice tend to explore for a period of time, and then reduce the level of exploration.

Habituation occurs within a single day. For procedural habituation, this is accomplished by using proper animal handling and experimental techniques.

e. Sheltered or Outdoor Housing [*Guide*, pp. 54-55]

i. Describe the environment (e.g., barn, corral, pasture, field enclosure, flight cage, pond, or island).

CAVHS does not have any protocols that require sheltered or outdoor housing. CAVHS is not equipped for such protocols.

ii. Describe methods used to protect animals from weather extremes, predators, and escape (windbreaks, shelters, shaded areas, areas with forced ventilation, heat radiating structures, access to conditioned spaces, etc.).

CAVHS does not have any protocols that require sheltered or outdoor housing. CAVHS is not equipped for such protocols.

iii. Describe protective or escape mechanisms for submissive animals, how access to food and water is assured, provisions for enrichment, and efforts to group compatible animals.

CAVHS does not have any protocols that require sheltered or outdoor housing. CAVHS is not equipped for such protocols.

f. Naturalistic Environments [*Guide*, p. 55]

i. Describe types of naturalistic environments (forests, islands) and how animals are monitored for animal well-being (e.g., overall health, protection from predation).

CAVHS does not have any protocols that require naturalistic environments. CAVHS is not equipped for such protocols.

ii. Describe how food, water, and shelter are provided.

CAVHS does not have any protocols that require naturalistic environments. CAVHS is not equipped for such protocols.

iii. Describe how animals are captured.

CAVHS does not have any protocols that require naturalistic environments. CAVHS is not equipped for such protocols.

C. Animal Facility Management

1. Husbandry

a. Food [*Guide*, pp. 65-67]

i. List type and source of food stuffs.

Most diets currently are Purina standard diets and are pelleted. Purina diets are delivered via truck. Specialized diets that contain special supplements are acquired from Purina, Harlan Teklad or Dyets, Inc. These may be pelleted or meal. Irradiated pellet rodent diet is used for some projects and is provided by Purina.

ii. Describe feed storage facilities, noting temperature, relative humidity, and vermin control measures, and container (e.g., bag) handling practices, for each of the following:

- vendors (if more than one source, describe each)
- centralized or bulk food storage facilities if applicable
- animal facility or vivarium feed storage rooms
- storage containers within animal holding rooms

Diets for this facility are not stored by the vendor. Since our requirement is for food no older than 15 days from the mill, all diets are delivered by truck from the manufacturer.

iii. Describe special food preparation areas, such as feedmills and locations where special diets are formulated, if applicable. Include in the description sanitation and personnel safety practices (noting that respiratory protection is described in Section 2.I.A.2.b. ii. Standard Working Conditions and Baseline Precautions above).

There are no diet preparation areas in this facility.

iv. Describe how food is provided to various species (*ad libitum*, limited amounts, types of feeders).

All food is dispensed via hanging or lid mounted containers for all species currently being used. Diet is provided ad libitum unless on an approved special diet study.

v. Describe special food quality control procedures including procedures for rotating stock, monitoring milling dates, nutritional quality, bio load, chemical contaminants, etc.

Older food is moved to the front and top of the storage rack and newly arrived food is placed on the bottom and to the rear of the rack. Milling dates are checked before acceptance of food. The VMU relies on the quality assurance statement provided by the manufacturer of each food item. Any food that does not meet stated requirements on milling (15 days from the mill) is rejected. Diets

older than 180 days past milling date are disposed of with the exception of diets containing vitamin C, which is disposed of after 90 days. If problems are noted in the appearance of food or clinical changes in animals suggestive of a nutritional nature, then feed analysis may be performed.

b. Drinking Water [*Guide*, pp. 67-68]

i. Describe the water source, treatment or purification process, and how it is provided to the animals (e.g., bowls, bottles with sipper tubes, automatic watering, troughs, ponds, streams).

Filtered city water is provided for all species within the VMU. No treatment or purification is necessary. Water is provided ad libitum via water bottles, automatic watering system (Edstrom Industries), or Sippy Sack System (Edstrom Industries). Automatic water systems on animal racks and sippy sack dispensing units are sanitized with a dilute solution of hypochlorite and then flushed with tap water every two (2) weeks.

ii. Describe methods of quality control, including monitoring for contaminants.

The hospital does not provide regular water quality monitoring other than that provided by the City of Little Rock, Arkansas on an annual basis. On a biennial basis, the VMU Supervisor tests samples of water from all animal wards for bacteria, lead, pesticides, nitrate/nitrite levels, chlorine pH, and hardness.

iii. If automatic water delivery systems are used, describe how they are maintained and sanitized.

The VMU is equipped with the Edstrom Automated Animal Watering System for all animal wards. This system was custom designed for this facility to include water purification and the delivery system. This system utilizes a series of filters prior to distribution to each animal ward.

All of the piping to all animal wards is stainless steel. The automatic flushing system is connected to all animal ward water pressure reduction stations. This system automatically flushes all of the water lines going into the animal wards once per day. This procedure rids the water supply of impurities that may have accumulated in the system.

c. Bedding and Nesting Materials [*Guide*, pp. 68-69]

i. Describe type(s) and how used for various species.

All bedding is used in direct contact with the research animal. Two types of bedding are currently in use at the VMU; Harlan Teklad ¼ inch cob and Sheperd Alpha Dri. The bedding is selected on a study by study basis to provide

the best possible nesting qualities within experimental parameters. Nestlets/nest boxes are provided in all mouse caganimaes and nest boxes in all rat cages to enhance rodent nesting behaviors.

ii. Describe bulk bedding storage facilities, if applicable, including vermin control measures.

The Veterinary Medical Unit bedding storage is located in room GB-196 of the VMU. This is a concrete room with hospital HVAC and is monitored weekly for signs of any vermin infestation. If signs are noted, sticky traps, glue boards, live traps, and other methods deemed appropriate are available for use. When placed, monitoring is carried out daily. Humidity ranges between 30-70% and is checked weekly.

iii. Describe quality control procedures, including monitoring for contaminants.

Bags of bedding are inspected by VMU personnel for wetness, excessive dust, foreign objects and signs of contamination. A sample analysis report from the vendor includes microbiological analysis, pesticide screen for organochlorine pesticides, polychlorinated biphenyls, organophosphorous pesticides, heavy metals, aflatoxins and pentachlorophenyl "PCP". The VMU relies on this report for quality assurance.

d. Miscellaneous Animal Care and Use Equipment

i. Describe motorized vehicles and other equipment (e.g., trailers) used for transporting animals, noting the type and how the cargo compartment is environmentally controlled, if applicable.

A van, equipped with side entry, rear entry doors and front/rear air conditioning units, is used by the Veterinary Medical Unit for transferring animals to UAMS or Little Rock National Airport when necessary.

ii. Describe other animal care related equipment used in the animal care program (specialized equipment for exercise or enrichment, high pressure sprayers, vacuum cleaners, tractors, trailers, spreaders, etc.).

A wet/dry vacuum cleaner is available for use in surgery, water spills, etc. It is not used in animal wards. One (1) HEPA filter vacuum cleaner is available to use in animal ward touch up cleaning (air vents, lights, etc.). Numerous stainless-steel carts are available for transporting supplies, animals, etc. within the Veterinary Medical Unit. Three (3) castor mounted floats are available for transporting bulky items. One (1) high pressure sprayer is available for washing animal racks. One (1) castor mounted high wall lab truck is available for refuse transport. Two (2) HEPA filtered soiled bedding disposal work stations are in service at all times.

e. Sanitation [*Guide*, pp. 69-73]

i. Bedding/Substrate Change

1) Describe frequency of contact and non-contact bedding change for each species and enclosure type (solid-bottom or suspended) or pen.

Cages with contact bedding are changed on the following schedule: Mice – Weekly or as often as necessary, depending on the condition of the bedding. Rats-Weekly or more often as necessary, depending on condition of bedding. Wet or heavily soiled cages are changed immediately.

2) Describe any IACUC/OB approved exceptions to frequencies recommended in the *Guide* or applicable regulations and the criteria used to justify those exceptions.

There are no exceptions to the Guide for bedding changes.

3) Note the location where soiled bedding is removed from the cages/enclosures and where clean bedding is placed into the cages/enclosures.

Soiled bedding is removed from the cages in the dirty area of the wash room under the provided HEPA filtered work station hood (GB 192). Clean bedding is dispensed to clean cages in the clean area of the wash room (GB 176).

ii. Cleaning and Disinfection of the Micro- and Macro-Environments
Note: A description of the washing/sanitizing frequency, methods, and equipment used should be included in **Appendix 14** (Cleaning and Disinfection of the Micro- and Macro-Environment) and **Appendix 15** (Facilities and Equipment for Sanitizing Materials).

1) Describe any IACUC/OB approved exceptions to the *Guide* (or applicable regulations) recommended sanitation intervals.

Cleaning and Disinfecting of Primary Enclosures-Solid bottom cages are sanitized weekly for the HEPA filtered cages and conventional cages. This VMU does not use wire bottom cages other than the metabolic cages. Metabolic cages, when used, are changed weekly and sanitized. Cage lids are sanitized weekly. Cage racks and shelves are sanitized every two weeks. The VMU at CAVHS does not have cage pans under suspended cages, playpens, floor pens, stalls, corral, or outdoor paddocks.

A Steris Basil 9500 cage, cart, and rack washer or a Getinge 3200 Series tunnel washer are used to process all equipment with three cycles, the final

cycle consisting of a 180 degree rinse.

The cleaning and sanitizing agents for cage and rack washing are: 1) Cage Klenz 100-detergent (Steris); 2) Cage Klenz 200-descaler (Steris); 3) S-Klenz-descaler (Steris); 4) Cage Klenz 220-descaler (Steris).

Sanitation: Cleaning and Disinfecting of Secondary Enclosures-Once a month the floors, walls, and ceilings of the animal wards are disinfected with a dilute solution of Process NPD (quaternary ammonia). The solution is applied to surfaces with a mop, cloth, sponge, or mechanical sprayer so as to wet all surfaces thoroughly. The animals are removed from the room and the Process NPD is applied, mopping commences and it is then allowed to stand for 15 minutes. The entire room is then flushed with clear water via the room water hose. The room is allowed to dry prior to reintroducing the animal colony. Floors are wet mopped following a weekly schedule. All disinfecting/sanitizing chemicals are dispensed via metered dispensing units. Rooms which house specialized HEPA filtered animal racks are sanitized by mopping the ceiling, walls, and floor with a dilute solution of Process NPD, once a month. These rooms are wet mopped following a weekly schedule.

Corridor ceilings and walls are mopped with either a dilute hypochlorite solution or a dilute solution of Process NPD on a monthly basis. Support areas are sanitized as needed, but no less than once per week. Corridor floors are swept and wet mopped once per week with dilute Process NPD, or more frequently as needed.

Push mops (laundered after each use) and brooms are not shared between animal wards. Mop handles and brooms are sanitized monthly in the animal facility tunnel washer. Mop heads are bleached, washed and dried in the provided commercial washer and dryer.

Animal ward cleaning equipment is not shared between animal wards. The only shared equipment are the handles for the squeegees and the disinfectant dispensing unit.

Sanitation of Cage Equipment: All feeders are sanitized every two weeks in a mechanical washer. Bottles and sipper tubes are changed and sanitized once per week in the Getinge 3200 Series tunnel washer. Automatic water manifolds and sipper valves on all racks are sanitized via chloro-flush station monthly. Sippy Sack tubes are sanitized bi-weekly, and the dispensing unit monthly. Water lines entering the automatic water distribution system are flushed automatically once per week.

This VMU does not have any enrichment devices other than nestlets and shacks.

Sanitation of Transport Cages, Equipment, and Vehicles: All transport vehicles such as carts, cages, and racks are received in the dirty cage washing room (GB 192) and sanitized after each use. The motor vehicle cargo hold is sanitized with a dilute bleach solution as needed following

transport.

There are no exceptions to the Guide for recommended sanitation intervals.

2) Assessing the Effectiveness of Sanitation and Mechanical Washer Function

a) Describe how the effectiveness of sanitation procedures is monitored (e.g., water temperature monitoring, microbiological monitoring, visual inspections).

When processing cages, water temperature indicators are attached to the cage equipment. Washer final rinse temperatures below 180°F are reported immediately to Engineering Service for immediate temperature adjustment. Cages will not be processed in this washer until the water temperature for final rinse has been raised to at least 180^0F. The Getinge tunnel washer is equipped with a digital temperature gauge and an automatic shut off if the rinse temperature does not reach 180^0F. Water temperature indicators are used to double-check the accuracy of these gauges. All used water temperature indicators are retained and dated in a logbook or attached to the event printer tape or logbook and retained. Microbial monitoring on polycarbonate rodent cages is performed quarterly by the VMU supervisor using Rodac Plates. The vendor, through maintenance agreements, checks the function of the detergent dispensing equipment for the tunnel and rack washers. Visual inspection is made during the process of sanitizing, for appearance of cages and related equipment. Articles that do not appear clean are reprocessed.

b) Describe preventive maintenance programs for mechanical washers.

The Steris Basil 9500 cage, cart, and rack washer and the Getinge 3200 Series tunnel washer are maintained on maintenance agreements with the vendor.

f. Conventional Waste Disposal [*Guide*, pp. 73-74]
Describe the handling, storage, method and frequency of disposal, and final disposal location for each of the following:

i. Soiled bedding and refuse.

Soiled bedding and refuse not designated as a biohazard are placed in plastic bag-lined cardboard boxes and sealed. These boxes will weigh no more than 35 lbs and are transported in a hand truck to the Medical Center refuse dump station.

ii. Animal carcasses.

Small animal carcasses are sealed in heavy-duty plastic bags and stored in the VMU freezer. No large animals are used at this time. All stored animal carcasses are cremated by a Medical Center contracted vendor on a monthly basis. All animal carcasses are placed in heavy red boxes marked 'Biohazard' and sealed before transporting to the incinerator.

Animal carcasses exposed to radioactive material are sealed in plastic bags, labeled with pertinent information, and placed in a designated Veterinary Medical Unit freezer. The Radiation Safety Officer is notified and the carcasses are monitored and disposed of by the Radiation Safety Officer. If such time has passed that the carcass can be incinerated routinely, VMU personnel handle the carcass as explained above.

g. **Pest Control** [*Guide*, p. 74]

i. Describe the program for monitoring and controlling pests (insects, rodents, predators, etc.). Include a description of:

- monitoring devices and the frequency with which devices are checked
- control agent(s) used and where applied, and
- who oversees the program, monitors devices, and/or applies the agent(s).

CAVHS has resident pest control personnel that can be consulted if evidence of vermin is discovered and work in conjunction with a contracted pest control service. The Medical Center Pest Control Policy states that the Chief, Environmental Management Service, is the Pest Management Officer and, as such, is responsible for implementing procedures that ensures a safe and comprehensive pest management program for the VMU. The Pest Management Officer coordinates pest management operations with the VMU Supervisor with consultation of the VMO. Environmental Management Service (EMS) has placed boric acid powder inside all wall bumper plates. Insect/vermin glue boards are used to periodically monitor the insect/vermin population. When placed, the glue boards are monitored daily for vermin. If any rodents are detected on the glue boards, these animals are humanely sacrificed. If pests are detected, a thorough inspection will be conducted by EMS and the appropriate action taken using non- toxic methods and traps. No insecticides are used in the animal wards. Only sticky boards are used in supply rooms. No notification of investigators is necessary.

ii. Describe the use of natural predators (e.g., barn cats) or guard animals (e.g., dogs, donkeys) used for pest and predator control, if applicable.

Not applicable

iii. Note how animal users are informed of pesticide use and how animal users may opt out of such use in specific areas.

No insecticides are used in the animal wards. No notification of investigators is

necessary.

h. **Weekend and Holiday Animal Care** [*Guide*, pp. 74-75]

i. Describe procedures for providing weekend and holiday care. Indicate who (regular animal care staff, students, part-time staff, etc.) provides and oversees care and what procedures are performed.

The VMU is staffed for two (2) hours on both Saturday and Sunday. This individual performs checks of all animals including condition of bedding, water, feed, room temperature, and daily room log entries. The Technician will also change cages in high density rooms to avoid interfering with investigators during the work week. The animal husbandry for holidays is rotated between VMU staff. The tour of duty is for eight (2) hours on holidays. The individual on duty for holiday animal husbandry performs daily checks of all animals, condition of bedding, water, feed, room temperature, and makes daily room log entries. Emergency animal health problems or environmental problems are conveyed to the VMU Supervisor, VMO, or Engineering Service as needed in response to the problem.

ii. Indicate qualifications of weekend/holiday staff if not regular staff.

Weekend/holiday staff are the same regular VMU staff who work during the weekdays.

iii. Describe procedures for contacting responsible animal care and/or veterinary personnel in case of an emergency.

The VMU Supervisor and the VMO are available for emergency consultation via cellular phone or home phone. The home phone numbers and cellular numbers of the VMU supervisor and the VMO are posted in the VMU and recorded with CAVHS Police.

Survival surgical procedures involving post op care require the investigator or his staff to monitor the patients during evening hours. The principal investigators' phone number and/or pager number is recorded on the door of the animal ward assigned to him or her, to be used for emergency consultation. In addition, the pager number for the Veterinary technician is also posted in the VMU.

The Heating, Ventilation and Air Conditioning (HVAC) are monitored continuously by a computer system by Engineering Service. A cascade call-back system has been developed for any unusual occurrence, fire, disaster, or outage that could result in harm to the animals within the facility which includes the notification of the VMU Supervisor. An electronic security system also monitors for unusual sounds, such as alarms during evening hours.

Alarms or unusual noises are reported via telephone to the Veterinary Medical

Unit supervisor by the facility police.

In the event of a disaster, a cascade callback system has been approved by the Medical Center emergency committee. This system outlines types of disasters, who will be called back and a plan for care or disposition of research animals. VMU personnel, Research Safety Officer, CAVHS Police, the VMO and Research Administrative staff will be involved in a response. A copy of the plan will be available. In addition, the VMU Supervisor is a member of the CAVHS Emergency Response Team. The VMU Supervisor is required to take FEMA training on disaster preparedness as an animal care provider.

2. Population Management [*Guide*, pp. 75-77]

a. Identification

Describe animal identification methods for each species (e.g., microchips, cage/tank cards, collars, leg bands, tattoo, ear tags, brands).

The method used for identification of each species is cage cards. Cage cards contain the following information: strain, sex, date of arrival, source, weight or date of birth (depending on investigator's preference), number received, investigator's name, and the IACUC protocol number. Rodents are identified by cage card and, when necessary, may be identified by ear punch, ear tags, tattooing ink number on tail or by subcutaneous electronic transponders. The use of cage cards is the preferred method of identification of animals on the lower phylogenic scale.

b. Breeding, Genetics, and Nomenclature

i. Describe the program for advising investigators on the selection of animals based on genetic characteristics.

Information and reference tests on inbred strains of rodents and other laboratory animals are available from the Veterinary Medical Officer or the facility supervisor. All animals are ordered by the VMU Supervisor and in most cases, only virus antibody free (VAF) animals are purchased. In special circumstances, rodents may be purchased from private institutions that do not provide health and genetic monitoring data (e.g., Washington University, St. Louis, Mo.; National Center for Toxicological Research). These animals are isolated from other colonies and maintained on isolation racks. Current vendors (e.g., Charles River, Harlan Laboratories, and Jackson Laboratories) have genetic monitoring programs. Information via Charles River Newsletter is available to investigators. The VMU Supervisor maintains information on availability of animal species, strains, and their genetic background. This information is available to all investigators.

ii. Describe the program for advising investigators on using standardized nomenclature to ensure proper reporting of the identification of the research animals with regard to both the strain and substrain or the genetic background of

all animals used in a study.

The importance of this issue escalates for breeding colonies. Many mechanisms of genetic drift can occur from generation to generation, especially in rodent colonies with high reproductive rates. Unless substrain divergence and other such issues are considered, data from a specified strain originating in one facility is incomparable to those from another. Breeding schemes and genetic monitoring are also designed to ensure heterozygosity or homozygosity and other genetic uniformity. Primary Investigators interested in breeding colonies are encouraged to discuss these issues with the VMO.

Complete information on every shipment of animals including sub strain designation is maintained in the Veterinary Medical Unit files. All information is transferred to cage cards. All information on the animal cage card is recorded by the VMU staff. This information includes strain and substrain.

iii. Describe genetic management techniques used to assess and maintain genetic variability and authenticity of breeding colonies, including recordkeeping practices (*Guide*, pp. 75-76).

Detailed pedigree records are kept, and genetic monitoring techniques are used to ensure genetic variability and authenticity. The IACUC carefully reviews the design of breeding strategies and methods of genotype assessments for each protocol.

iv. For newly generated genotypes, describe how animals are monitored to detect phenotypes that may negatively impact health and well-being. Note that the methods used to report unexpected phenotypes to the IACUC/OB should be described in section 2.1.B.1.c.ii, "Unexpected Outcomes that Affect Animal Well-Being."

Newly generated genotypes are carefully monitored by VMU Staff and new phenotypes that negatively affect well-being are reported to the IACUC and managed in a manner to ensure the animals' health and well-being. The Breeding Colony Update Report is presented quarterly to the IACUC by the VMU Supervisor.

III. Veterinary Care [*Guide*, pp. 105-132]

Note: Complete each section, including, where applicable, procedures performed in farm settings, field studies, aquatic environments, etc.

A. Animal Procurement and Transportation [*Guide*, pp. 106-109; *Ag Guide*, pp. 8; 45; 50-57]

1. **Animal Procurement**
Describe the method for evaluating the quality of animals supplied to the institution (from commercial vendors, other institutions, etc.).

Rodent sources are selected on the availability of Specific Pathogen Free (SPF) animals and reputation of the vendor. The vendors are selected based on character, discussions with colleagues that have used them, and documentation of health surveillance and health status of their animals. All animals and accompanying health documentation are examined upon arrival. Only vendors that provide quality research animals are used.

Animals are periodically screened to ensure their health status.

Only specific pathogen free rodents are admitted. Occasionally, exceptions are allowed at the discretion of the VMO and VMU Supervisor. For example, Primary Investigators may receive transgenic mice that are not available elsewhere, however, the PI needs to first exhaust known specific pathogen-free sources. These animals are isolated and screened for pathogens, generally by sampling at least 10% of the population.

2. **Transportation of Animals**
Describe how animals are transported between outside sources and the institution and within the institution, including loading, unloading, level of biosecurity, immune status and specific pathogen status (consider all species, including aquatic and semi-aquatic species).

Most rodents are delivered via air conditioned truck from the vendor to the VMU. Sources that do not provide this service are air freighted and picked up at the airport via air conditioned van. Animals are not transported through the hospital (floors 1- 7). If animals must be transported within the ground floor of the institution, their crates are draped and a flat bed cart is used. Most animal deliveries are made to the rear entry of the VMU. Access to the loading docks and the rear entrance of the VMU is controlled and monitored by the VA facility police.

B. Preventive Medicine

1. **Animal Biosecurity** [*Guide*, pp. 109-110]

a. Describe methods used to monitor for known or unknown infectious agents. Note that if sentinel animals are used, specific information regarding that program is to be provided below.

Sentinel animals are used to monitor the facility for known and unknown infectious agents. Each animal ward is checked every three (3) months via serology profile and once a year for whole body analysis which includes parasitology and gross examination, histopathology of any gross lesions, and microbiology of the upper respiratory and gastrointestinal tract. Sentinel mice within the colony are

euthanized; blood serum is collected and forwarded to Envigo for evaluation. If sentinel animals are found to be necessary, 2 sentinel mice per rack, female, CD-1 6-8 weeks of age, are procured from (b)(6) Laboratories per animal ward. Health reports defining the disease free status, including Helicobacter, must accompany the sentinel animals and copies retained by the VMU supervisor. Upon arrival, sentinel animals will be placed into cages and labeled as VMU sentinel animals. To begin the exposure process, when the next cage change is performed, the animal husbandry technician will use a disposable plastic spoon to collect a small sample of dirty bedding from each cage. The exposure process should continue uninterrupted for at least six routine cage changing processes or until the end of the experiment.

The VMU Supervisor will collect the live sentinel animals after the exposure period is complete and process them according to directions from the (b)(6) Diagnostic Laboratories. The sentinel animals are shipped in GNOTO Isolation Shipping containers provided by (b)(6). This ensures no contamination of the live animals during shipping.

b. Describe methods used to control, contain, or eliminate infectious agents.

Generally, all rats and mice are ordered Specific Pathogen Free (SPF) and received in filtered shipping crates. The crate is examined for any signs of damage that may have potentially exposed the animals within to adverse conditions during shipping. All crate exteriors are sprayed with a dilute solution of a provided Quatricide prior to opening in receiving room, (b)(6) Crates are then opened in the room of assignment and the interior examined for dead animals or animals in distress. The VMU staff is responsible for visually inspecting all incoming animals. If any animals are dead, overtly diseased (including, but not limited to, lethargy, weakness, rough coat, ocular or nasal discharge, diarrhea, sneezing, coughing or labored breathing, hunched posture, or physical injury that may potentially affect the well-being of the animal), or the shipping crate damaged such that an adverse exposure is imminent, then the affected animal(s) can be refused and returned to the vendor.

Rats and mice are housed in separate rooms. Only Specific Pathogen Free (SPF) animals are used, unless approval is given by the IACUC to use sources which will not guarantee SPF. Since most rodents housed at this facility are SPF, the data (health profile) supplied by the vendor are sufficient to define the health status of incoming animals so that quarantine is not necessary. Rodents received that are not certified SPF are housed on an isolation rack away from other colonies. A quarantine area is available in (b)(6).

Rodents are allowed to acclimate for up to two weeks but not less than seven (7) days prior to use, unless they are used for tissue harvest.
Only animals of the same species are housed together at this facility and in most cases, the rooms are assigned to only animals of the same vendor. Further effort is made to assign rooms to individual investigators although this is not always possible.

The facility does participate in Good Laboratory Practice protocols. As such, the facility is separated into clean areas (animal wards) and dirty areas (procedure rooms, washing area). There are standard operating procedures for the flow of cages to and from clean and dirty areas that are followed within the facility.

2. Quarantine and Stabilization [*Guide*, pp. 110-111]

a. Describe the initial animal evaluation procedures for each species.

Rodents are purchased only from vendors which guarantee their animals to be Specific Pathogen Free, unless there is overwhelming justification by the investigator. Current animal health monitoring information is requested and maintained for each vendor in the VMU supervisor's files. When shipments include animals of unknown health status or from a vendor that will not certify Specific Pathogen Free status, the most recent animal health monitoring information is requested with each shipment. Rodent crates are immediately taken to receiving (b)(6) upon arrival. All crate exteriors are sprayed with a dilute solution of a provided Quatricide prior to opening in receiving room. Crates are then transported to the assigned animal ward and opened. The animals are observed for general condition and if no ill or distressed animals are observed, they are housed in cages.

Animal receipt and evaluation procedures provide the initial means whereby rodent colonies are monitored for signs of clinical disease. Following this, the animals are closely monitored during a 14-day stabilization period, by the animal care personnel. If health problems develop, then a systematic process of testing (serology, necropsy) is designed to identify common rodent diseases which have been proven to affect research.

Those animals displaying clinical signs of diseases not related to the experimental protocol are separated into the quarantine ward if they cannot be euthanatized. Shoe box rodent cages with filter tops are available and can be used within the animal ward or in the quarantine room when necessary. If a contagious agent is suspected for a colony of animals, in which the entire colony was likely exposed, the room is placed on isolation status. In any case, animals or colonies under isolation or quarantine are serviced only after all “clean” rooms.

Treatment of animals is initiated only if there is an opportunity to restore the animal to full health without adversely affecting the outcome of the experiment.

b. Describe quarantine facilities and procedures for each species. For each species, indicate whether these practices are used for purpose-bred animals, random-source animals, or both.

Fifteen (15) mice breeding colonies are currently maintained. Daily observations by the Investigative and VMU staff are made. Animals showing signs of illness are reported to the Supervisor of the VMU and the Principal Investigator. If necessary, the VMO is consulted. The breeding colonies are checked every three (3) months via serology profile and once a year for whole body analysis which includes

parasitology and gross examination, histopathology of any gross lesions, and microbiology of the upper respiratory and gastrointestinal tract. Sentinel mice within the colony are euthanized, blood serum is collected and forwarded to Charles River Laboratories for evaluation.

Appropriate medical procedures will be established by the VMO if these serum profiles indicate the need.

Rodents received that are not certified SPF are housed on an isolation rack away from other colonies. A quarantine area is available in (b)(6) maintained under negative air conditions with respect to the corridor and is used exclusively for quarantine. Rodents not specifically bred and raised for research are not used at this facility.

c. Describe the required/recommended stabilization period for each species.

Animal receipt and evaluation procedures provide the initial means whereby rodent colonies are monitored for signs of clinical disease. Following this, the animals are closely monitored during a 7 day stabilization period, by the animal care personnel. Rodents are allowed to acclimate for up to two weeks but not less than seven (7) days prior to use, unless they are used for tissue harvest. If health problems develop, then a systematic process of testing (serology, necropsy) is designed to identify common rodent diseases which have been proven to affect research.

3. Separation by Health Status and Species [*Guide*, pp. 111-112]

a. Describe the program for the separation of animals by species, source, and health status. If the animals in different status are not maintained separately, describe circumstances in which mixing occurs and explain the rationale for mixing.

Rats and mice are housed in separate rooms. Only animals of the same species are housed together at this facility and in most cases, the rooms are assigned to only animals of the same vendor. Further effort is made to assign rooms to individual investigators although this is not always possible.

Sick animal observations made by laboratory animal technicians are reported to the VMU Supervisor, who makes an initial check followed by a verbal report to the VMO, if there is a medical emergency. All reports of sick animals are recorded in the animal ward logbook.

b. Describe situations where multiple species may be housed in the same room, area, or enclosure.

Only animals of the same species are housed together at this facility.

c. Describe isolation procedures and related facilities for animals.

Rats and mice are housed in separate rooms. Only animals of the same species are housed together at this facility and in most cases, the rooms are assigned to only animals of the same vendor. Further effort is made to assign rooms to individual investigators although this is not always possible.

C. Clinical Care and Management [*Guide*, pp. 112-115]

1. Surveillance, Diagnosis, Treatment and Control of Disease [*Guide*, pp. 112-113]

a. Describe the procedure(s) for daily observation of animals for illness or abnormal behavior, including:

- the observers' training for this responsibility
- method(s) for reporting observations (written or verbal)
- method(s) for ensuring that reported cases are appropriately managed in a timely manner.

The animals are observed for general condition and if no ill or distressed animals are observed, they are housed in cages.

Animal receipt and evaluation procedures provide the initial means whereby rodent colonies are monitored for signs of clinical disease. Following this, the animals are closely monitored during a 14-day stabilization period, by the animal care personnel. If health problems develop, then a systematic process of testing (serology, necropsy) is designed to identify common rodent diseases which have been proven to affect research.

Those animals displaying clinical signs of diseases not related to the experimental protocol are separated into the quarantine ward if they cannot be euthanatized. Shoe box rodent cages with filter tops are available and can be used within the animal ward or in the quarantine room when necessary. If a contagious agent is suspected for a colony of animals, in which the entire colony was likely exposed, the room is placed on isolation status. In any case, animals or colonies under isolation or quarantine are serviced only after all "clean" rooms.

Treatment of animals is initiated only if there is an opportunity to restore the animal to full health without adversely affecting the outcome of the experiment.

Sick animal observations made by laboratory animal technicians are reported to the VMU Supervisor, who makes an initial check followed by a verbal report to the VMO, if there is a medical emergency. All reports of sick animals are recorded in the animal ward logbook.

b. Describe methods of communication between the animal care staff and veterinary staff and the researcher(s) regarding ill animals.

Daily observations by the Investigative and VMU staff are made. Animals showing signs of illness are reported to the Supervisor of the VMU and the Principal

Investigator. If necessary, the VMO is consulted.

c. Describe the preventive medicine and health management/monitoring programs (e.g., physical examination, TB testing, vaccination, hoof/nail trimming, teeth cleaning/floating, vendor surveillance, use of sentinel animals) for each species.

Daily observations by the Investigative and VMU staff are made. Animals showing signs of illness are reported to the Supervisor of the VMU and the Principal Investigator. If necessary, the VMO is consulted. The breeding colonies are checked every three (3) months via serology profile and once a year for whole body analysis which includes parasitology and gross examination, histopathology of any gross lesions, and microbiology of the upper respiratory and gastrointestinal tract. Sentinel mice within the colony are euthanized, blood serum is collected and forwarded to Charles River Laboratories for evaluation.

Appropriate medical procedures will be established by the VMO if these serum profiles indicate the need.

2. Emergency Care [*Guide*, p. 114]

a. Describe the procedures to ensure that emergency veterinary care is continuously available for animals during and outside of regular work hours, including access to drugs or other therapeutics and equipment.

The VMU is staffed for two (2) hours on both Saturday and Sunday. This individual performs checks of all animals including condition of bedding, water, feed, room temperature, and daily room log entries. The Technician will also change cages in high density rooms to avoid interfering with investigators during the work week. The animal husbandry for holidays is rotated between VMU staff. The tour of duty is for four hours on holidays. The individual on duty for holiday animal husbandry performs daily checks of all animals, condition of bedding, water, feed, room temperature, and makes daily room log entries. Emergency animal health problems or environmental problems are conveyed to the VMU Supervisor, VMO, or Engineering Service as needed in response to the problem.

The VMU Supervisor and the VMO are available for emergency consultation via cellular phone or home phone. The home phone numbers and cellular numbers of the VMU supervisor and the VMO are posted in the VMU and recorded with CAVHS Police. Survival surgical procedures involving post op care require the investigator or his staff to monitor the patients during evening hours. The principal investigators' phone number and/or pager number is recorded on the door of the animal ward assigned to him or her, to be used for emergency consultation. In addition, the pager number for the Veterinary technician is also posted in the VMU.

In the event of a disaster, a cascade callback system has been approved by the Medical Center emergency committee. This system outlines types of disasters, who will be called back and a plan for care or disposition of research animals. VMU personnel, Research Safety Officer, CAVHS Police, the VMO and Research

Administrative staff will be involved in a response.

b. Describe the authority of the Attending Veterinarian or his/her designee relative to the emergency treatment of animals in the program.

The Attending Veterinarian (VMO) or the designee (VMU Supervisor) has the authority from the Institutional Official and the IACUC to treat an animal, remove an animal from an experiment, institute appropriate measures to relieve severe pain or distress, or perform euthanasia, if necessary.

3. Clinical Record Keeping [*Guide*, p. 115]

a. Describe the procedure for maintaining medical records and documenting treatment of ill animals including: clinical laboratory findings, diagnoses, treatments, medical progress records, etc. Identify the species for which individual records are maintained and where such records are kept.

Rodent health records received from the vendor are maintained in the VMU supervisor's office. All animal orders received are recorded in the VMU supervisor's computer records. The VMO, VMU Director and the Chairman of the IACUC have access to these records.

Daily logbooks are maintained in each animal ward by investigators and animal care personnel. The VMO, the VMU Director, the VMU Supervisor and the Chairperson of the IACUC have access to these records. Records also include detailed surgical and post-operative procedures, quarantine periods, and method of euthanasia for all species.

Breeding records are maintained by individual investigators.

b. Identify individual(s) (titles, not necessarily names) responsible for maintaining such records and identify where the records are maintained and who, including the IACUC/OB has access to the records.

Rodent health records received from the vendor are maintained in the VMU supervisor's office. All animal orders received are recorded in the VMU supervisor's computer records. The VMO, VMU Director and the Chairman of the IACUC have access to these records. Daily logbooks are maintained in each animal ward by investigators and animal care personnel. The VMO, the VMU Director, the VMU Supervisor and the Chairperson of the IACUC have access to these records. Records also include detailed surgical and post-operative procedures, quarantine periods, and method of euthanasia for all species.

Breeding records are maintained by individual investigators.

c. Describe the role of the Attending Veterinarian in recordkeeping.

Rodent health records received from the vendor are maintained in the VMU supervisor's office. All animal orders received are recorded in the VMU Supervisor's computer records. The VMO, VMU Director and the Chairman of the IACUC have access to these records. Daily logbooks are maintained in each animal ward by investigators and animal care personnel. The VMO, the VMU Director, the VMU Supervisor and the Chairperson of the IACUC have access to these records. Records also include detailed surgical and post-operative procedures, quarantine periods, and method of euthanasia for all species.

Breeding records are maintained by individual investigators.

4. **Diagnostic Resources.** Describe available diagnostic methods used in the program including:

a. In-house diagnostic laboratory capabilities.

Clinical Laboratory-The clinical laboratory is located in room GB 169. The laboratory is equipped with a microscope, centrifuge, hood and other equipment and supplies used to perform simple laboratory tests (e.g., CBC, cytologic exams, etc.). The pharmacy and health care supplies are also located in this area. Since animals on the higher phylogenic scale are not housed, this diagnostic facility is available, but not currently used for diagnosis.

b. Commercially provided diagnostic laboratory services.

Commercial Diagnostic Resources-The (b)(6) Livestock and Poultry Commission provides a full range of diagnostic capabilities for most domestic species, on a per test fee basis, including blood work (chemistries, serology, CBC), microbiology, toxicology and necropsy.

The services of the (b)(6) Livestock and Poultry Commission have not been used or needed since 2003.

A commercial vendor provides diagnostic and consultative assistance for animal health monitoring of common laboratory animal species.

Routine laboratory services provided include serology and histopathology of rodent samples. Estimated average usage is 1-2 cases per year.

c. Necropsy facilities and histopathology capabilities.

Necropsies are performed in the necropsy room ((b)(6)). The necropsy room is used for rodents.

d. Radiology and other imaging capabilities.

We have a GE Lunar PIXImus 2 mouse bone densitometer available ((b)(6)).

5. **Drug Storage and Control**

a. Describe the purchase and storage of controlled and non-controlled drugs.

As per policy of the Department of Veterans Affairs, all controlled and non-controlled drugs are ordered through the VA facility pharmacy. All controlled and non-controlled anesthetics and analgesics are stored in an Omnicell. The Omnicell is a drawer system software which immediately detects changes in drawer configurations, logs user access, and is programmed to limit accessibility to specific personnel (VMU Director and VMU Supervisor), with independent lock/double-lock capability for each drawer. All other pharmaceuticals are stored in a locked surgical instrument cabinet.

Only the supervisor of the VMU and the VMU Director dispense these drugs.

b. Describe record keeping procedures for controlled substances.

Entries for receipt of drug, date of receipt, and amount/volume received are recorded within the CAVHS Pharmacy Log and the Omnicell. All withdrawals are recorded with the date, amount, investigator's project, and drug total brought forward within the Omnicell. The Medical Center Pharmacy performs unannounced inspections and inventory of all controlled substances. The United States Drug Enforcement Agency performs unannounced inspections of the drug inventory. It is the duty of the surgery technologist to inventory, once per month, all drugs and perishable supplies. Drugs and materials stamped with an expiration date will be discarded on the month before expiration.

D. Surgery [*Guide*, pp. 115-123]

1. **Pre-Surgical Planning** [*Guide*, p. 116]
Describe the process(es) used to ensure adequate pre-surgical planning, including: identifying personnel; locating equipment, supplies, veterinary involvement for selecting analgesic and anesthetic agents and facilities; planning; and pre- and post-operative care.

The Veterinary Medical Officer (VMO) reviews all research protocols involving animals. This includes a thorough review of anesthetic and/or analgesic protocols. The VMO is also available to the investigators for consultation and advice in developing anesthetic/analgesic protocols prior to submission to the Animal Care and Use Committee. The supervisor of the VMU and the technologist assigned to the surgical unit oversee surgical projects once they are approved and initiated.

Before the initiation of surgical procedures, the investigative staff meets with the VMU Supervisor and if needed, the VMO. The investigative staff is given the opportunity to review equipment, supplies and surgical support areas. Equipment or supplies not found in the VMU inventory that are necessary to the project are procured by either the

investigative staff or the VMU before initiation of the project.

The investigative staff meets with the VMU Supervisor and if needed, the VMO to make certain that all guidelines are followed for that particular species pertaining to pre-operative care (i.e. withhold water, food; pre-anesthetic drugs, surgical site preparation) and post-operative care (i.e. maintaining animal in a controlled environment recovery unit; administering post-operative drugs; observation of animal for signs of distress and return of reflexes). The appropriate anesthetic is selected, and it is determined who will administer anesthesia.

Surgeons who have expertise in their field, but no experience with laboratory animals, must seek the training needed to adapt to variations in anatomy, physiology, anesthetics, analgesics and post-operative requirements of the species of animal that is selected for their project.

Scheduling the operative procedure must be done with the VMU staff at least 48 hours in advance. In order to schedule a procedure, VMU staff will request species, IACUC protocol number, PI's name, time and date of the anticipated procedure, and a brief description of the procedure.

2. **Surgical Facilities** [*Guide*, pp. 116-117, 144-145]
List building name(s) and room number(s) or other locations (coded, if confidential) where surgical procedures are performed. For each, describe:
   - the type of species (including rodents, fish, agricultural species, etc.)
   - nature of procedure(s) (major/minor/emergency, survival and non-survival, etc.)
   - the amount of use [heavy (daily), moderate (weekly), or light]
   - major surgical support equipment available (gas anesthesia machines, respirators, surgical lights, etc.)
   - facilities for aseptic surgery, surgical support, animal preparation, surgeon's scrub, operating room, and postoperative recovery
   - construction features of the operating room(s), including interior surfaces, ventilation, lighting, and fixed equipment used to support surgical procedures and other means of enhancing contamination control

Note: If preferred, the information requested in this section may be provided in Table.

Surgical prep ((b)(6) is separated from the main operating room by rodent aseptic surgery. The room is 240 sq. ft. Instrument and sterile supply preparation and storage ((b)(6)) is 182 sq. ft. and is located in the surgical area with a doorway into the main operating room suite.

Surgical dressing facilities are provided in (b)(6) There is 196 sq. ft. of space with lockers provided for storage of street clothes. This area is located away from the main operating room. Surgeon's scrub ((b)(6)) may be entered from the hallway door and enters into the main operating room.

The surgical rooms are used for both sterile and non-sterile procedures with (b)(6) serving primarily as rodent surgery and (b)(6) serving for rodents or animals on the higher phylogenic scale. These rooms are not used for functions other than sterile and non-sterile surgical procedures.

3. **Surgical Procedures** [*Guide*, pp. 117-118]

   a. Describe the criteria used to differentiate major from minor survival surgery, including classification for certain procedures (e.g., laparoscopic technique).

A major surgical procedure is one that is invasive and requires general anesthesia and close vital signs monitoring. It may expose the body cavity or produce impairment of physical or physiologic function.

Survival surgery is one in which the surgical procedure is aseptic, and the animal is allowed to regain consciousness. The surgical site is prepared by clipping and applying a topical disinfectant. The surgical linen and instruments are steam or gas sterilized. The surgeon's attire is sterile, and the surgical site is isolated and kept sterile. Non-survival surgery is one in which the animal does not regain consciousness but is euthanized while under analgesia or anesthesia. However, the surgical site will be clipped, in most cases, and the surgeon will wear gloves.

During non-survival surgical procedures, personnel must wear, at least, non-sterile protective clothing such as gloves, gown or apron.
Monitoring of vital signs and reflexes to ascertain the depth of anesthesia is mandatory. During euthanasia, the vital signs are closely monitored to establish death. The surgical area should be cleaned and uncluttered.

Classification of major and minor surgery is done by the IACUC in consultation with the VMO.

   b. How is non-survival surgery defined?

Non-survival surgery is one in which the animal does not regain consciousness but is euthanized while under analgesia or anesthesia.

4. **Aseptic Technique** [*Guide*, pp. 118-119]

   a. Describe procedures, equipment, and protective clothing used for aseptic surgery. Include patient and surgeon preparation.

The surgical room will be sanitized with a disinfectant prior to aseptic surgery. The animal patient designated for survival surgery will be prepared by clipping (and shaving when possible) the hair at the surgical site, cleansing the surgical site with an appropriate surgical soap and chemically disinfecting the surgical site. Surgeons and personnel that will come in direct contact with the surgical field will scrub hands with an appropriate antibacterial soap, wear protective sterile gowns, and gloves, and disposable face mask.

b. Describe methods used to sterilize instruments and protective clothing, including a description of approved liquid sterilants and instrument exposure time(s) required for each, if applicable.

Surgical instruments are first washed and dried. They are then wrapped and placed in an autoclave and steam sterilized for 35 minutes and dried for 45 minutes. Surgical linen such as drapes, gowns, 4 x 4's, etc. are sterilized in the same manner as surgical instruments.

c. Describe methods for instrument re-sterilization between serial surgeries.

Instruments are not re-sterilized between serial surgeries.

d. Indicate how effectiveness of sterilization is monitored.

The autoclave used for steam sterilization of surgical instruments will be checked each day before use by the following Steam Biological Monitoring System: a) a biological indicator will be run every day before the first full run of the day, and placed in the incubator after proper cooling (10 minutes); b) one control biological indicator will be placed in the incubator at the same time as the regular biological indicator. An additional control will be placed in the incubator if there is a change in lot number; c) all biological indicators will remain in the incubator for a period of 48 hours. The indicators will be periodically read for changes at 12, 24, and 48 hours. All biological results will be annotated in the Steam Logbook; and d) if a positive test occurs, all items will be recalled, and the autoclave will be immediately checked.

The autoclave must be re-challenged with biological indicators. If the spore test remains positive after proper use of the autoclave is documented and an operational inspection has been performed, use of the autoclave will be discontinued, and it will be serviced. Until satisfactory results are achieved, the autoclave will not be used.

Positive biological indicator results will be reported immediately in writing by the Supervisor of the VMU to Engineering Service.

e. Describe surgical support functions provided by the program to investigators.

The rooms are prepared, by the VMU Staff, for aseptic surgery by wiping all equipment such as the surgical table, lamp holders, etc. with an approved disinfectant or sterilant. The floors are swept and mopped with an approved disinfectant or sterilant. All non-essential equipment is either removed from the room or covered with a clean drape. All waste receptacles are lined with a plastic bag. Doors are secured until the time of surgery begins to keep unnecessary traffic out of the room, which might compromise the room's sterile field. The VMU Staff will prepare the surgical instruments. These are first washed and dried.

They are then wrapped and placed in an autoclave and steam sterilized for 35 minutes and dried for 45 minutes. Surgical linen such as drapes, gowns, 4 x 4's, etc. are sterilized in the same manner as surgical instruments.

5. **Intraoperative Monitoring** [*Guide*, p. 119]
Describe monitoring and recording requirements for each species, including the type of record(s) maintained. Also note monitoring of anesthesia during non-survival procedures.

For all rodent surgeries, the MouseOx Plus is the monitoring system used at this facility. The monitoring includes anesthetic depth, body temperature, cardiac and respiratory rates, pulse distension, pulse rate, oxygen saturation, and breath rate. The readings are maintained as part of the surgical record.

6. **Postoperative Care** [*Guide*, pp. 119-120]
Describe the postoperative care program, including who is responsible for overseeing and providing the care, types of records maintained (e.g., perioperative), where the records are maintained, etc.

Post-surgical care is provided by the VMU staff. When post-operative care is also provided by the investigator, it is monitored by the VMU staff by means of review of the individual animal health chart entries or ward logbook. The post-surgical program for all species of animals housed at this facility is carried out initially in room (b)(6) Animals recovering from surgical procedures are placed in an environmentally controlled Kershner Intensive Care Unit. The internal temperature is adjusted to accommodate the species of animal being recovered. Animals are maintained in this area until fully recovered. Frequent observations by the investigative staff and the Veterinary Medical Unit staff are made during recovery.

Medical records for rodents are found in the individual room logs and also recorded in the investigator's record gathering system. Surgical procedures and post-operative care, notations of procedures performed, notes of anesthetic regimens, physical examination findings, treatment for spontaneous clinical ailments and ultimate disposition of the animal(s) are maintained and copies are available through the VMU Supervisor.

Medical emergencies occurring during recovery are handled by VMU staff and/or the VMO. Animals above the rodent species use individual health records and are

maintained in the animal ward until disposition of the animal, at which time the record is moved to a filing cabinet in the VMU Supervisor's office. These records reflect the procedure, date, drugs administered, recovery status and personnel making observations.

E. Pain and Distress [*Guide*, pp. 120-121]

1. Describe how and by whom pain and distress are assessed.

The levels of pain and distress are assessed and categorized by the VMO and the IACUC using the following guidelines:

USDA Category B: Include in Category B all animals that will be bred or purchased exclusively for breeding, and that will not undergo any procedures other than those required by currently accepted standards of medical care. This includes breeders, and any young that may be culled because of unusable gender, genotype, or date of birth. If numbers cannot be determined exactly, estimate the maximum expected, as closely as possible. (Note: Animals that must undergo tail snips for genotyping must be assigned to category C, D, or E.)

USDA Category C: Include in Category C all animals that will only undergo procedures that involve no more than very brief or minor pain or distress, for which no pain relieving drugs are needed. Examples include observational studies, most intravenous and parenteral injections of non-irritating agents, most blood collections from peripheral vessels, and euthanasia for post- mortem collection of cells and/or tissues.

USDA Category D: Include in Category D all animals that will only undergo no more than procedures that are potentially painful or distressing, but for which the pain or distress is prevented or relieved by appropriate anesthetics, sedatives, analgesics, or other means (e.g., acupuncture).
Examples include surgery performed under anesthesia (major or minor, survival or non-survival), tissue or organ collections or other painful procedures performed on living animals under anesthesia (such as retro- orbital blood collection in rodents), prolonged restraint accompanied by tranquilizers or sedatives, and experiments with provisions for immediate euthanasia to effectively prevent pain and/or suffering in animals that are becoming sick. If an endpoint is defined such that the animals are likely to experience significant pain or distress, Category E is more appropriate.

USDA Category E: Include in Category E all animals that will undergo procedures in which pain or distress CANNOT be relieved. An important rule of thumb for deciding whether an animal should be assigned to Category E is to consider whether a human experiencing a comparable condition would be expected to seek relief. Examples include studies in which animals must be allowed to die without intervention (e.g. LD50, mortality as an end-point), studies that require endpoints that may be painful or stressful, studies that require withdrawal from addictive drugs (without palliative treatment), pain research, and studies that involve noxious stimuli that are not immediately escapable, food or water deprivation beyond that necessary for standard pre-surgical preparation, or paralysis or immobility in conscious animals.

2. Describe training programs for personnel responsible for monitoring animal well-being, including species-specific behavioral manifestations as indicators of pain and distress.

All VMU staff and research staff are trained to recognize animals in pain and/or distress before they are allowed to enter the VMU. This training includes online learning components from CITI ("Working with Mice in Research Settings." "Working with Rats in Research Settings") and from the VMU supervisor.

Research staff with new projects approved by the IACUC are required to meet with the VMU supervisor to discuss any potential study-specific observations.

F. Anesthesia and Analgesia [*Guide*, pp. 121-123]

1. List the agents used for each species.
Note: If preferred, this information may be provided in Table or additional Appendix.

ANESTHESIA
RAT and MOUSE

Ketamine + Xylazine (Rompun) Forane (Isoflurane) Pentobarbital Sodium
Ketamine + Xylazine + Acepromazine

ANALGESICS and TRANQUILIZERS
RAT and MOUSE

Buprenorphine

PRE-ANESTHETICS
RAT and MOUSE

Ketamine + Acepromazine

2. Describe how the veterinarian provides guidance and advice to researchers concerning choice and use of anesthetics, analgesics or other pain moderating methods.

The VMO and the Supervisor of the VMU consult with the Principal Investigator during the initial phase of writing the Animal Component of Research Protocol and advise the investigator as to analgesics and anesthetics appropriate to the species of animal and will provide training for its administration, if required. A list of appropriate analgesics/anesthetics and their dose rate are available to all investigative staff.

3. Describe the monitoring of the effectiveness of analgesics, including who does the monitoring. Include in the description any non-pharmacologic means used to diminish pain and distress.

All anesthetics and analgesics are controlled and dispensed by the VMU. The VMU Supervisor makes certain that the use of all anesthetics/analgesics is personally monitored during and after the surgical procedure.

If the Principal Investigator or his/her staff will be administering anesthesia/analgesia, they must state their training and expertise in the Animal Component of Research Protocol. This is approved/disapproved by the IACUC. If further training is necessary, that training will be given by VMU Supervisor. This service can also be provided by the VMO.

4. Describe how the veterinarian(s) and the IACUC/OB evaluate the proposed use of neuromuscular blocking agent to ensure the well-being of the animal.

Neuromuscular blocking agents are not used at this facility. It is a Department of Veterans Affairs policy not to use these agents.

5. Describe policies and practices for maintaining and ensuring function of equipment used for anesthesia.

The waste anesthetic gas is scavenged via hose from the anesthetic machine and connected to the Medical Center HVAC air exhaust register or Medical Center vacuum system. The anesthetic machines are monitored by Engineering Service on an annual basis for function and Safety Service for leakage.

G. Euthanasia [*Guide*, pp. 123-124]

1. Describe approved methods of euthanasia, including humane slaughter (for additional guidance, see pertinent AAALAC Reference Resources). Include:
   - consideration of species, age, condition (e.g., gestational period, or neonatal) and
   - location(s) for the conduct of the procedure.

   Note: If preferred, this information may be provided in Table or additional Appendix.

All guidelines for euthanasia established by the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia are followed. For rodents these are as follows: carbon dioxide inhalation, sedation with carbon dioxide followed by cervical dislocation, exsanguination while under general anesthesia, and sodium pentobarbital overdose.

Only investigators or their technicians who have undergone specific training may perform euthanasia on lab animals. All VMU technicians have undergone this training. With few exceptions all euthanasia on animals on the phylogenetic scale higher than rodents is performed by the VMU staff.

However, at this time, only rodents are housed at this facility. The training in lab animal euthanasia is conducted by the VMO and/or the VMU Supervisor.

2. Describe policies and practices for maintaining and ensuring function of equipment used for euthanasia.

The carbon dioxide regulators and the euthanasia equipment are monitored by

Engineering Service on an annual basis for function.

3. Describe the methods used to confirm death of an animal.

Detection of cessation of vital signs, following secondary method of euthanasia, by trained personnel. The training in lab animal euthanasia is conducted by the VMO and the VMU Supervisor.

IV. Physical Plant [*Guide*, pp. 133-155]

A. Facilities Overview

Provide a brief introduction to the animal housing and use facilities. Note that this overview should augment the information provided in **Appendix 2** (Summary of Animal Housing and Support Sites), which includes area, average daily census, and person responsible for each site. Please use consistent terminology for the buildings/areas/sites described in the Location section of the Appendix. Please do not repeat information, but supplement the descriptions provided elsewhere to assist the reviewers understanding of the interaction between facilities, special housing locations, and separate procedural areas.

The Veterinary Medical Unit is located in the Central Arkansas Veterans Healthcare System on the (b)(6) floor in (b)(6), (b)(6) Wing. The VMU is adjacent to and in the same quadrant as the Medical Research laboratories. The Veterinary Medical Unit is a conventional animal housing facility separated from the main research labs by a corridor and secured doors.
The VMU has animal wards, work rooms, surgical suite, necropsy and procedure rooms for special drug and radioactive material administration. Animal cubicles are not available at this facility.

Total net sq. ft. excluding corridors, restrooms, change areas and mechanical spaces is 8142 sq. ft. There are fourteen animal rooms with a total of 3024 sq. ft. All of these areas are indoors with both heating and air conditioning. There is no indoor space that is not environmentally controlled. This VMU does not have outdoor facilities. In addition, the VMU at CAVHS does not have any farm facilities.

B. Centralized (Centrally-Managed) Animal Facility(ies)

In this section, describe each centralized or centrally-managed animal housing and use facility. Include in **Appendix 3** the floor plans of each on 8.5" x 11" or A4 paper. Ensure that the drawings are legible and the use of each room is indicated (animal housing, procedure room, clean cage storage, hazardous waste storage, etc.). Note that a separate section for describing "satellite housing areas" is included below.

Separately describe **each** Location or Animal Facility, addressing each of the features outlined below (1-8). A complete description of each must be provided; however, common

features among locations or facilities may be indicated as such and do not need to be repeated.

1. General arrangement of the animal facilities (conventional, clean/dirty corridor, etc.).
2. Physical relationship of the animal facilities to the research laboratories where animals may be used.
3. Types of available animal housing spaces used, such as conventional, barrier, isolation/quarantine, hazard containment (infectious, radioactive, chemical), "animal cubicles" or facilities specifically designed for housing certain species such as ponds, pastures, feedlots, etc.
4. Finishes used throughout the animal facility for floors, walls, ceilings, doors, alleyways, gates, etc. (note any areas that are not easily sanitized and describe how these are maintained).
5. Engineering features (design, layout, special HVAC systems, noting exhaust air treatment, if applicable) used in hazardous agent containment.
6. Security features, such as control of entry, perimeter fences, gates, entryways, cameras, guards; identify and describe exceptions for individual facilities or areas incorporating fewer or additional security features than the general features described.
7. Consideration for facilities with exterior windows, if applicable, including management of environmental conditions (i.e., temperature and photoperiod control) and potential security risks.
8. Storage areas for flammable or hazardous agents and materials (e.g., disinfectants, cage-washing chemicals, pesticides, fuel).

The Veterinary Medical Unit is located in the Central Arkansas Veterans Healthcare System on the (b)(6) floor in (b)(6), (b)(6) Wing. The VMU is adjacent to and in the same quadrant as the Medical Research Laboratories. The Veterinary Medical Unit is a conventional animal housing facility separated from the main research labs by a corridor and secured doors.

The VMU has animal wards, work rooms, surgical suite, necropsy and procedure rooms for special drug and radioactive material administration. Animal cubicles are not available at this facility.

Total net sq. ft. excluding corridors, restrooms, change areas and mechanical spaces is 8142 sq. ft. There are fourteen animal rooms with a total of 3024 sq. ft. All of these areas are indoors with both heating and air conditioning. There is no indoor space that is not environmentally controlled. This VMU does not have outdoor facilities. In addition, the VMU at CAVHS does not have any farm facilities.

The VMU is adjacent to and in the same quadrant as the Medical Research laboratories. The Veterinary Medical Unit is a conventional animal housing facility separated from the main research labs by a corridor and secured doors.

The Veterinary Medical Unit is a conventional animal housing facility. The receiving room for animals is (b)(6), 130 sq. ft. Quarantine for random source animals or rodents is accomplished by isolation in available empty animal wards, the quarantine area, (b)(6), 130 sq. ft.) or on isolation racks. The isolation for sick animals is accomplished in the

same manner. Aseptic surgery is performed in two rooms, (b)(6) 463 sq. ft. and (b)(6) (b)(6) 126 sq. ft. The necropsy room is (b)(6) 156 sq. ft. There are two (2) feed storage cold rooms, (b)(6) , 47 sq. ft. and (b)(6) , 34 sq. ft. The bedding storage room is (b)(6) . The cage washing equipment is in room (b)(6) 503 sq. ft. Storage for clean cages is (b)(6) , 447 sq. ft. (b)(6) is also used for procedure space. (b)(6) , 288 sq. ft. is the post-operation procedure laboratory. The Diagnostic laboratory is (b)(6) , 130 sq. ft. Personnel facilities, including bathrooms, showers and changing areas, are (b)(6) (b)(6) , (b)(6) , (b)(6) , (b)(6) , (b)(6) , (b)(6) and (b)(6) for a total of 620 sq. ft. Lounge facilities for VMU personnel are (b)(6) 115 sq. ft. Service corridors equal 2408 sq. ft. Administrative space, including offices, (b)(6) (b)(6) and (b)(6) for 378 sq. ft. There is 22 sq. ft. of mechanical space. CAVHS supplies the incinerator and waste disposal for the VMU. The VMU does not have facilities for a diet kitchen or a radiology room.

Animals are only housed in the facility.

Corridors
All corridors are granite composite over concrete. Walls are dry wall, reinforced with fiberglass cloth, and coated with epoxy paint. Ceilings are waterproof sheet rock and coated with epoxy paint. Corridors are 72" wide with 8" bumper rails mounted 6" from the floor. All animals housed at this facility must use a common corridor. When animals are received, they are left in the shipping crate, the crate sprayed with a dilute quatracide, and transported to the animal ward where they are housed. Soiled bedding transported to the cage washing area is left in the cage, placed on a cart, and covered before transporting. Carts are sanitized before use.

Animal Room Doors
Doors are 84"H x 44"W with a 9 ½ " x 9 ½" viewing window and constructed of laminated wood.

Floors
Floors are constructed of granite composite over concrete.

Drainage and Plumbing
The floor drains in all animal wards are 4" in diameter, recessed and are covered with a perforated steel plate that is hinged. Each animal ward is equipped with a wall-mounted, manually-operated flush valve. These drains are flushed every day. Floor drains in the cage wash area and clean cage storage measure 3" in diameter, recessed, and covered with an unhinged, perforated steel plate. There is no manual flush valve in either room. Flushing is accomplished via a water hose.

Walls
Walls in all animal wards are plaster, covered with fiberglass cloth, and painted with epoxy paint and are in good condition. Walls in the cage wash area and the cage storage area are plaster and painted with epoxy paint and are in good condition.

Ceilings
Ceilings in all animal wards and the cage wash/storage areas are constructed of plaster coated with epoxy paint. All animal ward ceilings are in good condition. The ceiling in the cage wash area is in fair condition due to the high humidity conditions.

There are no exterior windows in this facility.

C. Satellite Animal Housing Facilities

In addition to the Appendices summarizing Heating, Ventilation, and Air-Conditioning (**Appendix 11**) and Lighting Systems (**Appendix 16**), summarize animal housing areas that are not centrally-managed or maintained in (**Appendix 17**), "Satellite Animal Housing Areas."

1. Describe the criteria used to determine/define a "Satellite Animal Housing Area," which may include remote housing facilities or laboratories temporarily or consistently housing animals.

   No satellite animal housing facilities used.

2. Describe the process used by the IACUC/OB to authorize, provide oversight of, and ensure compliance with *Guide* standards for the housing of animals outside of centrally-maintained facilities. Include a description of Attending Veterinarian access and physical security.

   No satellite animal housing facilities used.

D. Emergency Power and Life Support Systems

Note: Complete a Heating, Ventilation, and Air-Conditioning (HVAC) Summary (**Appendix 11**) and Lighting Summary (**Appendix 16**) for each Location described in the Summary of Animal Housing and Support Sites (**Appendix 2**).

1. **Power** [*Guide*, p. 141]
   For each Location, Centralized Animal Facility, and Satellite Housing Facility, provide a brief description of the following:
   - Availability of emergency power and if so, what electrical services and equipment are maintained in the event the primary power source fails.
   - History of power failures, noting frequency, duration, and, if emergency power was not available, steps taken to ensure the comfort and well-being of the animals present and the temperature extremes reached in animal rooms during the failure.

   Emergency power is provided for the VMU. All animal wards electrical outlets, selected corridor ceiling lights, surgery ceiling lights and electrical outlets in surgical support areas have emergency power. The HVAC is on emergency power but only for exhaust fans.

   Annual scheduled tests of Emergency Power Systems are done at this facility to meet Joint Commission requirements. These power outages have a duration of four hours. There have never been any animal loss or health problems resulting from a power failure at this facility.

2. **Other System Malfunctions.** If not previously reported, describe animal losses or health problems resulting from power, HVAC, or other life support system (e.g., individually ventilated cages) failures, and mechanisms for reporting such incidences. AAALAC International Rules of Accreditation (Section 2.f).

There have never been any animal loss or health problems resulting from a power failure at this facility.

E. Other Facilities [*Guide*, pp. 144, 150]

1. **Other Animal Use Facilities** [*Guide*, pp. 146-150]
Describe other facilities such as imaging, irradiation, and core/shared behavioral laboratories or rooms. Include a description of decontamination and methods for preventing cross-contamination in multi-species facilities.

CAVHS does not have any other animal use facilities.

2. **Other Animal Program Support Facilities**
Describe other facilities providing animal care and use support, such as feedmills, diagnostic laboratories, abattoirs, etc.

CAVHS does not have any other support facilities.

According to the privacy principles on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, we wish to advise you that the personal data in the Program Description will become part a permanent file owned by AAALAC International, and that can be shared with AAALAC International offices and representatives in order to perform an evaluation of the institution's animal care and use program and provide accreditation services. The institution has the option of exercising rights of data access, rectification, cancellation, and opposition at: accredit@aaalac.org

Appendix 1: Glossary of Abbreviations and Acronyms

Abbreviation/Acronym	Definition
AALAS	American Association for Laboratory Animal Science
ACORP	Animal Component of Research Protocol
ACOS	Associate Chief of Staff
ALAT	Assistant Laboratory Animal Technician
AO	Administrative Officer
APN	Advanced Practical Nurse
ARB	Accident Review Board
AVMA	American Veterinary Medical Association
AVMA	American Veterinary Medical Association
CAVHS	Central Arkansas Veterans Healthcare System
CBC	Complete Blood Count
CITI	Collaborative Institutional Training Initiative
DMBA	Dimethylbenz[a]anthracene
EMS	Environmental Management Service
EOD	Entered on Duty
FEMA	Federal Emergency Management Agency
HEPA	High-Efficiency Particulate Arrestance
HVAC	Heating, Ventilation and Air Conditioning
IACUC	Institutional Animal Care and Use Committee
IO	Institutional Official
IP	Intraperitoneal
MSDS	Material Safety Data Sheet
OLAW	Office of Laboratory Animal Welfare
PCP	Pentachlorophenyl
PHS	Public Health Service
PI	Principal Investigator
PPD	Purified Protein Derivative
PPE	Personal Protective Equipment
Process NPD	Quaternary Ammonia
R&D	Research and Development
SDS	Safety Data Sheet
SOP	Standard Operating Procedure
SPF	Specific Pathogen Free
SRS	Subcommittee for Research Safety
UAMS	University of Arkansas for Medical Sciences
USDA	United States Department of Agriculture
VAF	Virus Antibody Free
VHA	Veterans Healthcare Administration
VMO	Veterinary Medical Officer
WOC	Without Compensation

Appendix 2: Summary of Animal Housing and Support Sites

Animal Housing and Support Sites						
Location (building, site, farm name, etc.[a])	**Distance from main facility[b]**	**Approx. ft², m², or acreage for animal housing**	**Approx. ft², m², or acreage for support or procedures**	**Species housed**	**Approx. Daily Animal Census by species**	**Person in charge of site**
JLM/VMU	Within Facility	3024 ft²	8951 ft²	Mice Rats	4187 2	(b)(6)
Satellite Housing Facilities Total (Expand in Table 17)						

Totals:		
Total animal housing and support space:	11,975 ft²	
	(please specify ft² or m²)	

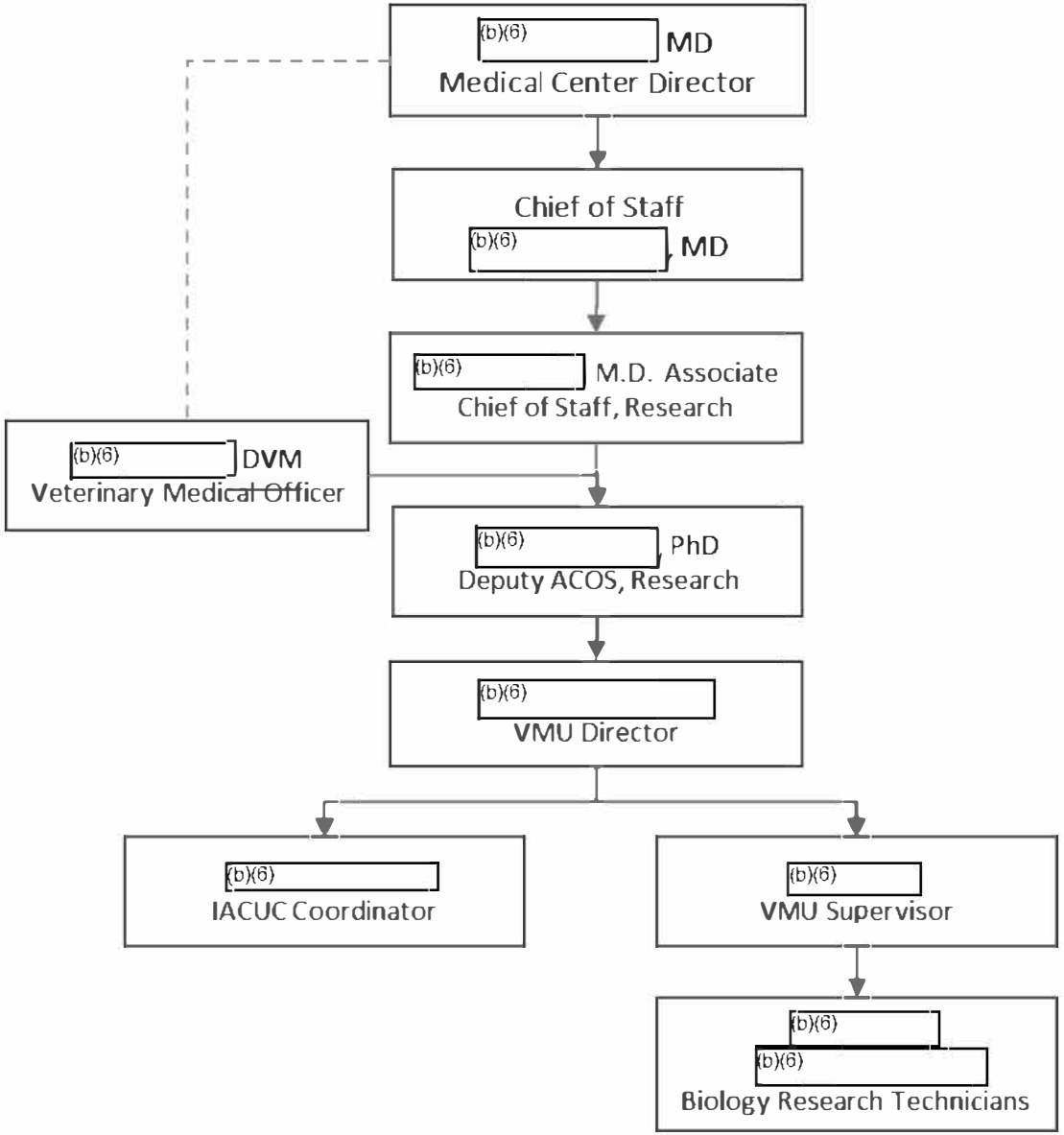
[a]Please state name and/or use acronyms described in **Appendix 1** for building names, if not coded for confidentiality.
[b]Campus or site map(s) may also be provided in lieu of this information.

Appendix 3: Line Drawings

Please see attachment

Appendix 4: Organizational Chart(s)

Central Arkansas Veterans Healthcare System Veterinary Medical Unit (VMU)
Organizational Chart



Appendix 5: Animal Usage

Project/Protocol Title	IACUC/ OB Number	Principal Investigator	Species	Total Number of Animals Approved	Pain & Distress Category (1)	Special Considerations (use checkmark if applicable)					
						SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
Sp-1, Kappa-B Enhancers and Transcription in Neurons	(b)(6)	(b)(6)	Mouse	248	B, C						
Molecular aspects of endocrine and metabolic dysregulation in neurodegeneration	(b)(6)	(b)(6)	Mouse	1313	B, C			✓			
Molecular Links of Alzheimer's and Diabetes (Phase II)	(b)(6)	(b)(6)	Mouse	772	B, C, D	✓				✓	
Studies of neuronal function in cell culture	(b)(6)	(b)(6)	Rat	195	C						
Effects of DNase inhibitors on acute brain ischemia	(b)(6)	(b)(6)	Mouse	516	B, D	✓					
Amelioration of acute kidney failure by DNase inhibitors	(b)(6)	(b)(6)	Mouse	1400	B, D	✓					
Environmental risk assessment of carbon nanomaterials used as plant growth regulators	(b)(6)	(b)(6)	Mouse	72	D						
Role of insulin-like growth factor-binding protein 1 in acute kidney injury	(b)(6)	(b)(6)	Mouse	1768	B, C, D	✓				✓	
Genetic Models Core of the Center for Musculoskeletal Disease Research	(b)(6)	(b)(6)	Mouse	15312	B, C, D	✓				✓	
Mechanisms of Acute and Chronic Renal Injury	(b)(6)	(b)(6)	Mouse	402	B, D	✓	✓			✓	
Androgens, Estrogens and Bone Loss in Males	(b)(6)	(b)(6)	Mouse	3765	B, C, D	✓				✓	
LOX-1, Angiogenesis and Atherosclerosis: Search for New Therapies (new title)	(b)(6)	(b)(6)	Mouse	759	B, C, D	✓				✓	
PCSK9, inflammation and infarct size	(b)(6)	(b)(6)	Mouse	1140	B, C, D	✓				✓	
Hormonal Control of Bone Mass	(b)(6)	(b)(6)	Mouse	828	C, D	✓					
Molecular mechanisms of glucocorticoid-induced bone loss	(b)(6)	(b)(6)	Mouse	693	C, D						

Appendix 5: Animal Usage

Project/Protocol Title	IACUC/ OB Number	Principal Investigator	Species	Total Number of Animals Approved	Pain & Distress Category (1)	Special Considerations (use checkmark if applicable)					
						SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
A transgenic mouse model of uromodulin related kidney disease	(b)(6)	(b)(6)	Mouse	272	C, D	✓					
Ex vivo preparatory studies of protective mechanisms for cryoprotectant toxicity in the rat	(b)(6)	(b)(6)	Rat	45	B, C						
Ex vivo studies of protective mechanisms from cryoprotectant toxicity	(b)(6)	(b)(6)	Mouse	75	C						
Sirt1 and FoxO Deacetylation Effects in Skeletal Homeostasis	(b)(6)	(b)(6)	Mouse	21794	B, C, D					✓	
Glucocorticoid-induced osteonecrosis of the hip, osteocytes and canalicular fluid	(b)(6)	(b)(6)	Mouse	360	B, C, D						

(1) If applicable, please provide a description / definition of any pain/distress classification used within this Appendix in the space below. If pain/distress categories are not used, leave blank.
(2) Survival Surgery (SS)
(3) Multiple Survival Surgery (MSS)
(4) Food or Fluid Regulation (FFR)
(5) Prolonged Restraint (PR)
(6) Hazardous Agent Use (HAU)
(7) Non-Centralized Housing and/or Procedural Areas (NCA), i.e., use of live animals in any facility, room, or area that is not directly maintained or managed by the animal resources program, such as investigator laboratories, department-managed areas, teaching laboratories, etc.

Pain/Distress Classification Description/Definition, if applicable:

USDA Category B: All animals that will be bred or purchased exclusively for breeding, and that will not undergo any procedures other than those required by currently accepted standards of medical care. This includes breeders, and any young that may be culled because of unusable gender, genotype, or date of birth.
USDA Category C: All animals that will only undergo procedures that involve no more than very brief or minor pain or distress, for which no pain relieving drugs are needed. Examples include observational studies, most intravenous and parenteral injections of non-irritating agents, most blood collections from peripheral vessels, and euthanasia for post-mortem collection of cells and/or tissues.

Appendix 5: Animal Usage

USDA Category D: All animals that will only undergo no more than procedures that are potentially painful or distressing, but for which the pain or distress is prevented or relieved by appropriate anesthetics, sedatives, analgesics, or other means (e.g., acupuncture). Examples include surgery performed under anesthesia (major or minor, survival or non-survival), tissue or organ collections or other painful procedures performed on living animals under anesthesia (such as retro-orbital blood collection in rodents), prolonged restraint accompanied by tranquilizers or sedatives, and experiments with provisions for immediate euthanasia to effectively prevent pain and/or suffering in animals that are becoming sick. If an endpoint is defined such that the animals are likely to experience significant pain or distress, Category E is more appropriate.

USDA Category E: All animals that will undergo procedures in which pain or distress CANNOT be relieved. An important rule of thumb for deciding whether an animal should be assigned to Category E is to consider whether a human experiencing a comparable condition would be expected to seek relief. Examples include studies in which animals must be allowed to die without intervention (e.g. LD_{50}, mortality as an end-point), studies that require endpoints that may be painful or stressful, studies that require withdrawal from addictive drugs (without palliative treatment), pain research, and studies that involve noxious stimuli that are not immediately escapable, food or water deprivation beyond that necessary for standard pre-surgical preparation, or paralysis or immobility in conscious animals.

In the Table below, provide an approximate annual usage for all species:

Animal Type or Species	Approximate Annual Use
Mice	17163
Rats	80

Animal Type or Species	Approximate Annual Use

Appendix 6: Personnel Medical Evaluation Form

CENTRAL ARKANSAS VETERNAS HEALTHCARE SYSTEM VMU ANNUAL MEDICAL QUESTIONNAIRE

Name:

Date of birth: Gender: Pregnancy Status:

Job Title:

Species Encountered:

Contact time per week:
(Include contact time with animal tissues, waste, body fluids, carcasses, and animal housing areas)

Are human or animal pathogens included in your work?

Positive PPD?

Have you received immunosuppressive therapy within the past year that could increase the risk of zoonotic disease?

Do you wear the personal protective equipment (PPE) suggested for the assigned tasks? Do you smoke, eat or drink in the animal or procedure areas?
Do you wash hand, changes clothing (if soiled), or shower after handling animals during the day?

Is there any history of asthma, hay fever, allergic skin problems, eczema, sinusitis, chronic respiratory infections or disease?

Do you have any allergic symptoms occur during or after contact with a laboratory animal species, and if so, which species is involved and how frequently each symptom occurs?

Do you have any house pets that could be responsible for the allergic symptoms or that could represent a disease transmission hazard to the employee or to the animals in the research facility?

In the past year, have you ever suffered from an inguinal or similar hernia, from back pain, or from joint problems or arthritis? If so, the severity and corrective measures need to be described.

Do you have your immunization schedule?

Appendix 6: Personnel Medical Evaluation Form

Signature of Employee	Date
Representative of Service	Date

Appendix 7: IACUC/OB Membership Roster

Please provide a Committee roster, indicating names, degrees, membership role, and affiliation (e.g., Department/Division).

Name	Phone #	Address
(b)(6) Managing Dir., Transgenic Core Chair-Scientist Voting Member	(b)(6) (cell)	(b)(6)
(b)(6) Ph.D. Vice Chair- Scientist/Voting Member	(b)(6)	(b)(6)
(b)(6) Non-Affiliated Voting Member	(b)(6)	(b)(6)
(b)(6) Ph.D. Scientist/Affiliated Voting Member	(b)(6)	(b)(6)
(b)(6) Ph.D. Scientist/Voting Member	(b)(6)	(b)(6)
(b)(6) D.V.M. Veterinarian, Ex-Officio Voting Member	(b)(6)	(b)(6)
(b)(6) M.D. Scientist/Affiliated Voting Member	(b)(6)	(b)(6)
(b)(6) VMU Supervisor Voting Member	(b)(6)	(b)(6)
(b)(6) Lay Member/Unaffiliated Voting Member	(b)(6)	(b)(6)
(b)(6) Ph.D. Scientist/Affiliated Voting Member	(b)(6)	(b)(6)

Appendix 8: IACUC/OB Minutes

Please provide the latest two Minutes of the IACUC/OB meetings.

Please see attachment

Appendix 9: IACUC/OB Protocol Form

Please attach a ***blank*** copy of form(s) used by the IACUC/OB to review and approve studies. Include forms used for annual (or other periodic) renewal, modifications, amendments, etc., as applicable.

Please see attachment

Appendix 10: IACUC/OB Periodic Report

Please attached a copy of the latest facilities (including laboratory inspections) and program assessment report conducted by the IACUC/OB.

Please see attachment

Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

Location/Building/Facility:	Central Arkansas Veterans Healthcare System, Little Rock, AR

The animal facility is supplied with 100% fresh, filtered, outside air with at least 15 room changes per hour. The supply diffusers are located in the ceilings with return ducts near the floor. The air is heated or cooled to the desired temperature and controlled by a computerized energy management system. The temperature and humidity sensors for each room are located in the diffusers which alarm when temperature is out of the designated range in the Command Center for Engineering Service. Temperatures in animal rooms rarely fluctuate more than 4 degrees above or below the set point for the room.

An emergency cascade is in place for any temperature or humidity reading that falls out of range in an animal ward. The cascade is tested on an annual basis.

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified / Measured
		(settings to be verified)					(values to be measured)	
(b)(6)	Animal Ward	72°F	Y	NA	Y	-	19	4/1/2019
(b)(6)	Animal Ward	72°F	Y	NA	Y	-	11	4/1/2019
(b)(6)	Animal Ward	72°F	Y	NA	Y	-	18	4/1/2019
(b)(6)	Animal Ward	72°F	Y	NA	Y	-	20	4/1/2019
(b)(6)	Animal Ward	72°F	Y	NA	Y	-	14	4/1/2019
(b)(6)	Animal Ward	72°F	Y	NA	Y	-	12	4/1/2019
(b)(6)	Animal Ward	72°F	Y	NA	Y	-	13	4/1/2019
(b)(6)	Animal Ward	72°F	Y	NA	Y	-	13	4/1/2019

Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified / Measured
		(settings to be verified)					(values to be measured)	
(b)(6)	Necropsy	72°F	Y	NA	Y	+	9	4/1/2019
(b)(6)	Surgery Work	72°F	Y	NA	Y	-	19	4/1/2019
(b)(6)	Surgery Scrub	72°F	Y	NA	Y	-	15	4/1/2019
(b)(6)	Surgery	72°F	Y	NA	Y	+	15	4/1/2019
(b)(6)	Post Op	72°F	Y	NA	Y	-	11	4/1/2019
(b)(6)	Surgery	72°F	Y	NA	Y	+	11	4/1/2019
(b)(6)	Cage Storage (Clean)	70°F	Y	NA	Y	+	15	4/1/2019
(b)(6)	Cage Storage (Clean)	70°F	Y	NA	Y	-	16	4/1/2019
(b)(6)	Animal Ward	72°F	Y	NA	Y	-	12	4/1/2019
(b)(6)	Animal Ward	72°F	Y	NA	Y	-	15	4/1/2019
(b)(6)	Air Lock	72°F	Y	NA	Y	NA	NA	4/1/2019
(b)(6)	Animal Ward	72°F	Y	NA	Y	-	12	4/1/2019
(b)(6)	Support Room	70°F	Y	NA	Y	-	10	4/1/2019
(b)(6)	Animal Ward	72°F	Y	NA	Y	-	16	4/1/2019
(b)(6)	Animal Ward	72°F	Y	NA	Y	-	17	4/1/2019
(b)(6)	Animal Ward	72°F	Y	NA	Y	-	12	4/1/2019
(b)(6)	Procedure Room	72°F	Y	NA	Y	-	9	4/1/2019

Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified / Measured
		(settings to be verified)					(values to be measured)	
(b)(6)	Cage Washing (Dirty)	70°F	Y	NA	Y	-	15	4/1/2019
(b)(6)	Bedding Storage	70°F	Y	NA	Y	+	14	4/1/2019
(b)(6)	Quarantine	72°F	Y	NA	Y	-	15	4/1/2019
(b)(6)	Animal Ward	72°F	Y	NA	Y	-	19	4/1/2019
(b)(6)	Animal Ward	72°F	Y	NA	Y	-	11	4/1/2019
(b)(6)	Animal Ward	72°F	Y	NA	Y	-	18	4/1/2019
(b)(6)	Animal Ward	72°F	Y	NA	Y	-	20	4/1/2019
(b)(6)	Animal Ward	72°F	Y	NA	Y	-	14	4/1/2019
(b)(6)	Animal Ward	72°F	Y	NA	Y	-	12	4/1/2019
(b)(6)	Animal Ward	72°F	Y	NA	Y	-	13	4/1/2019
(b)(6)	Animal Ward	72°F	Y	NA	Y	-	13	4/1/2019
(b)(6)	Necropsy	72°F	Y	NA	Y	+	9	4/1/2019
(b)(6)	Surgery Work	72°F	Y	NA	Y	-	19	4/1/2019

Appendix 12: Aquatic Systems Summary – Part I

Part I

Location (1)	Species (2)	System Design					
		Group / Individual (3)	Water Type (4)	Pre-treatment (5)	Circulation (6)	Filtration (7)	Disinfection (e.g., UV, ozone)
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Note: Records of equipment maintenance (filter changes, UV bulb changes, probe changes, calibrations, *etc.*) should be available for review.

Appendix 12: Aquatic Systems Summary – Part II

Part II

Monitoring *Indicate in the boxes below the frequency of monitoring and method of control for the following parameters. (1)*									
Location (from Part I)	**Temperature**	**Salinity**	**pH**	**NH_4**	**NO_2**	**NO_3**	**Dissolved O_2**	**Total Dissolved Gases**	**Other. Please List (2):**
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Note: This information may be provided in another format, provided that all requested data is included.

Appendix 13: Primary Enclosures and Animal Space Provisions

Please complete the Table below considering performance criteria and guiding documents (e.g., Guide, Ag Guide, ETS 123 and/or other applicable standards) used by the IACUC/OB to establish adequacy of space provided for all research animals including traditional laboratory species, agricultural animals, aquatic species, and wildlife when reviewing biomedical, field, and agricultural research studies.

Species	Dimensions of Enclosure (cage, pen, tank*, corral, paddock, etc.)	Maximum Number Animals / Enclosure	Guiding Document Used to determine the Institution's Space Standards (Guide, Ag Guide, ETS 123, Other)	Enclosure Composition & Description**
Mice	7"W x 11.25"L x5"D	4	Guide	Conventional
Mice	7"W x 11.25"L x5"D	4	Guide	IVCS
Mice	10.5"W x 19"L x 6"D	10	Guide	Conventional
Mice	7.25"W x 13"L x 5.5"D	5	Guide	Conventional
Mice	16.5"W x 13"L x 5.75D	10	Guide	Conventional
Rat/Guinea Pig	10"W x 19"L x 8"D	2	Guide	IVCS
Rat/Guinea Pig	10"W x 19"L x 8"D	2	Guide	Conventional

*For aquatic species, provide tank volume.

**Include descriptors such as open-topped, static microisolator, individually-ventilated cage systems (IVCS).

Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

Please describe the cleaning and disinfection methods in the Table below. Note the washing/sanitizing frequency and method for each of the following:

Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Chemical(s) Used*	Other Comments (e.g., autoclaved)
Micro-environment				
Solid-bottom cages (static)	Mechanical Washer	Weekly	Getinge Clean LS-920	
Solid-bottom cages (IVC)	Mechanical Washer	Weekly	Getinge Clean LS-920	
Suspended wire-bottom or slotted floor cages	Mechanical Washer	As Needed	Getinge Clean LS-920	Before and After Use
Cage lids	Mechanical Washer	Biweekly	Getinge Clean LS-920	
Filter tops	Mechanical Washer	Biweekly	Getinge Clean LS-920	
Cage racks and shelves	Mechanical Washer	Biweekly	Getinge Clean LS-920	
Cage pans under suspended cages	Not Used	N/A	NA	
Play pens, floor pens, stalls, etc.	Not Used	N/A	NA	
Corrals for primates or outdoor paddocks for livestock	Not Used	N/A	NA	
Aquatic, amphibian, and reptile tanks and enclosures	Not Used	N/A	NA	N/A
Feeders	Mechanical Washer	Biweekly	Getinge Clean LS-920	
Watering devices	Mechanical Washer	Weekly	Getinge Clean LS-920	

Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Chemical(s) Used*	Other Comments (e.g., autoclaved)
Exercise devices and manipulanda used in environmental enrichment programs, etc.	Only Disposable Enrichment Products Used	N/A	Getinge Clean LS-920	
Transport cages	Disposable	N/A	N/A	
Operant conditioning & recording chambers, mechanical restraint devices (chairs, slings, etc.)	Hand Sanitized	As Needed	Process NPD (quaternary ammonia)	
Euthanasia chambers	Mechanical Washer	As Needed	Getinge Clean LS-920	After Each Use
Macro-Environment				
Animal Housing Rooms:				
Floors	Disposable Mopping System	Weekly	Process NPD (quaternary ammonia)	Or Between Studies
Walls	Disposable Mopping System	Monthly	Process NPD (quaternary ammonia)	Or Between Studies
Ceilings	Disposable Mopping System	Monthly	Process NPD (quaternary ammonia)	Or Between Studies
Ducts/Pipes	Disposable Mopping System	Monthly	Process NPD (quaternary ammonia)	Or Between Studies
Fixtures	Disposable Mopping System	Monthly	Process NPD (quaternary	Or Between Studies

Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Chemical(s) Used*	Other Comments (e.g., autoclaved)
			ammonia)	
Corridors:				
Floors	Mopping System	Weekly	Process NPD (quaternary ammonia)	
Walls	Disposable Mopping System	Monthly	Hypochlorite or Process NPD (quaternary ammonia)	
Ceilings	Disposable Mopping System	Monthly	Hypochlorite or Process NPD (quaternary ammonia)	
Ducts/Pipes	Disposable Mopping System	Monthly	Hypochlorite or Process NPD (quaternary ammonia)	
Fixtures	Disposable Mopping System	Monthly	Hypochlorite or Process NPD (quaternary ammonia)	
Support Areas (e.g., surgery, procedure rooms, etc.); complete for each area:				
Floors	Mopping System	Weekly	Hypochlorite or Process NPD (quaternary ammonia)	Or As Needed
Walls	Disposable Mopping System	Biweekly	Hypochlorite or	Or As Needed

Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Chemical(s) Used*	Other Comments (e.g., autoclaved)
			Process NPD (quaternary ammonia)	
Ceilings	Disposable Mopping System	Biweekly	Hypochlorite or Process NPD (quaternary ammonia)	Or As Needed
Ducts/Pipes	Disposable Mopping System	Biweekly	Hypochlorite or Process NPD (quaternary ammonia)	Or As Needed
Fixtures	Disposable Mopping System	Biweekly	Hypochlorite or Process NPD (quaternary ammonia)	Or As Needed
Implements (note whether or not shared):				
Mops	Mechanical Washer	Monthly	Getinge Clean LS-920	Not Shared
Mop buckets	Mechanical Washer	Weekly	Getinge Clean LS-920	Not Shared
Aquaria nets	None Used	N/A	N/A	N/A
Other	Hand then Mechanical Washer	After each use	Hypochlorite	
Other:				
Vehicle(s)	Hand Sanitized	Monthly	Hypochlorite	Or As Needed/After Transport
Other transport equipment (list)	Mechanical Washer	Daily	Getinge Clean	Floats and Carts

Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Chemical(s) Used*	Other Comments (e.g., autoclaved)
			LS-920	

*Please provide chemical, not trade name.

Getinge Clean LS-920: Moderate Alkaline Cage Wash (Proprietary Mixture)

Appendix 15: Facilities and Equipment for Sanitizing Materials

Building	Room No.	Equipment Type	Safety Feature(s)	Methods of Monitoring Effectiveness
JLM	(b)(6)	Rack washer	Emergency "off" button; labeled exit door, de-energizing cord on both sides, instructional signage	Guarantee 180-degree hot water rinse; temperature-sensitive tape used weekly; RODAC plates of caging tested quarterly
JLM	(b)(6)	Tunnel washer	Emergency "off" button; instructional signage	Guarantee 180-degree hot water rinse; temperature-sensitive tape used weekly; RODAC plates of caging tested quarterly
JLM	(b)(6)	Bulk autoclave	Emergency "off" button; lock-out key	ATP-based luminescence swabs performed quarterly

Appendix 16: Lighting Summary

Location:	**Central Arkansas Veterans Healthcare System, Little Rock, AR**

Room Type[a]	**Light Intensity Range**	**Lighting Fixture Construction Features**[b]	**Photo-period** (hrs)[c]	**Photoperiod and Lighting Control**	**Override Mechanisms** (if applicable)
Rodent Holding Rooms	300-320 lux	Surface mounted, water resistant	12:12	Automatic control light times mounted outside each room.	Manual override allowing user to turn on/off lights manually.
Surgery	500 lux	Recessed, water resistant; arm-mounted, water resistant	NA	N/A	N/A
Necropsy	Not measured	Recessed, water resistant	NA	N/A	N/A
Cage-Washing Room	Not measured	Recessed, water proof	NA	N/A	N/A

[a] A list of each room is not needed; group or cluster rooms by species or function
[b] Include such features as water resistance, red lighting, *etc.*
[c] Note if light cycle inverted/reversed.

Appendix 17: Satellite Housing Facilities

Note: In the Program Description Section 2. IV. (Physical Plant), item C., describe the criteria used to determine a "Satellite Animal Holding Area." In the Table below, summarize these animal housing areas. Note that the total square footage for all each of these must also be included in the Summary of Animal Housing and Support Sites **(Appendix 2)**, and applicable information regarding these areas included in the Heating, Ventilation, and Air Conditioning (HVAC) Summary (**Appendix 11**) and Lighting Systems Summary (**Appendix 16**).

Building	Room(s)	Person Responsible	Species Used	Approximate Area (ft^2 or m^2) Devoted to Housing	Maximum Period of Stay	Purpose / Rationale / Justification	Construction Features and Finishes
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Central Arkansas Veterans Healthcare System
Institutional Animal Care and Use Committee
Application for Protocol Modification
Version 12-07

This form should only be used to make a change to an approved protocol. If changes are substantial, e.g. change of/or additional animal species, survival surgery, or the proposed change increases the potential for pain or distress in an animal, or involves a significant procedure not previously approved for these particular animals, a new ACORP must be submitted. A new experiment or a pilot study cannot be approved as a modification, even if the same funding source will be used. All proposed changes must be reviewed and/or discussed with the Veterinary Medical Officer before submission to the IACUC Chairperson.

A. Protocol Information

1. **Principal Investigator:**
2. **Approved Protocol #:**
3. **Protocol Title:**
4. **Species used in protocol:**

B. Modification Request

Check all changes requested.

- ☐ **VisualSonic**
- ☐ **Test Substance**
- ☐ **Anesthesia/analgesia**
- ☐ **Experimental Procedure**
- ☐ **Animal Numbers**
- ☐ **Animal Strain (Addition or Deletion)**
- ☐ **Euthanasia**
- ☐ **Personnel (Addition or deletion)**
- ☐ **Other (Specify)**

C. Description of modification

D. Will animals be euthanized following use of the VisualSonic? Describe use and dose of additional anesthetics required as well as post-procedural care

E. Justification for modification

F. Who will perform the procedure? Are they trained in this procedure for this species? If they are not trained for this procedure, how will they be trained and who will train them?

G. Additional: Will the proposed changes increase the total number of animals used in this protocol? ☐ **Yes** ☐ **No**

If Yes, how many additional animals are needed, and in which USDA Category will they be used (B, C, D, or E)?

INVESTIGATOR ASSURANCE: I have determined that the research proposed in this modification is not unnecessarily duplicative of previously reported research and that the use of animals is necessary. I agree to conduct this project in accordance with applicable provisions of the Animal Welfare Act, the Public Health Service Policy and the Guide for the Care and Use of laboratory Animals.

H. Principal Investigator's Signatures

PRINCIPAL INVESTIGATOR SIGNATURE		DATE

The undersigned have reviewed this request and find it to be acceptable.

I. Approval Signatures

VETERINARY MEDICAL OFFICER	SIGNATURE(S)	DATE
(b)(6) **D.V.M.**		
IACUC Chair		
(b)(6)		

Once this modification has been approved, it will be attached to the original approved ACORP.

Protocol #: Principal Investigator: Date:

☐ Designated or ☐ Full Review Reviewer:

I. All Protocols

Has the funding source been named on the protocol?

Are the objectives of the proposed research clear?

Are the procedures clearly described?

Are experimental endpoints and duration of experiments clear?

Are the effects on the condition of the animals clearly stated?

Is the justification for the number of animals clear and logical?

Are alternatives to animal use and refinements of procedures documented?

Number of databases searched

Narrative discussion of search for alternatives(i replacement, ii reduction, iii refinement)

Are the methods of euthanasia appropriate?

Are the training and experience of the individuals performing the procedures satisfactory?

II. As Required

If alternative housing and husbandry methods are proposed, are they acceptable and justified?

If pain relief would be withheld, is the scientific justification adequate?

If multiple survival surgery is proposed, is the scientific justification adequate?

If biohazardous material use is proposed, are appropriate measures described for handling?

Is there volatile anesthetics use on this protocol?

If animals may become seriously ill or debilitated, are criteria for interventional euthanasia defined?

Has the investigator answered the environmental enrichment question?

III. Veterinary

Are the proposed anesthesia and analgesia appropriate?

Are there refinements to the procedures which you would like the Investigator to consider?

Do you anticipate complications to the procedures not considered by the Investigator?

Are post-procedural care and observation adequate?

IV. Summary

Other Comments:

Recommendation: ☐ **Approve** ☐ **Disapprove**

☐ **Required Modifications to Secure Approval**

☐ **RMSA followed by FCR**

☐ **RMSA followed by Designated Member Review**

Full Review:

For protocols subjected to full review, please provide written answers to the following questions, and use these points to guide your presentation of the protocol before the committee. Discussion is not limited to these points and these points do not substitute for the reviewer checklist: they are meant to facilitate discussions which focus on animal welfare.

1) What procedures would be performed on the animals?

2) What is the expected clinical condition of the animals after the procedure?

3) What would be done to relieve pain or improve the welfare of the animal?

4) In your opinion, is the pain category selected by the Investigator appropriate?

5) In your opinion, can additional measures be taken to improve the welfare of the animals? If so, describe the measures.

6) Are the appropriate appendices included?

Request for Continued Approval of Animal Use
Institutional Animal Care and Use Committee
Central Arkansas Veterans Healthcare System

Principal Investigator:

Project Title:

Approval Period:

Approved Species/Strain:

If using animals for breeding only, check here: ☐
Enter number of animals used for breeding purposes:

1. Project Status (Check one):
   - ☐ Project has terminated.
   - ☐ Project is active and animal subjects are being used.
   - ☐ Project is active but animal subjects are currently not being used and will not be used in the future in this Project. Delete Animal Use Approval.
   - ☐ Project is active but animal subjects are currently not being used but will be used in the future.

2. Animal use has been in accord with the approved protocol. ☐ Yes ☐ No
   If item 2 is No, attach an explanation of changes and a new Animal Use form.

3. Changes in animal use are anticipated during the approval period. ☐ Yes ☐ No

I am aware that all research projects using animals must receive prior approval by the Animal Studies Committee, that any change in animal use requires prior approval by the Subcommittee, that continuation of approval requires annual review, that animal use in projects not reviewed and approved must be discontinued, and that a copy of all animal-related matters must be retained by Principal Investigator for three (3) years after the study has terminated. This form, together with any requested additional information, is submitted in compliance with these regulations.

_____ _____
Signature Date

Approved/Disapproved:

_____ _____
(b)(6) Date
Chair/Member, Institutional Animal Care and Use Committee

ANIMAL COMPONENT OF RESEARCH PROTOCOL (ACORP)
Main Body
VERSION 4

See Instructions for Completion of the Animal Component of Research Protocol (ACORP Instructions), for help in completing specific items.

A. **ACORP Status.**

1. Full Name of Principal Investigator(s)►

2. VA Station Name (City) and 3-Digit Station Number►

3. Protocol Title►

4. Animal Species covered by this ACORP►

5. Funding Source(s). Check each source that applies:

►( ) Department of Veterans Affairs.
►( ) US Public Health Service (e.g. NIH).
►( ) Private or Charitable Foundation -- Identify the Foundation:
►( ) University Intramural Funds – Identify the University and Funding Component:
►( ) Private Company – Identify the Company:
►( ) Other – Identify Other Source(s):

6. Related Documentation for IACUC reference.

   a. If this protocol applies to a project that has already been submitted to the R&D Committee for review, identify the project:

      (1) Title of project►

      (2) If approved by the R&D Committee, give the date of approval►

   b. Triennial review. If this protocol is being submitted for triennial *de novo* review, complete the following:

      (1) Identify the studies described in the previously approved ACORP that have already been completed
      ►

      (2) Indicate the numbers of animals of each breed/strain/genotype that have already been used, and adjust the numbers shown in Item I accordingly
      ►

      (3) Describe any study results that have prompted changes to the protocol, and <u>briefly summarize</u> those changes, to guide the reviewers to the details documented in other Items below.
      ►

c. List any other relevant previously approved animal use protocols (copy the lines below as needed for each protocol listed).

(1) Title of other protocol ►
(2) IACUC approval number of other protocol ►
Give the name of the VA station or other institution that approved it, if it was not approved by the IACUC that will review this ACORP ►

7. Indicate the type(s) of animal use covered by this protocol (check all that apply):

►( ) Research
►( ) Teaching or Training
►( ) Testing
►( ) Breeding and colony management only; not for any specific research project
►( ) Holding protocol (as specified by local requirements; not required by VA, PHS, or USDA)
►( ) Other. Please specify►

Proposal Overview

B. **Description of Relevance and Harm/Benefit Analysis.** Using non-technical (lay) language that a senior high school student would understand, briefly describe how this research project is intended to improve the health of people and/or other animals, or otherwise to serve the good of society, and explain how these benefits outweigh the pain or distress that may be caused in the animals that are to be used for this protocol.
►

C. **Experimental Design.**

1. **Lay Summary**. Using non-technical (lay) language that a senior high school student would understand, summarize the conceptual design of the experiment in no more than one or two paragraphs.
►

2. **Complete description of the proposed use of animals.** Use the following outline to detail the proposed use of animals.

a. **Summarize** the design of the experiment in terms of the specific groups of animals to be studied.
►

b. **Justify the group sizes and the total numbers of animals requested.** A power analysis is strongly encouraged; see ACORP instructions.
►

c. **Describe each procedure** to be performed on any animal on this protocol. (Use Appendix 9 to document any of these procedures that involve "departures" from the standards in the *Guide*. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)
►

D. **Species.** Justify the choice of species for this protocol.
►

Personnel

E. **Current qualifications and training.** (For personnel who require further training, plans for additional training will be requested in Item F.)

1. PI

Name►
Animal research experience ►

Qualifications to perform specific procedures

Specific procedure(s) that the PI will perform personally	Experience with each procedure in the species described in this ACORP

2. Other research personnel (copy the lines below for each individual)

Name►
Animal research experience ►

Qualifications to perform specific procedures

Specific procedure(s) that this individual will perform	Experience with each procedure in the species described in this ACORP

3. VMU animal care and veterinary support staff personnel (copy the lines below for each individual)

Name►

Qualifications to perform specific support procedures in the animals on this protocol

Specific support procedure(s) assigned to this individual	Qualifications for performing each support procedure in the species described in this ACORP (e.g., AALAS certification, experience, or completion of special training)

4. For each of the research personnel listed in items 1 and 2 above, enter the most recent completion date for each course

Name of Individual	Working with the VA IACUC	ORD web-based species specific course (Identify the species)	Any other training required locally (Identify the training)

F. **Training to be provided.** List here each procedure in Item E for which anyone is shown as "to be trained", and describe the training. For each procedure, describe the type of training to be provided, and give the name(s), qualifications, and training experience of the person(s) who will provide it. If no further training is required for anyone listed in Item E, enter "N/A"
►

G. **Occupational Health and Safety.**

1. Complete one line in the table below for each of the personnel identified in Item E:

Name	Enrollment in OHSP		Declined optional services	Current on Interactions with OHSP? (yes/no)
	VA program	Equivalent Alternate Program – identify the program		
	( )	( )	( )	
	( )	( )	( )	
	( )	( )	( )	

2. Are there any non-routine OHSP measures that would potentially benefit, or are otherwise required for, personnel participating in or supporting this protocol?

► ( ) Yes. Describe them ►

► ( ) No.

Animals Requested

H. **Animals to be Used.** Complete the following table, listing the animals on separate lines according to any specific features that are required for the study (see ACORP Instructions, for guidance, including specific terminology recommended for the "Health Status" column):

Description (include the species and any other special features not shown elsewhere in this table)	Gender	Age/Size on Receipt	Source (e.g., Name of Vendor, Collaborator, or PI of local breeding colony)	Health Status

I. **Numbers of animals requested.** See ACORP Instructions, for descriptions of the categories and how to itemize the groups of animals.

USDA Category B

Procedures►						
Species / Experimental Group / Procedures(s)	Year 1	Year 2	Year 3	Year 4	Year 5	**Category B TOTAL**

USDA Category C

Procedures►						
Species / Experimental Group / Procedure(s)	Year 1	Year 2	Year 3	Year 4	Year 5	**Category C TOTAL**

USDA Category D

Procedures►						
Species / Experimental Group / Procedure(s)	Year 1	Year 2	Year 3	Year 4	Year 5	**Category D TOTAL**

USDA Category E

Procedures►						
Species / Experimental Group / Procedure(s)	Year 1	Year 2	Year 3	Year 4	Year 5	**Category E TOTAL**

TOTALS over all Categories

Species / Experimental Group /Procedure(s)	Year 1	Year 2	Year 3	Year 4	Year 5	**GRAND TOTAL**

J. **Management of USDA Category D procedures**. Indicate which statement below applies, and provide the information requested.

► ( ) This protocol does NOT include any Category D procedures.

► ( ) This protocol INCLUDES Category D procedures. List each Category D procedure and provide the information requested. (For surgical procedures described in Appendix 5, only identify the procedure(s) and enter "See Appendix 5 for details.)

Procedure	Monitoring (indicate the method(s) to be used, and the frequency and duration of monitoring through post-procedure recovery)	Person(s) responsible for the monitoring	Method(s) by which pain or distress will be alleviated during or after the procedure (include the dose, route, and duration of effect of any agents to be administered)

K. **Justification of Category E procedures.** Indicate which statement below applies, and provide the information requested.

► ( ) This protocol does NOT include any Category E procedures

► ( ) This protocol INCLUDES Category E procedures. Identify each Category E procedure included in this ACORP and justify scientifically why the pain or distress cannot be relieved.
►

Veterinary Care and Husbandry

L. **Veterinary Support**.

1. Identify the laboratory animal veterinarian who is responsible for ensuring that the animals on this protocol receive appropriate veterinary medical care.

   Name►
   Institutional affiliation►
   email contact►

2. Veterinary consultation during the planning of this protocol.

   Name of the laboratory animal veterinarian consulted►
   Date of the veterinary consultation (meeting date, or date of written comments provided by the veterinarian to the PI) ►

M. **Husbandry.** As a reference for the animal husbandry staff, summarize here the husbandry requirements of the animals on this protocol. (Use Appendix 6 to justify the use of any special husbandry and to detail its effects on the animals. Use Appendix 9 to document any aspects of the husbandry that involve "departures" from the standards in the *Guide*. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)

1. Caging needs. Complete the table below to describe the housing that will have to be accommodated by the housing sites for this protocol:

a. Species	b. Type of housing*	c. Number of individuals per housing unit**	d. Is this housing consistent with the *Guide* and USDA regulations? (yes/no***)	e. Estimated maximum number of housing units needed at any one time

*See ACORP Instructions, for guidance on describing the type of housing needed. If animals are to be housed according to a local Standard Operating Procedure (SOP), enter "standard (see SOP)" here, and enter the SOP into the table in Item Y. If the local standard housing is not described in a SOP, enter "standard, see below" in the table and describe the standard housing here:
►

** The *Guide* states that social animals should generally be housed in stable pairs or groups. Provide a justification if any animals will be housed singly (if species is not considered "social", then so note)
►

***Use Appendix 9 to document "departures" from the standards in the *Guide*.

2. Enrichment. Complete the table below to indicate whether "standard" exercise and environmental enrichment will be provided to the animals on this protocol, or whether any special supplements or restrictions will be required (See ACORP Instructions, for more information on enrichment requirements. Use Appendix 9 to document any enrichments requirements that represent "departures" from the standards in the *Guide*.):

a. Species	b. Description of Enrichment*	c. Frequency

*If enrichment will be provided according to a local SOP, enter "standard (see SOP)" and enter the SOP into the table in Item Y. If the local standard enrichment is not described in a SOP, enter "standard, see below", and describe the standard species-specific enrichment here.
►

3. Customized routine husbandry. Check all of the statements below that apply to the animals on this protocol, and provide instructions to the animal husbandry staff with regard to any customized routine husbandry needed.

► ( ) This ACORP INCLUDES genetically modified animals.

List each group of genetically modified animals, and describe for each any expected characteristic clinical signs or abnormal behavior related to the genotype and any customized routine husbandry required to address these. For genetic modifications that will be newly generated on or for this protocol, describe any special attention needed during routine husbandry to monitor for unexpected clinical signs or abnormal behavior that may require customized routine husbandry.
►

► ( ) Devices that extend chronically through the skin WILL be implanted into some or all animals on this protocol. Describe any customized routine husbandry to be provided by animal husbandry staff to minimize the chances of chronic infection where the device(s) penetrate the skin.
►

► ( ) Some or all of the animals on this protocol WILL require other customized routine husbandry by the animal husbandry staff, beyond what has been described above. Describe the special husbandry needed.
►

► ( ) This ACORP does NOT include use of any animals that will require customized routine husbandry.

N. **Housing Sites**. Document in the tables below each location where animals on this protocol may be housed.

► ( ) Housing on VA property. Identify each location on VA property where animals on this protocol will be housed, and indicate whether or not each location is inside the VMU.

Building	Room number	Inside of VMU?	
		Yes	No
		( )	( )
		( )	( )
		( )	( )

► ( ) Housing in non-VA facilities. Identify each location not on VA property where animals on this protocol **will** be housed, and provide the information requested in the table.

Name of Non-VA Facility	Is this facility accredited by AAALAC?		Building	Room Number
	Yes -- enter status*	No**		
	( )	( )**		
	( )	( )**		
	( )	( )**		

*See ACORP Instructions, for a list of AAALAC accreditation status options.

**For any facility listed above that is not accredited by AAALAC, attach documentation that a waiver has been granted by the CRADO.

Special Features

O. **Antibody Production.** Will any of animals on this protocol be used for the production of antibodies?

► ( ) Some or all of the animals on this protocol WILL be used in the production and harvesting of antibodies. Check "Appendix 2" in Item Y, below, and complete and attach Appendix 2, "Antibody Production".

► ( ) NO animals on this protocol will be used in the production and harvesting of antibodies.

P. **Biosafety.** Will any substances (other than those used in routine husbandry or veterinary care) be administered to the animals on this protocol?

► ( ) This protocol INVOLVES administration of substances to the animals other than those used in routine husbandry and veterinary care. Check "Appendix 3" in Item Y, below, and complete and attach Appendix 3, "Biosafety".

► ( ) This protocol does NOT involve administration of any substances to the animals other than those used in routine husbandry and veterinary care.

Q. **Locations of procedures.** Complete the table below, listing the location(s), inside or outside of the animal facility, for each of the procedures to be performed on animals on this protocol.

Procedure	Surgical?		Bldg/Room Number	Requires transport through non-research areas?	
	Yes	No		Yes – describe method of discreet transport	No
	( )	( )		( )	( )
	( )	( )		( )	( )
	( )	( )		( )	( )
	( )	( )		( )	( )

R. **Body Fluid, Tissue, and Device Collection.** List each body fluid, tissue, or device to be collected, and complete the table below to indicate the nature of the collection. Check the relevant Appendices in Item Y, below, and complete and attach them, as shown in the column headings.

Body Fluid, Tissue, or Device to be Collected	Collected AFTER Euthanasia	Collected BEFORE Euthanasia		
		Blood Collection Associated with Antibody Production (Appendix 2, "Antibody Production")	Collected as Part of a Surgical Procedure (Appendix 5, "Surgery")	Other Collection from Live Animals (Appendix 4, "Antemortem Specimen Collection")
	( )	( )	( )	( )
	( )	( )	( )	( )
	( )	( )	( )	( )

S. **Surgery.** Does this protocol include any surgical procedure(s)?

► ( ) Surgery WILL BE PERFORMED on some or all animals on this protocol. Check "Appendix 5" in Item Y, below, and complete and attach Appendix 5, "Surgery".

► ( ) NO animals on this protocol will undergo surgery.

T. **Endpoint criteria.** Describe the criteria that **will** be used to determine when animals will be removed from the protocol or euthanatized to prevent suffering. (Use Appendix 9 to document any "departures" from the standards in the *Guide* represented by these criteria. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)
►

U. **Termination or removal from the protocol**. Complete each of the following that applies:

► ( ) Some or all animals **will** NOT be euthanatized on this protocol. Describe the disposition of these animals. (Use Appendix 9 to document any "departures" from the standards in the *Guide* represented by these methods of disposition. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)
►

► ( ) Some or all animals MAY be euthanatized as part of the planned studies. Complete the table below to describe the exact method(s) of euthanasia to be used. (Use Appendix 9 to document any departures from the standards in the *Guide* represented by these methods. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)

Check each method that may be used on this protocol	Method of Euthanasia	Species	AVMA Classification		
			Acceptable	Conditionally Acceptable	Unacceptable
( )	CO_2 from a compressed gas tank Duration of exposure after apparent clinical death► Method for verifying death► Secondary physical method►		( )	( )	( )
( )	Anesthetic overdose Agent► Dose► Route of administration►		( )	( )	( )
( )	Decapitation under anesthesia Agent► Dose► Route of administration►		( )	( )	( )

( )	Exsanguination under anesthesia Agent► Dose► Route of administration►		( )	( )	( )
( )	Other (Describe) ►		( )	( )	( )
( )	Other (Describe) ►		( )	( )	( )

1. For each of the methods above that is designated as "Conditionally Acceptable" by the AVMA, describe how the conditions for acceptability will be met:
   ►

2. For each of the methods above that is designated as "Unacceptable" by the AVMA, give the scientific reason(s) that justify this deviation from the AVMA Guidelines:
   ►

3. Identify all research personnel who will perform euthanasia on animals on this protocol and describe their training and experience with the methods of euthanasia they are to use in the species indicated.
   ►

4. Instructions for the animal care staff in case an animal is found dead.
   a. Describe the disposition of the carcass, including any special safety instructions. If disposition is to be handled according to a local SOP, enter "according to local SOP" and enter the information requested about the SOP into the table in Item Y.
      ►

   b. Describe how the PI's staff should be contacted.
      ► ( ) Please contact a member of the PI's staff immediately. (Copy the lines below for each individual who may be contacted)
      Name►
      Contact Information►

      ► ( ) There is no need to contact the PI's staff immediately. Describe the routine notification procedures that will be followed. If the routine notification procedures are described in a local SOP, enter "according to local SOP" and enter the information requested about the SOP into the table in Item Y.
      ►

V. **Special Procedures.** List each special procedure (including special husbandry and other special procedures) that is a part of this protocol, and specify where the details of the procedure are documented. See ACORP Instructions, for examples.

Name of Procedure	Identify Where the Details of the Procedure are Documented		
	SOP (title or ID number)*	Other Items in this ACORP -- specify the Item letter(s)	Appendix 6
		Items:	( )**
		Items:	( )**
		Items:	( )**
		Items:	( )**

*If any special procedure is detailed in a SOP, identify the SOP and enter the information requested about the SOP in the table in Item Y.

**If any special procedure is detailed in Appendix 6, check "Appendix 6" in Item Y, below, and complete and attach Appendix 6.

(Use Appendix 9 to document any "departures" from the standards in the *Guide* represented by these procedures. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)

W. **Consideration of Alternatives and Prevention of Unnecessary Duplication.** These are important to minimizing the harm/benefit to be derived from the work.

1. Document the database searches conducted.
   List each of the potentially painful or distressing procedures included in this protocol.
   ►

   Then complete the table below to document how the database search(es) you conduct to answer Items W.2 through W.5 below address(es) each of the potentially painful or distressing procedures.

Name of the database	Date of search	Period of years	Potentially painful or	Key words and/or search strategy used	Indicate which mandate each search addressed

		covered by the search	distressing procedures addressed		Replacement of animals (item W.2)	Reduction in numbers of animals used (item W.3)	Refinement to minimize pain or distress (item W.4)	Lack of unnecessary duplication (item W.5)
					( )	( )	( )	( )
					( )	( )	( )	( )
					( )	( )	( )	( )
					( )	( )	( )	( )

2. Replacement. Describe the replacements that have been incorporated into this work, the replacements that have been considered but cannot be used, and the reason(s) that further replacements are not acceptable.
   ►

3. Reduction. Describe how the number of animals to be used has been minimized in this protocol and explain why further reduction would disproportionately compromise the value of the data.
   ►

4. Refinement. Describe the refinements that have been incorporated into this work and explain why no further refinements are feasible.
   ►

5. Describe how it was determined that the proposed work does not unnecessarily duplicate work already documented in the literature.
   ►

X. **Other Regulatory Considerations**.

1. **Controlled drugs**.

   a. Complete the table below for each drug that is used in animals on this protocol and that is classified as a controlled substance by the DEA. See ACORP Instructions, for explanations about the information requested.

Controlled substances	Storage		Personnel Authorized to Access	Location for Use		Procurement	
	Double-locked	Not Double-locked*		VA Property	Not on VA Property	VA Phar-macy	Non-VA
	( )	( )*		( )	( )	( )	( )
	( )	( )*		( )	( )	( )	( )

	( )	( )*		( )	( )	( )	( )

*For any controlled substance that will NOT be stored under double lock, with limited access, describe how it will be stored, and explain why this is necessary.
►

b. Check each statement below that applies, to confirm that all controlled substances used on this protocol **will** be procured according to VA pharmacy policies:

► ( ) Some controlled substances will used on VA property, and all of these will be obtained through the local VA pharmacy.

► ( ) Some controlled substances will not be obtained through the local VA pharmacy, but none of these will be used on VA property. See the ACORP Instructions, for further information.

► ( ) Other. Explain►

2. **Human patient care equipment or procedural areas**. Does this protocol involve use of any human patient care equipment or procedural areas?

► ( ) Yes, some human patient care equipment or procedural area(s) will be used for the animal studies on this protocol. Check "Appendix 7" in Item Y, below, and complete and attach Appendix 7, "Use of Patient Procedural Areas for Animal Studies".

► ( ) No human patient care equipment or procedural areas **will** be used for the animal studies on this protocol.

3. **Explosive agents**. Does this protocol involve use of any explosive agent?

► ( ) Yes, some explosive agent(s) will be used on this protocol. Check "Appendix 3" and "Appendix 8" in Item Y, below, and complete and attach Appendix 8, "Use of Explosive Agent(s) within the Animal Facility or in Animals", as well as Appendix 3, "Biosafety".

► ( ) No explosive agent(s) will be used as part of this protocol.

Y. **Summary of Attachments.** To assist the reviewers, summarize here which of the following apply to this ACORP.

Appendices. Indicate which of the Appendices are required and have been completed and attached to this protocol. Do not check off or attach any appendices that are not applicable to this ACORP.

► ( ) Appendix 1, "Additional Local Information"
► ( ) Appendix 2, "Antibody Production"
► ( ) Appendix 3, "Biosafety"
► ( ) Appendix 4, "Ante-mortem Specimen Collection"
► ( ) Appendix 5, "Surgery"
► ( ) Appendix 6, "Special Husbandry and Procedures"
► ( ) Appendix 7, "Use of Patient Care Equipment or Areas for Animal Studies"
► ( ) Appendix 8, "Use of Explosive Agent(s) within the VMU or in Animals"

► ( ) Appendix 9, "Departures from "Must" and "Should" Standards in the *Guide*"

Standard Operating Procedures (SOPs). List in the table below, each of the SOPs referred to in this protocol, providing the information requested for each one. The approved SOPs must be included when the approved ACORP and Appendices are submitted for Just-in-Time processing before release of VA funding support.

Item	SOP		Approval Date
	Title	ID	

Z. **Certifications.** Signatures are required here for any ACORP that is to be submitted to VA Central Office in support of an application for VA funding. Include the typed names and dated signatures as shown below for the Main Body of the ACORP and for each of the Appendices that apply to this protocol. Do NOT include signatures for, or attach, any appendices that do NOT apply.

1. **Main Body of the ACORP.**

   a. **Certification by Principal Investigator(s):**

   I certify that, to the best of my knowledge, the information provided in this ACORP is complete and accurate, and the work will be performed as described here and approved by the IACUC. I understand that IACUC approval must be renewed at least annually, and that the IACUC must perform a complete *de novo* review of the protocol at least every three years, if work is to continue without interruption. I understand further that I am responsible for providing the information required by the IACUC for these annual and triennial reviews, allowing sufficient time for the IACUC to perform the reviews before the renewal dates, and that I may be required to complete a newer version of the ACORP that requests additional information, at the time of each triennial review.

   I understand that further IACUC approval must be secured before any of the following may be implemented:

   - Use of additional animal species, numbers of animals, or numbers of procedures performed on individual animals;
   - Changing any procedure in any way that has the potential to increase the pain/distress category to which the animals should be assigned, or that might otherwise be considered a significant change from the approved protocol;
   - Performing any additional procedures not already described in this ACORP;
   - Use of any of these animals on other protocols, or by other investigators.

I further certify that:

- No personnel will perform any animal procedures on this protocol until the IACUC has confirmed that they are adequately trained and qualified, enrolled in an acceptable Occupational Health and Safety Program, and meet all other criteria required by the IACUC. When new or additional personnel are to work with the animals on this protocol, I will provide this information to the IACUC for confirmation before they begin work;
- I will provide my after-hours contact information to the animal care staff for use in case of emergency.

Name(s) of Principal Investigator(s)	Signature	Date

b. **Certification by IACUC Officials.**

We certify that:

- We, with the IACUC, have evaluated the care and use of animals described on this ACORP, in accordance with the provisions of the USDA Animal Welfare Act Regulations and Standards, PHS Policy, the *Guide for the Care and Use of Laboratory Animals*, and VA Policy;
- The IACUC has determined that the care and use of animals described in this ACORP is appropriate, and has therefore approved the protocol;
- The full text of any minority opinions is documented here as indicated below:

► ( ) No minority opinions were submitted by any IACUC participant for inclusion.

► ( ) Minority opinions submitted by IACUC participants are copied here
►

► ( ) Minority opinions submitted by IACUC participants are attached on separate pages labeled "IACUC Minority Opinion" (indicate the number of pages►)

Name of Attending Veterinarian (VMO or VMC)	Signature	Date
Name of IACUC Chair	Signature	Date

2. **Appendix 2. Antibody Production.** No signatures required.

3. **Appendix 3. Biosafety.**

   a. **Certification by PI(s) and IACUC Officials:**

   We certify that:

   - Before any animal experiments involving hazardous agents (identified in Item 10.a of Appendix 3) are performed, SOPs designed to protect all research and animal facility staff as well as non-study animals will be developed and approved by the appropriate VA or affiliated university safety committee and by the IACUC;

   - All personnel who might be exposed to the hazardous agents (identified in Item 10.a of Appendix 3) will be informed of possible risks and will be properly trained ahead of time to follow the SOPs to minimize the risks of exposure.

Name(s) of Principal Investigator(s)	Signature(s)	Date
Name of Institutional Veterinarian	Signature	Date
Name of IACUC Chair	Signature	Date

   b. **Certification by Biosafety Official.** I certify that:

   - Each agent to be administered to animals on this protocol has been properly identified in Item 1 of Appendix 3 as to whether it is "toxic", "infectious", "biological", or "contains recombinant nucleic acid";

   - The use of each of the agents thus identified as "toxic", "infectious", or "biological", or "contains recombinant nucleic acid" is further documented as required in Items 4, 5, 6, and/or 8, as applicable, and in Item 10.a of Appendix 3;

   - The use of each of these agents has been approved by the appropriate committee(s) or official(s), as shown in Item 10.a of Appendix 3.

Name of the Biosafety Officer, or of the Chair of the Research Safety or Biosafety Committee	Signature	Date

c. **Certification by Radiation Safety Official.** I certify that:

- Each agent to be administered to animals on this protocol has been properly identified in Item 1 of Appendix 3 as to whether it is "radioactive";
- The use of each radioactive agent is further documented as required in Items 7 and 10.a of Appendix 3;
- The use of each radioactive agent has been approved by the appropriate committee(s), as shown in Item 10.a of Appendix 3.

Name of the Radiation Safety Officer, or of the Chair of the Radiation Safety or Isotope Committee	Signature	Date

4. **Appendix 4. Ante-mortem Specimen Collection.** No signatures required.

5. **Appendix 5. Surgery. Certification by the PI(s).** I certify that:

- To the best of my knowledge, the information provided in Appendix 5 of this ACORP is complete and accurate;
- The surgical procedures will be performed and the post-operative care (including administration of post-operative analgesics) will be provided as described;
- The spaces where any survival surgical procedures will be performed (listed in Item 4 of Appendix 5) are suitable for sterile/aseptic surgery;
- The names and contact information for research personnel to notify or consult in case of emergencies will be provided to the VMU supervisor and veterinary staff;
- Post-operative medical records will be maintained and readily available for the veterinary staff and the IACUC to refer to, and will include the following:

- Identification of each animal such that care for individual animals can be documented.
- Daily postoperative medical records for each animal, that include documentation of daily evaluation of overall health and descriptions of any complications noted, treatments provided, and removal of devices such as sutures, staples, or wound clips;
- Documentation of the administration of all medications and treatments given to the animals, including those given to reduce pain or stress.
- Daily records covering at least the period defined as "post-operative" by local policy.
- The signature or initials of the person making each entry.

Name(s) of Principal Investigator(s)	Signature(s)	Date

6. **Appendix 6. Special Husbandry and Procedures.** No signatures required.

7. **Appendix 7. Use of Patient Care Equipment or Areas for Animal Studies.**

   a. **Certification by the Principal Investigator(s).** I certify that, to the best of my knowledge, the information provided in Appendix 7 of this ACORP is complete and accurate, and the use of patient care equipment or areas for these animal studies will be as described.

Name(s) of Principal Investigator(s)	Signature(s)	Date

   b. **Certification by the officials responsible for the use of any human patient care equipment in animal procedural areas.** Each of the following must sign to indicate that they have granted approval for the human patient care equipment to be moved to the VMU or other animal procedural area to be used on animals and then returned to the human patient care area, as described in Appendix 7. Leave this section blank, if not applicable.

Name of IACUC Chair	Signature	Date

Name of the Manager of the Human Patient Care Equipment	Signature	Date

c. **Certification by the officials responsible for the use of the equipment in human patient care areas for these animal studies.** Each of the following must sign to indicate that they have granted approval for animals to be transported into human patient care areas for study or treatment, as described in Appendix 7. Leave this section blank, if not applicable.

Name of IACUC Chair	Signature	Date
Name of Attending Veterinarian (VMO or VMC)	Signature	Date
Name of the Chair of the Clinical Executive Board, or the Service Chief responsible for the Patient Care Area and Equipment	Signature	Date
Name of ACOS for R&D	Signature	Date
Name of Chief of Staff	Signature	Date
Name of Director or CEO of the Facility (Hospital or Clinic)	Signature	Date

8. **Appendix 8. Use of Explosive Agent(s) within the Animal Facility or in Animals.**

a. **Certification by the Principal Investigator(s).**

I certify that, to the best of my knowledge, the information provided in Appendix 8 of this Animal Component of Research Protocol (ACORP) is complete and accurate, and the use of explosive agents in these animal studies will be as described.

I further certify that:

- Procedures involving explosive agent(s) will be performed within a properly operating, ventilated safety hood;
- All electrical equipment operating when explosive agent(s) are in use will be positioned and powered outside of the hood;
- Once the seal is broken on any containers of explosive agents, they will be kept in a safety hood throughout use, stored in an explosion-proof refrigerator or other approved storage area, and discarded properly once completely emptied;
- Proper procedures will be used for safe and appropriate disposal of items (including animal carcasses) that may contain residual traces of the explosive agent(s).

Name(s) of Principal Investigator(s)	Signature(s)	Date

b. **Certification by the officials responsible for overseeing the use of explosive agent(s) in this protocol.** Each of the following must sign to verify that they or the committee they represent have granted approval.

Name of IACUC Chair	Signature	Date
Name of Attending Veterinarian (VMO or VMC)	Signature	Date
Name of Safety/Biosafety Officer for the Facility	Signature	Date
Name of ACOS for R&D	Signature	Date

Name of VISN Regional Safety Officer	Signature	Date

9. **Departures from "Must" and "Should" Standards in the *Guide*.** No signatures required.