Program Description
Animal Care and Use Program

Central Virginia VA Health Care Systems
Hunter Holmes McGuire VA Medical Center

VA-061

Research Service 151
1201 Broad Rock Blvd
Richmond, VA 23249
June 2020

For
AAALAC International

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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.

Hunter Holmes McGuire Veterans Affairs Medical Center- Animal Research Facility

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.

The mission of the VA Medical Center includes the provision for research and educational activities in all disciplines. Our goal is to develop and communicate new knowledge, to improve the quality of life and promote the best use of human and environmental resources. We recognize that the humane use of animals is essential to medical research and education.

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.

The McGuire VAMC is a federal research facility with an Office of Laboratory Animal Welfare Assurance. We use the standards of the Guide and PHS Policy for all animals in the Animal Research Facility and the Animal Welfare Act regulations for all 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 publicly available, provide the titles and names; for individuals, whose information is not publicly available, you may provide titles only.), and degree (if applicable) of everyone 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 responsible officials in our medical center are as follows: Medical Center Director/Institutional Official (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.

- (b)(6)
- (b)(6)
- (b)(6)
- (b)(6)
- (b)(6)

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.

We currently have 39 active animal protocols and 23 Principal investigators. We have six Principal investigators with fourteen protocols in the cardiology field, six investigators with six protocols studying lipid/cholesterol metabolism, , three investigators with six protocols in the neurology field of study, one investigator with onea protocol in traumatic brain injury, four investigators with eight protocols in oncology, two investigators with two protocol studying liver toxicity and one investigator with two rodent health surveillance protocols for the Animal Research Facility

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

We receive grant monies from NIH funding sources, VA Merit Grants and private companies.

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.

We have no other animal care units. We utilize one laboratory outside of the vivarium within the same building where rodents are housed for 3-7 days in caging. They are housed in specially designed boxes that provide light/dark cycles on timers, appropriate ventilation and temperature controls. This laboratory and associated protocol are reviewed by the same IACUC.

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.

We do not use any contract facilities

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

Investigators receiving VA Merit Grant funds may apply for an off site waiver and house animals purchased by VA money at our affiliate institution, Virginia Commonwealth University (VCU). VCU is AAALAC accredited and maintains its own IACUC which reviews all protocols and procedures conducted at that facility.

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.

The Institutional official attends at least two IACUC meetings per year to discuss the Semi-Annual Program review and Semi-Annual Facility Inspections. If the IO is not available to meet with during the convened IACUC meeting, a separate meeting is scheduled involving the IACUC chairman, veterinarian and additional IACUC voting member to discuss the Semi-Annual Program review. The Institutional Official is also available for meetings with the Veterinarian, IACUC Chairman or ACOS, if needed.

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, is employed as the consultant veterinarian with the McGuire VAMC Animal Research Facility. He visits at least weekly for 1-2 hours to review charts, to monitor the animal's physical and psychological well-being and to ensure the adequacy of animal husbandry in the facility. Additionally, he pre-reviews all animal related protocols prior to initial IACUC submission and serves on the IACUC as a voting member to review and approve all protocols. He advises and monitors all handling/restraint practices, anesthesia/analgesia protocols, post-surgical recovery practices and euthanasia.

He also plans and advises with all disease surveillance, prevention, diagnosis and treatment programs. (b)(6) is available 24 hours a day via cell phone for emergencies and veterinary questions.

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) DVM serves as (b)(6) alternate when (b)(6) is unavailable. She would take over all the responsibilities listed above in Dr. (b)(6) absence (b)(6) received her DVM from (b)(6) and holds a current License to practice as a veterinarian from the Commonwealth of Virginia. (b)(6) is a research associate with the (b)(6) (b)(6) (b)(6)

(b)(6)

(b)(6) is the Animal Health Technician who coordinates with the Attending Veterinarian and is directly responsible for carrying out veterinary orders and communicating with the Veterinarian. (b)(6) is the on site veterinary professional who reports to the VMU Supervisor. A document has been established that is signed by AV and LVT and reviewed/approved by the IACUC detailing procedures the LVT is approved to conduct with and without prior veterinarian approval.

(b)(6) is the Facility Surgical Technician and can assist with carrying out Veterinarian or LVT orders . (b)(6) can perform many surgical and/or medical procedures, as required by the veterinary staff.

(b)(6) is the VMU Supervisor and can assist with carrying out Veterinarian or LVT orders. (b)(6) communicates directly with (b)(6) and (b)(6)

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.

An MOU is established between the affiliate university, Virginia Commonwealth

University, that covers all VA sponsored research being conducted at the university. This MOU charges VCU with notifying McGuire VAMC with any deficiencies or reportable incidents associated with VA sponsored research at their facility. This document is reviewed and approved annually by the IACUC.

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.

Prior to approval, the IACUC requires all personnel working with animals in a research setting to complete the online training. The training certificates are maintained by the IACUC Coordinator and noted in the IACUC meeting minutes. The Animal Health Technician provides Post Approval monitoring of training by observing surgeries and procedures and reporting any deficiencies back to the VMU Supervisor. The Animal Health Technician, VMU Supervisor and/or Veterinarian can conduct hands on training as needed. This training is documented in the IACUC meeting minutes.

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) and is the Attending Veterinarian. (b)(6) voting member of the IACUC and he receives training through AALAS online courses, CITI Program online training modules, scientific journals and conferences. He attended the (b)(6) (b)(6) He receives continuing education by attending the National AALAS Meeting annually and attends the Veterinary Medical Officer's seminar given by the CVMO while at the meeting. He maintains a license to practice veterinary medicine in the state of Virginia and (b)(6)

(b)(6) has her (b)(6)

(b)(6) and is the VMU Supervisor. She has (b)(6) (b)(6) She earns continuing education credits throughout the year to maintain the CMAR and RLATG certifications through AALAS learning library, local AALAS Branch meetings/seminars, PRIM&R IACUC Conferences and attending the (b)(6) (b)(6) (b)(6) She attended the (b)(6) (b)(6) (b)(6) Additionally, she takes all species modules in the CITI online training program.

(b)(6) is licensed as a veterinary technician in the state of Virginia. (b)(6) (b)(6) She earns continuing education credits throughout the year to maintain the RLATG and LVT certifications through AALAS learning library, local AALAS branch meetings and attending Veterinary technician seminars and conferences. Additionally, she takes all species modules in the CITI online training program.

(b)(6) has her (b)(6) and (b)(6) (b)(6) She is available to conduct a wide variety of surgical procedures for approved protocols as well as emergency surgeries as approved by the Veterinarian. She earns continuing education credits through AALAS learning library, local AALAS branch meetings, specialized training conferences and attending the National AALAS meeting to earn continuing education credits to maintain the RLATG. Additionally, she takes all species modules on the CITI online training program. She attended (b)(6) (b)(6) (b)(6)

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

1) Indicate the number of animal care personnel.

2 full time, two part time (20-30 hours per week) and one relief (less than 8 hours/week)

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.

Full time Animal Health Technician has more than (b)(6)

(b)(6)

(b)(6) She completes training through CITI Program online every three years and attends the annual animal handler training course conducted by the VMU Supervisor for continuing education. She is registered through Employee Health as an animal handler. She provides oversight of the animal caretakers and revises daily duties/responsibilities as needed. She helps with animal husbandry when needed and is available for veterinary care. She attends National AALAS Meeting, PRIM&R IACUC conference and other LVT specific continuing education seminars throughout the year.

Full Time animal caretaker has more than (b)(6)

(b)(6)

She completes training through CITI program online and is (b)(6)

(b)(6) She has reviewed the Animal facility standard operating procedures and is registered through Employee Health as an animal handler.

Part Time animal caretaker has greater than (b)(6)

(b)(6) She completes training through CITI program online every three years and attends the annual animal handler training course conducted by the VMU Supervisor for continuing education. She reviews the Animal facility standard operating procedures and receives frequent hands on training. She is registered through Employee health as an animal handler.

Part time Surgical Technician has more than (b)(6)

(b)(6) She has her (b)(6)

(b)(6) She completed training through CITI Program online training every three years and attends the annual animal handler training conducted by the VMU Supervisor for continuing education. She is registered through Employee Health as an animal handler

Relief Caretaker has greater than (b)(6)

(b)(6) She completes CITI training every three years and attends the annual animal handler training course conducted by the VMU Supervisor for continuing education. She is registered through Employee health as an animal handler. She works 2-8 hours every week.

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.

All research personnel involved in animal procedures must complete the species-specific modules in the CITI Program training course prior to beginning the study and every three years thereafter. The CITI program site administrator maintains records of training to ensure everyone is up to date. Additionally, the investigator must describe to the IACUC how each researcher will be trained in the specific procedures involved in the animal component of the research protocol. The VMU supervisor and/or the Animal Health Technician observe the procedures initially and randomly throughout the course of the study and they are both available, along with the Veterinarian, to provide training in specific procedures if necessary. Each laboratory is given a current copy of the Guide for the Care and Use of Laboratory Animals. The VMU Supervisor conducts annual training on safe operating procedures using animals.

a) Briefly describe the content of any required training.

All researchers involved in animal procedures are required to take "Working with the IACUC" which includes modules on federal mandates, alternatives, USDA Pain/Distress categories, surgery, antibody production, occupational safety, housing social animals, dog exercise, prolonged restraint, euthanasia, making changes to your approved protocol and reporting misuse/mistreatment or noncompliance.
All research personnel must take the species-specific module for their protocol. These modules discuss the research mandates/occupational health issues, alternatives, housing standards, acclimation/quarantine standards, detecting pain/distress, injections, blood collections, surgery, supportive care and euthanasia specific to the species.
All research personnel using rodents must take an additional course "Post Procedural Care of Rodents" which details minimizing pain/distress, minimizing sources of non-experimental variation, monitoring for pain/distress, detecting pain/distress, physical exam for clinical condition, body weight, fluid balance, and body temperature, alleviation of pain/distress and documentation of post-procedure care.
These courses are required prior to initiation of protocol and every three years thereafter.
Training is conducted annually by the VMU Supervisor detailing specific rules/guidelines pertinent to the Richmond Animal facility.
Transportation, procurement, quarantine, identification, housing and husbandry guidelines are discussed.

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

The IACUC will not approve a protocol until all listed personnel have completed the required training courses. If an investigator submits an amendment requesting additional personnel, this amendment is not administratively approved until the completion of these courses. Therefore, work cannot commence until the training requirements are met.

c) Describe continuing education opportunities offered.

The CITI program courses must be completed every three years. The AALAS Library is offered to all personnel as continuing education. Everyone is encouraged to take the AALAS certification examinations for continuing education. Additionally, the VMU Supervisor provides annual animal handler/safety training for continuing education.

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]

The IACUC determines if the amount of training is sufficient for personnel to perform the surgical procedure. Investigators are required to list their surgical experience as well as the experience of their technical staff on the IACUC protocol form (ACORP). Investigators are responsible for training all members of their staff. The required CITI program courses cover certain species specific surgical issues. Additional training by experienced personnel and/or observation and assistance by the consultant veterinarian is available at all times.

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

Investigators are required to list their training and experience with delivering anesthesia agents on the IACUC protocol form (ACORP). If the IACUC determines the experience is sufficient, no further training is given. If it is determined more training is needed, then additional training is given by hands on experience with trained personnel, anesthesia guides written by veterinarians and/or observation of the procedures by the consultant veterinarian. Investigators are responsible for the training of their technical staff. All personnel must complete an Animal Handler Competency form that

includes an addendum that outlines the properties and side effects of all common anesthetic and analgesic agents. This form is signed by each person and their supervisor/investigator.

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

Experience in euthanasia procedures are listed by the investigators on their IACUC protocol form (ACORP) and is verified by the investigator on the Animal Training competency form. The IACUC reviews the experience and decides if the experience is sufficient. If it is determined that more training is needed, then the consultant veterinarian assists and observes the procedure until satisfied and reports back to the IACUC. Methods used are from the most current AVMA Guidelines for the Euthanasia of Animals unless scientifically justified by the investigator and approved by the IACUC. The CITI program training courses discuss appropriate euthanasia methods for each species. The Animal Handler Competency form also requires acknowledgment of experience with the euthanasia procedures and is signed by the employee and 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).

The Employee Health Department at the McGuire VAMC conducts the animal handler physical examinations, maintains handler's records and treats all injuries. The Employee Health Department is staffed by qualified clinicians and nurses. The IACUC requires all researchers involved in animal procedures to complete the animal handler physical examination prior to approval. All chemicals/potential hazards are initially reviewed and continually monitored by the Subcommittee on Research Safety (SRS) and Institutional Biosafety Committee (IBC). The Radiation Safety Office monitors all studies involving radiation. The Facility Safety Office (Industrial Hygienist and Safety Officer) along with the Research Safety Coordinator monitor ergonomics, proper

sharps disposal/safety and chemical hazards. All injuries are reported to the Employee Health, Facility Safety Office, and Research Safety Coordinator and are reviewed by the SRS. All facilities and personnel are located at the McGuire VAMC main hospital.

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.].

When an investigator proposes a study involving hazardous materials, professionals knowledgeable in the requirements necessary to handle the specific hazard(s) are consulted. The investigator then specifies in his written protocol the level of safety which will be required to handle the materials, care for the affected animals and how to provide a safe working environment for all personnel involved. A detailed outline of the protocol and safety measures that must be followed is given to all personnel involved in the project. These projects must be reviewed and approved by the IACUC, SRS, IBC (if needed) and subsequently the Research and Development Committee before being initiated.

Each employee involved in such studies undergoes special training by his or her supervisor to ensure his/her understanding of hazards involved, safety measures necessary for the protection of self and environment, emergency procedures to be implemented and monitoring systems to be employed. It is the responsibility of the investigator to orient and train his laboratory staff in occupational hazards. We have an active Research Laboratory Safety program that complies with the laboratory standards established by OSHA. Employees attend a mandatory annual safety class. Class attendance is documented. A CITI training module is available in lieu of in person Safety training. The Research Safety Manual is updated annually and available online at all times. Animal Research Facility personnel receive on-the-job training and education related to personal hygiene, zoonosis, prevention of cross-contamination, and occupational hazards. The AALAS Learning Library, VAMC TMS, and CITI Program online training are used for continuing education on these subjects. Employees are given thorough instruction in proper animal handling and use of personal protective equipment to minimize number of animal bites and scratches. The Animal Research Facility has acquired two HEPA filtered vacuum cleaners to minimize employee exposure to animal hair and dander during pre-surgical animal hair removal.

All rodents are housed in individually ventilated caging which is sealed to

prevent allergen release. The exhaust air is HEPA filtered before being directly exhausted in to the hospital HVAC ducting.
There is a HEPA filtered cage change station in every animal room that offers ISO 4 protection for the animals while protecting the caretakers from allergens during cage changes. Additionally, a HEPA filtered cage dump station is located in the dirty cage room to protect caretakers from allergens when dumping soiled rodent bedding.
Veterans Affairs ORD has issued a Handbook 1200.07 appendix C entitled Occupational Health and Safety for Research Personnel with Animal Contact. This has been given to every laboratory using animals and is also available online at www.citiprogram.org The IACUC is working closely with the Employee Health physician on documenting employee physicals, tests, vaccinations offered, and workers' right to know statements and has implemented a screening survey for animal handlers to identify potential allergy problems, etc. This survey is maintained by Employee Health and is incorporated as part of the Occupational Health and Safety program. All accidents are to be reported immediately to the supervisor and referred to Employee Health service who decides what treatment is necessary.
It is the responsibility of the investigator to orient and train his laboratory staff in occupational hazards.
A health program that especially applies to personnel potentially exposed to hazardous agents is carried out on a case-by-case basis. At present, we have limited use of such agents. The Industrial Hygienist monitors Research employees who work with hazardous agents to ensure that Permissible Exposure Limits set by OSHA are not exceeded.
The Non affiliated and non scientific member of the IACUC are advised of the hazards prior to entering the animal facility and are both offered the opportunity to enroll in Occupational Health and Safety.
A notice is placed at the main entrance of the Animal Facility stating the hazards associated with entering the facility and contact numbers for Employee Health.

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

The Subcommittee for Research Safety (SRS) and Institutional Biosafety committee reviews each protocol annually for changes in work related hazards (chemical, biological, recombinant DNA, animal, radiation, etc.).

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]

The institution uses the Department of Labor's "Employee's Compensation Operations & Management Portal" (ECOMP) to log, track and review all

injuries and incidents that occur on site. The employee complets and OSHA 301 form and this is reviewed by the supervisor, Facility Safety office, Employee Health and Research Safety coordinator. All injuries in Research are logged and reviewed by the SRS.

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 personnel involved in animal research (caretakers, investigators, technicians, veterinarians) must complete the animal handler physical examination through Employee Health. They complete a questionnaire that includes information regarding their allergies, vaccination history and work history. A complete physical is conducted and recorded with the IACUC. All personnel involved in animal research are required to complete this examination. Personnel who are exempt are hospital employees who may enter the facility periodically for maintenance or equipment failures (physical plant employees, electricians, etc.). However, all employees are notified of their opportunity to enroll in this program and notified of the risks involved with entering the animal facility.

b) Describe provisions for allowing an individual to decline participation in all or parts of the medical evaluation and preventive medicine programs (if applicable). Provide an estimate (percentage) of personnel associated with the animal care and use program that have declined participation in the medical evaluation program.

We do not allow anyone to work with animals that have not completed the medical evaluation. We have 100% participation in the preventative medicine program with zero animal handlers declining this evaluation.

c) Describe provisions for assuring confidentiality of medical information.

The medical questionnaire is maintained in the files of Employee Health and only a signed cover sheet is returned to the IACUC coordinator. If an injury occurs, all efforts are made to redact personnel identifiers in the committee minutes and in discussions.

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

At each entrance of the animal facility, the right to know statement detailing the risks involved with entering the facility is clearly posted. Signs are also posted at each entrance listing specific risk factors and what to do in the event of an emergency.

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 medical evaluation starts with a questionnaire that includes work history, species to be handled, medical history involving allergies or animal injuries, current medications, ongoing medical problems, current allergies and vaccination history. The physical exam includes bloodwork and general physical exam. All personnel receive an initial PPD and are offered the opportunity to receive a Rabies vaccine if working with dogs. This facility does not house other potentially hazardous species so no other precautions are necessary. Personnel may continue to receive immunizations including influenza, as needed. Should a health issue arise that precludes someone from working with animals, they can communicate this to their supervisor, the VMU Supervisor or the ACOS/Research.

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.

If an injury occurs after hours or when Employee Health is unavailable, the

hospital Emergency Department is open and available for all employees 24 hours a day. Infectious disease specialists are available for consultation 24 hours a day who are trained in animal and institutional hazards and risks.

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.

All research employees can view the Occupational Health Program for Animal Handlers (document 1200.07 Appendix C), which was written by VA ORD and is located online. This document describes zoonotic diseases and details the occupational health program. All animal handlers of the research service are required to participate in the occupational health and safety program whether they are research staff, animal care staff, students, etc.
All employees must either attend Annual Research Safety training conducted by the Chemical Hygiene officer that includes safe handling instructions for chemicals and proper PPE use or complete the CITI online safety training modules. Training is tracked and monitored by the Chemical Hygiene Officer. Additionally, the VMU Supervisor conducts annual animal handler training that includes information regarding species specific handling, occupational health and safety guidelines and information on allergies.
All personnel must complete the CITI training modules for Working with the IACUC and the species-specific module every three years.

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.

Each employee is oriented to prevention of cross-contamination methods and receives on-the-job training. Work clothing (i.e., scrub suits and pants, gowns & lab coats) are provided and laundered by the laundry service at our facility. Disposable (i.e. caps, masks, gloves, gowns and shoe covers) are also provided. Employees are required to wear work clothing provided and are instructed in the proper use of disposables. Eye and ear protection, back braces, face and hand protection (example: leather gloves for handling rabbits) are also used when necessary. Caretakers are provided slip resistant shoes to be worn in the ARF only.

b) Describe arrangements for laundering work clothing.

The hospital has a laundry service for all employees and the VMU has a household clothes washer and dryer. Scrubs are laundered in the VMU machines with the hospital laundry service being available as well.

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.

Showers within the locker rooms are available for men (b)(7)(F) and women (b)(7)(F). Hand washing stations are provided in all animal rooms and throughout the facility. Wearing of work clothing is prohibited outside of the facility and lockers are provided for exchanging street clothes with work clothes.

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

Eating and drinking are restricted to designated lounge areas only (b)(7)(F) (b)(7)(F) and (b)(7)(F). As of May 15, 1991, smoking is prohibited inside the Medical Center. As of June 2019,smoking is prohibited on the medical center grounds.

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).

Chemicals for cage wash are purchased in 30G drums and are moved using a two-wheel cart to prevent back injury. An emergency shower and eye wash station are within 15 feet of the drums in case of spill. The facility

maintains leather gloves for handling mice/rats to prevent bites and we have muzzles for dogs that show aggression. Large animals are evaluated upon arrival to ensure appropriate temperament and are handling frequently to maintain socialization. Hearing protection and back braces are available for caretaker use, if needed to prevent injury.

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

All mice and rats are housed in individually ventilated caging that is directly vented to the HVAC to prevent allergens from entering the room. All rodents are changed in HEPA filtered cage change stations to prevent allergen release. All rodents are housed in conventional caging with filter tops for the initial quarantine/conditioning period of 5-7 days before being transferred to IVC. A HEPA filtered dump station is provided to contain allergens when caretakers dump soiled rodent bedding. Large animal runs are cleaned daily and caretakers wear gloves and masks during cleaning. Caretakers wear dedicated clothing in the animal facility. All other personnel must wear gowns, gloves and mask when entering any animal room and discard PPE before leaving.

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

The rodents are checked quarterly with a standard health profile that looks for a large variety of pathogens. The Veterinarian, VMU Supervisor, IACUC and Safety committee review these reports to ensure the animals and personnel are safe. All employees must wear appropriate PPE (gloves, masks, gowns, shoe covers) when entering or exiting the animal rooms. Handwashing sinks are available in every animal room and shower facilities are provided. Rabies vaccinations are offered to all personnel who work with canines. Sheep are tested for Q fever, TB and Orf prior to receipt.

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

Filters are changed in the change station every three months. The pre-filter and exit filter in the IVC blower units are vacuumed monthly with the HEPA main filter being changed per manufacturer every two years. The emergency shower is inspected by the Facility Safety office monthly and the eyewash station is tested by the Facility Safety office weekly. The cage change stations are certified and serviced by an outside contractor

annually.

e) Respiratory Protection

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

Surgical masks are available in all animal rooms. N95 masks are available for use in cage dumping areas. If a situation arises that requires additional respiratory protection, an occupational health evaluation will be done in coordination with the Industrial Hygienist.

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

The Facility Safety Office provides yearly fit testing for N-95 masks.

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

When physical methods are not available to remove allergens, the N95 mask is available to use. The cage change stations are in every animal room and they are serviced by an outside contractor annually.

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).

The facility includes a Steris Cage/Rack washer that has emergency release information posted a both doors. Caretakers are trained in emergency exit procedures and are provided an opportunity to open the door from the inside to practice escape in the event of emergency. The washer has a red emergency stop.
The facility has two Consolidated autoclaves. Thermal gloves are provided at both locations and caretakers are trained on proper use before operation.

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 is used in the facility

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.

All rodents are transported in a government vehicle. The animals will be contained in a transport box with filters to prevent allergen exposure during transport. Once the animal transfer is complete, any areas where the animal cage rested are sprayed with disinfectant and the vehicle is returned to the motor pool where it is cleaned thoroughly. No one may use personal vehicles for animal transport. USDA regulated species will only be transported using government vehicles in the event of emergency evacuation.

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

Waste anesthetic gases are filtered through CO2 filter canisters on the anesthesia machines or vented out of the room through the hospitals vacuum system or fume hoods. Vaporizers for isoflurane are certified annually through the Surgivet Exchange program. Anesthesia machines for isoflurane use in rodents are used in or near fume hoods. These machines also have canisters for filtering waste anesthetic gases. The hospital Industrial Hygienist periodically monitors waste anesthetic gas exposure and results are reported to the SRS.

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.

Several protocols utilize replication deficient Lentiviral or Adenoviral vectors to over express genes of interest. These agents will be injected IV, IP and Intracranial in mice and rats. These procedures will be conducted in a BSL2 laboratory using a biological safety cabinet. Protocols utilizing these agents will be monitored/reviewed by the Institutional Biosafety Committee. Complete Freund's adjuvant, Pertussis toxin, inactivated Mycobacterium tuberculosis will be used to induce EAE in mice. These agents will be monitored by the Subcommittee for Research Safety. All staff has been trained in the use of these agents and will wear protective equipment.

Modified Vesicular Stomatitis Virus will be used to trace efferent projections in rats with dystonia via injection into a specific region of the brain. This vector is replication competent and appropriate PPE and handling precautions will be used. A safety SOP was approved by the SRS and the use of this vector will be monitored by the IBC and SRS annually.
Pertussis toxin is used to induce EAE and Diphtheria toxin is used to remove Kupffer cells. The laboratory personnel use appropriate PPE and handle in a biological safety cabinet.

Patient Derived Xenografts (PDX) colon cancer cells will be injected subcutaneously into the flanks of mice. Once a tumor has formed, it will be removed and inoculated into another mouse for treatment. The human cancer cells will be transfected with lentiviral plasmid encoding luciferase to allow for bioluminescence monitoring. All personnel will wear appropriate PPE when working with these human cells and the cells will be received from the National Cancer Institute Patient Derived Models repository. The use of the cells is reviewed by the SRS and IBC.

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

Anti-cancer agents (Z960, 961, OSI-906, Everolimus, G2.2, G5C, HS06, 5-flourouracil, Oxaloplatin, Bevacizumab, Simvastin and Sorafenib) will be injected in mice following tumor induction. These agents are considered toxic and personnel will wear protective equipment and manipulate the agents in a biological safety cabinet.

Formaldehyde and paraformaldehyde will be used in several protocols for perfusion studies in mice and rats. Personnel will be monitored by the Industrial Hygienist for exposure limits and all experiments involving these agents will be conducted in a chemical fume hood.
One protocol injects several toxic agents intracerebrally in rats to block certain receptors or channels for treatment of Dystonia. These agents are reviewed by the Subcommittee for Research Safety and all staff have been trained in the use of these agents.
Tamoxifen is used in several protocols to induce the selective deletion of neurofascin gene in EAE models.
One protocol will inject a toxic agent 5-Bromo-Deoxyuridine (BrdU) intraperitoneally in rats to assess stimulation induced neurogenesis. Once injected, the cages are labeled as toxic and a Safety protocol is posted on the animal holding room door. Animal caretakers do not change these cages for 3 days and the research staff provides husbandry for the rats. The bedding is placed in a separate bag and tied to prevent dust release and then discarded with the normal bedding.
The staff has been trained in their storage and use of all the above listed agents.

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

In one protocol, a radioactive tracer, tritium, will be injected in to mice which will be euthanized less than 24 hours post injection.
A fluoroscope (C-Arm) is used for catheter guidance for protocols involving canines, sheep and swine. Personnel will wear lead aprons, thyroid lead guards and are monitored with badges checked by Radiation Safety monthly. New lead aprons, thyroid shields and eye protection were purchased in 2018. The lead aprons are inspected annually by the Radiation Safety office.

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.

When an investigator proposes a study involving hazardous materials, knowledgeable professionals in the requirements necessary to handle the specific hazard(s) are consulted. The investigator then specifies in his written protocol the level of safety which will be required to handle the materials,

care for the affected animals and how to provide a safe working environment for all personnel involved. A detailed outline of the protocol and safety measures that must be followed is given to all personnel involved in the project. These projects must be reviewed and approved by the IACUC (if animals are to be used), the Subcommittee on Research Safety (SRS), the Institutional Biosafety Committee (IBC), the Radiation Safety Committee and subsequently the Research and Development Committee before being initiated.

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.

The Subcommittee for Research Safety (SRS) reviews the risks for every protocol conducting research at this facility. The SRS Review form is completed detailing risks involved. The SRS reviews the safety and containment procedures for each risk. The committee is composed of an infectious disease specialist, a radiation safety representative, an IACUC voting member as well as three scientists. The IACUC also reviews the Appendix 3 of the ACORP which outlines all hazards associated with the agents in the protocol and determines if additional procedures are required.

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.

There is a locked freezer in (b)(7)(F) for holding radioactive animal carcasses and biological waste that is monitored and disposed of by Radiation safety office.
All radioactive bedding, food and water will be collected for the Radiation safety office. The cages, water bottles and wire bars will be collected by the Radiation safety office to be stored for decay. Once the Radiation safety officer has deemed the cages free of radiation, the animal facility will put them back into circulation.
Infectious agents are prepared and injected under a biological safety cabinet and needles are disposed in sharps containers. The SRS reviews and approves all decontamination procedures for laboratories and cultures for these procedures. The infectious disease suite in the animal facility has a pass-through autoclave to decontaminate soiled bedding and caging, if necessary.
All perfusions with paraformaldehyde are conducted in a chemical fume hood and waste is collected in approved containers. The Green Environmental Management Systems Coordinator of Engineering Service removes the waste for appropriate disposal with the hospital's hazardous waste disposal

procedures.
Toxic - Biohazard Safety staff through Engineering (Industrial Hygienist and Green Environmental management coordinator) manages disposal.
All sharps are disposed in hospital approved sharps containers. These containers are removed and replaced by the Environmental Management Service.
Glass is disposed in approved broken glass boxes and removed by the Environmental Management service.

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

All personnel working with animals must register with the Occupational Health Service of the hospital prior to beginning any procedures. A health questionnaire detailing allergies, hazardous agents and species is reviewed by the nurse and a complete physical exam is completed.
Personal Protective Equipment is provided to all staff including but not limited to: gloves, surgical masks, N95 masks, face shields, gowns and shoe covers. Engineering service provides fit testing for anyone requiring the use of a N95 mask.
Any staff working with the Fluoroscope will have an individual badge that is sent to Landauer, Inc for monthly testing. Any levels above acceptable range will be reported immediately Staff receives quarterly reports for their records from the Radiation Safety Office.

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.

Each employee involved in such studies undergoes special training by his/her supervisor to ensure his/her understanding of hazards involved, safety measures necessary for the protection of self and environment, emergency procedures to be implemented and monitoring system to be employed. In addition, each employee must attend a hazardous communications lecture annually in which chemical hygiene, chemical inventories, material safety data sheets, etc. are discussed and shown to employees. The locations of these reference materials are displayed, and employees are encouraged to keep copies of pertinent information in their labs. Chemical inventories are updated twice per year.
Chemical fume hoods are certified by outside contractor annually.
Isotope use - Prior approval by Radiation Safety Office is required with specific safety guidelines where animal care is involved. Responsible individuals must be certified through formal training. All studies using isotopes are reviewed and approved by the IACUC (if animals are used), the Subcommittee on Research Safety, the Radiation Safety Subcommittee, the Institutional Biosafety

Committee and the Research and Development Committee prior to being conducted.
The investigator or supervisor who is responsible for the orientation and training of staff in safe management and environmental protection controls biohazard agents, toxic chemicals, carcinogens, mutagens, etc. Employees are required to report all accidents or possible exposure to hazardous substances to their supervisor immediately and to see the Employee Health physician for first aid treatment and emergency care. Employee Health maintains all medical records for employees.
Since the use of animals in such experimentation requires special considerations, the facilities and procedures for animal care and use tailored to the needs of each study, are subject to review by the IACUC, the SRS, the IBC and the R & D Committee to assess hazards, determine safeguards and ensure the staff is trained and facilities adequate for the safe conduct of the study.

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.

All protocols have the animals injected and housed solely in the animal research facility. One protocol involves injecting mice with a tritium tracer with survival for 24 hours. These animals are housed in disposable caging with disposable water packs in (b)(7)(F) which has a dedicated and approved animal housing area.
The rats injected with BrDU are housed in (b)(7)(F) as normal. However, the cages are marked and the Safety protocol is put on the entry doorway to alert all personnel. The caretakers have been educated on the agent and do not encounter the bedding or rat for 3 days after injection.

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.

There is a dedicated animal holding area outside of the animal research facility in (b)(7)(F) This area is monitored by radiation safety. Animals are only housed in this area for 24 hours on approved protocol. The Veterinarian can approve temporary housing in this dedicated animal holding area in (b)(7)(F) if the environment in the VMU is not suitable. The IACUC will be notified. This occurred once in 2018 when the HVAC was being replaced throughout the VMU. Noise levels were disrupting sensitive breeding pairs

and the Veterinarian approved housing 3 cages in (b)(7)(F) during the HVAC repair (approximately 2 months) to improve breeding efficiency.

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

The facility has two steam sterilizers that are maintained by Engineering Service and a preventative maintenance program with the company is maintained. Temperatures are checked monthly using biological indicators to ensure appropriate sterilization. Both steam sterilizers were replaced in 2019.
The Biological Safety cabinets are certified annually by a contract company managed by Engineering Service.
The emergency shower is tested by the Facility Safety Office monthly and the emergency eye wash station is tested by the Facility Safety Office weekly.

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

The animals injected with a tritium tracer in (b)(7)(F) are housed in disposable caging with disposable water packs. These items are bagged for Radiation Safety disposal.
Animal care staff are provided with surgical scrub suits to wear in the work place, long sleeve gowns, caps, masks, and disposable gloves when working in animal areas or manipulating animals. Non-skid shoes are worn when working in areas where floors are wet (during sanitation procedures).
Goggles and/or face shields, heavy rubber gloves are required when working with acids and disinfectant detergents. An eyewash/emergency shower is available in the cage wash. Lab coats are provided to be used over the scrub suits outside the Animal Facility, but within the grounds of the institution.
Steel toed shoes can be provided for protection of feet. Back supports are provided if heavy lifting is involved during tasks. Hearing protection is issued for areas involving noise. (e.g. dogs barking. This noise level does not exceed permissible levels but is issued for employee comfort during dog housing sanitation) Gloves and masks are provided for many reasons. (e.g. gloves are used as protection from zoonotic diseases, prevention of cross contamination between species and rooms, minimal protection from allergens, etc.) HEPA filtered vacuum cleaners are used in animal hair clipping areas to reduce exposure to animal dander and hair fibers.
A HEPA filtered dump station is used in the Dirty Cage area to filter allergens while dumping soiled rodent bedding.

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.

We currently have no areas that are used for both animal and human based research or patient areas. The ACORP contains an appendix requesting the use of patient areas for animal research that requires justification and approval from several administrators and officials.

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 Animal facility has a dedicated elevator that is used solely to transport animals and researchers from the animal facility to the research laboratory area. In the rare and short-term event that this elevator is not functioning, a freight elevator has been approved for rodent transport only. In this event, rodents are transported in sealed rodent caging with a filter top. The cages are completely wrapped in a sheet and placed on a cart. USDA regulated species may not be transported by any other method except the dedicated animal facility elevator.

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.

Committee members are chosen to fill the roles laid out by the Guide and PHS Policy. When a member is selected, they must complete "Essential for IACUC Members" through CITI program and are given a copy of the "AVMA Guidelines for Euthanasia, the Guide for the Care and Use of Laboratory Animals, PHS Policy, the Animal Welfare Act and Animal Welfare regulations, the OLAW/ARENA IACUC Guidebook and the approved Animal Welfare Assurance. These documents are updated as needed. They are also encouraged to attend a PRIM&R IACUC 101, 201 and 301 training courses.

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

Monthly

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

Copies of all documents listed in B1. a.i. and institutional specific policies are provided and updated as needed. Members take an Internet course entitled "Essentials For IACUC Members" on a VAMC website www.citiprogram.org every three years.
Members are encouraged to attend IACUC focused conferences and education materials/articles are reviewed periodically as agenda items in the monthly meetings. Several members have attended the PRIM&R IACUC 101, 201 and 301 courses as well as the iCARE training programs. The IACUC coordinator and Veterinarian attend the National AALAS meeting annually and report back all pertinent information to the IACUC. The IACUC coordinator attends the PRIM&R IACUC conference and reports back any relevant information to the IACUC.

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 must review all research proposals when such research includes the use of live vertebrate animals and when such research is supported by VA funds and/or conducted on VA premises regardless of funding. The IACUC procedures for reviewing new, amendments to ongoing protocols, or three-year renewals of research protocols are: Prior to review, each IACUC member is provided with an agenda and a copy of every protocol submitted for review. The facility uses the VA

Innovation Research and Review System (VAIRRS) or IRBnet for online submission and review. Investigators will submit all documents through the online system. The committee reviews each agenda item and can approve, require modifications to secure approval, defer, table or withhold approval. The Institution does not practice the use of designated member review without prior full committee review and only allows administrative changes for specific situations outlined below. All protocols are initially reviewed by the IACUC at a convened meeting with a quorum of members (FCR). The Chairman presents the protocol to the committee and each member makes suggestions for modifications to the protocol where appropriate. Approval of research protocols may be granted only at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present. If the any IACUC member present finds modifications are required to secure approval, the IACUC chairman may appoint two designated member reviewers (DMR) to give final approval once the modifications have been made by the Principal investigator. The Program and IACUC standard operating procedures, approved by all IACUC members, state the use of DMR can be granted by the quorum present at the meeting subsequent to FCR. Any member present at the convened meeting may request the modifications required to secure approval be reviewed at the next fully convened meeting. If the committee votes to defer approval, the protocol requires extensive modifications and the protocol cannot be subsequently reviewed by DMR but must return to full committee for review once resubmitted. If the committee loses quorum or the protocol lacks required elements, the committee will table the protocol and it cannot be subsequently reviewed by DMR but must return to full committee for review. The investigator is notified of deferred or tabled actions via VAIRRS and given instructions for what is needed to resubmit for FCR.

Once the IACUC has outlined the specific modifications required to secure approval and the Chair has appointed the two Designated Member Reviewers, the investigator is notified in writing of the requests. When the revised protocol is submitted, the entire protocol is forwarded electronically the VAIRRS or by hard copy to the previously appointed DMRs. The reviewers may approve the protocol, require additional modifications to secure approval or request the protocol be reviewed by the full committee. The reviewers must unanimously agree. If further modifications are required, the IACUC chair is notified and the same reviewers are used. The IACUC chair or DMRs may request the protocol return to the full committee for review at any time. All items reviewed by the DMRs will be detailed in the IACUC minutes as a new package for the members to review at the next convened meeting. No member may participate in the review or approval of a research protocol where the member has a conflict of interest (e.g., is personally involved in the project or has financial involvement with) except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum. The IACUC may invite consultants to assist in the review of complex issues. Consultants may not approve or withhold approval an activity or vote with the IACUC unless they are also members of the IACUC.

The IACUC allows the following changes to be approved administratively by the IACUC coordinator:

- correction of typographic or grammatical changes
- contact information updates
- personnel changes other than the PI. For personnel changes, the IACUC coordinator will accept a revised ACORP with the new personnel added or personnel removed using Track Changes. The training, enrollment with Occupational Safety and health and employment status will be confirmed. Once approved, this information is presented on the IACUC agenda at the next convened meeting as a notification to ensure all IACUC members are up to date on personnel. The Animal Health Technician will follow up during post approval monitoring to ensure personnel have completed training outlined in the animal protocol.
- Moving of approved animal numbers from a previous year to a current year. This is not approving additional overall animal numbers but shifting unused animals from a previous year to a current year. A modified ACORP will be submitted to the IACUC coordinator for administrative approval. Once approved, this information is presented on the IACUC agenda at the next convened meeting as a notification to ensure all IACUC members are up to date on animal numbers.

Evaluations of the animal protocol forms are based on standards promulgated by the United States Department of Agriculture as authorized by the Animal Welfare Act, PHS Policy, the Guide for the Care and Use of Laboratory Animals, Handbook 1200.07, this program, and other federal regulations or guidelines that impact the conduct of business. All research projects involving animals must be approved by the IACUC, SRS and IBC before receiving final written approval by the R&D Committee prior to commencement. The date of continuing review will be based on the date of IACUC approval. All investigators are sent letters of final IACUC approval through the VAIRRS and are notified of all decisions/modifications required through VAIRRS.

The research office must provide packets or access through IRBnet to IACUC members no later than 5 business days before the IACUC meeting. The packet or online agenda must include an agenda with all business items listed, research protocol, and copies of all protocol forms.

The VMO must perform a veterinary consult with each investigator during the planning stages of a project. The review of a protocol by the VMO during an IACUC meeting does not satisfy the requirements of this item. Any new protocol will be sent to the VMO for review prior to being sent to the full committee.

The funding period of a project has no bearing on the need for annual reviews and triennial reviews. Principal Investigators will be sent a reminder to submit their annual review with required elements listed.

The IACUC may suspend an activity that it previously approved if it determines

that the protocol is not being conducted in accordance with the written protocol provided by the PI and approved by the IACUC. The IACUC may suspend a protocol only after review of the matter at a properly convened meeting of the IACUC and with the suspension vote of a majority of a quorum of voting members present. The following guidelines shall be followed when suspending projects:

1. No additional animals may be entered into studies.
2. No animal should be removed from a project if doing so will result in pain or distress to the animal.
3. No animal should be removed from a project if doing so will invalidate the data obtained and necessitate the use of additional animals in the future.
4. Breeding of valuable animals should not be interrupted, but the entry of new animals into research studies is prohibited.
5. If the IACUC suspends a project previously approved, the following must be notified within 5 days of the suspension in writing through the ACOS/R&D and Medical Center Director:

- The CVMO
- OLAW, if animals purchased with PHS funds are present in the facility.
- AAALAC, in the spirit of self-regulation.
- An affiliate's IACUC, if the project involves animals purchased with funds awarded to the affiliate.

Additionally, the VMO may suspend all animal activities. This suspension of animal activities will extend until the next convened IACUC meeting where the entire committee will determine if the protocol should be suspended and what action plans are necessary. This suspension of animal activities may include but is not limited to animal ordering, animal procedures, animal surgery, breeding, injections, drug administration and animal facility access. The principal investigator will be notified in writing of the scope of this temporary suspension and with the date of the next convened meeting.

Protocols that have a potential to cause pain or distress to animals are reviewed thoroughly for scientific justification of the procedure, least sentient species, least animal number used and earliest endpoint. The Veterinarian consults with the investigator prior to protocol submission to determine if methods to minimize animal discomfort can be used. The IACUC requires justification based on scientific merit for consideration of potentially painful procedures. The IACUC requires a detailed animal management plan and asks that the investigator describe methods for monitoring and ensuring animal pain and distress is kept at a minimum level. Any procedure involving unalleviated pain or distress requires justification within the ACORP detailing what pain or distress will be experienced, why analgesics cannot be used or why they are not effective and what measures will be in place to prevent unnecessary pain and distress from continuing. Extra monitoring procedures may be stipulated by the IACUC at protocol review or if problematic issues arise. The Veterinarian attends all animals at least once a week and checks the investigator's post-operative records. The IACUC conducts a facility inspection at least twice a year to oversee the program and check animal health and well-being.

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.

The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows: The IACUC will review and approve, require modifications in (to secure approval), defer, table or withhold approval of proposed significant changes in ongoing research protocols the same as specified in B.1.b.i. Prior to review, each IACUC member is provided a copy of proposed research protocol via VAIRRS with significant changes to be reviewed. The appointment of designated member reviewers by the IACUC chairperson will follow the same process of FCR followed by DMR as used for review of new protocols outlined above in section B.1.b.i. Our program does not delineate between major or minor amendments.
The following changes can be may be handled administratively by the IACUC Coordinator and does not require full committee review:

- Correction of typographic or grammatical errors
- Contact information updates
- Changes to personnel other than the PI-The IACUC coordinator will ensure all training has been completed, the employee health animal handler physical exam has been filed with Employee Health Service and all W●C/VA employee paperwork has been completed.
- Moving of approved animal numbers from a previous year to a current year. This is not approving additional overall animal numbers but shifting unused animals from a previous year to a current year.

Any administrative changes approved will be documented in the IACUC agenda as a notification for the full committee at the next meeting.

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.

The ACORP requests investigators to specifically state endpoint criteria for animals on their study. The Veterinarian carefully determines if these criteria are suitable for the study. Investigators can be required to weigh animals daily or maintain logs of appearance activity. These items are reviewed during Semi-Annual facility inspections and when requested by the Veterinarian.

Additionally, the animal care staff reports any signs of pain or distress during their daily observations.

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 ACORP outlines all endpoints and if a humane alternate endpoint is not available a detailed monitoring and analgesia schedule must be outlined in the ACORP. Vital signs, weight, temperature and physical appearance must be carefully documented and reported to the Veterinarian.

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.

Monitoring for pain and distress is a multi-level system at this facility. The caretakers observe the animals on a daily basis and can detect changes in their behavior immediately. The Animal Health Technician observes all animals daily and provides thorough physical examinations if any changes in behavior are noted. Any changes in behavior or signs of distress are immediately reported to the VMU Supervisor, Animal Health Technician and Veterinarian. The investigator is notified and efforts are made to alleviate the pain and distress. The VMU Supervisor, Animal Health Technician and Veterinarian can decide to alleviate pain and distress if the investigator is not available. The researchers must outline a monitoring schedule in the ACORP for any procedure that may cause pain or distress. This typically includes hourly to daily observations, weights and/or temperature monitoring. All information is logged in an observation sheet and any signs of pain or distress are immediately alleviated, if possible. This monitoring schedule is reviewed during Post approval monitoring by the Animal Health Technician. Finally, the Veterinarian makes weekly rounds to observe animals and can note pain and distress.
All personnel must take species specific CITI training modules which outline pain and distress signs in each species. The VMU Supervisor, Veterinarian and animal caretakers must take all species-specific modules.

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.

The ACORP asks the investigator to detail any characteristic clinical signs or abnormal behaviors associated with the genotype of their genetically engineered/modified animals. Every protocol is reviewed annually using a

Continuing review form that asks if there have been any unanticipated problems affecting animal welfare. The Investigator would be able to self-identify any of these unanticipated phenotypes. Additionally, the Veterinarian and/or animal care staff observe the animals daily to identify any new phenotypes. When observed, the VMU Supervisor, Animal Health Technician and/or Veterinarian are notified who will subsequently report the finding to the IACUC at the next convened meeting.
Unexpected outcomes that affect animal well-being during surgical or non-surgical procedures are reported to the VMU Supervisor or Veterinarian. A plan will be devised to reduce these outcomes or change the procedure to improve animal well-being. These events are reported to the IACUC at the next convened meeting unless an emergency meeting is deemed necessary by the chairman or Veterinarian. All unanticipated and anticipated adverse events are communicated to the IACUC through the VMU event report submitted to the IACUC at every meeting. If necessary, the ACORP will be revised or procedures terminated to protect the welfare of the animals. Procedures are reviewed and monitored by the Animal Health Technician during Post approval monitoring periodically and animals are closely monitored post operatively.

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."

The IACUC reviews these procedures in detail to ensure prolonged restraint is necessary and done humanely. The IACUC defines prolonged restraint as anything greater than 15 minutes and restricts normal and natural movement of the animal. The IACUC requires justification as well as details for conditioning.

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.

One study restrains the rat for 3-4 hours daily using a head restrainer while microelectrodes are placed in the brain for recordings. The head is gently restrained but the body can assume normal postures. The animals are acclimated to this restraint and the time of recording is gradually increased to achieve the 3-4 hour time period. If an animal shows signs of distress, thrashing or twisting, it is immediately removed. If any adverse clinical consequences occur from either of these procedures, the VMU Supervisor and Veterinarian are notified immediately for veterinary care.
The protocols involving swine and sheep are approved to use prolonged restraint (not longer than 1 hour) via a specialized sling during ultrasound. The animals are conditioned to rest comfortably in the sling using short intervals prior to conducting the full ultrasound. The sling is designed for swine/sheep and has cotton padding around the leg openings to prevent chafing. The animals are provided with positive reinforcement through treats and affection during this time in the sling. They are never unattended while in the sling. If any animal does not adjust the sling, anesthesia is approved to prevent distress. If any adverse consequences occur due to this sling, the veterinarian is immediately notified

iv. Multiple Survival Surgical Procedures [*Guid*e, 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 institutional policy is to discourage animal experimental proposals involving multiple major procedures. The IACUC requires justification based on scientific merit for consideration of multiple survival surgical procedures. The IACUC requires a detailed animal management plan and asks that the investigator describe methods for monitoring and ensuring animal pain and distress is kept at a minimum level.

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.

We have several protocols that involve approved multiple major surgeries.

Seven cardiology protocols involve multiple major survival surgeries in dogs (three) , swine (three) and sheep (one). All of these protocols describe a second survival surgery only in the event that a lead gets dislodged from the right atria or right ventricle. This is not a common occurrence and will not occur in every

animal. The lead revision can be done intravenously or via thoracotomy.

One of these protocols, also involves a second and third major survival surgery for one group of dogs. These surgeries would involve a sino-aortic afferent denervation procedure in which the aortic depressor nerve will be ligated on one side during one surgery following by a third survival surgery to complete the denervation on the other side. This procedure has caused substantial impairment and has been labeled major by the Veterinarian and VMU supervisor. There will be an interval of 4-6 weeks between the first major and second major survival surgery and 3-4 weeks between the second and third major survival surgery. The Veterinarian, Animal Health Technician and VMU Supervisor monitor the animal's post-operative recovery very closely and reports are provided to the IACUC.
Two cardiology protocols(one canine and one swine) involve a primary thoracotomy to implant the radiotelemetry device and a second bilateral thoracotomy will be performed 3-4 weeks later to inject the experimental agents. The second thoracotomy will use a different intercostal space.
Two rat protocols involve multiple survival surgeries in the brain. A second surgery is done to minimize the time that the dura is exposed. The first surgery places the head holder and EMG wires. The second surgery a burr hole is made and agents injected to produce a lesion. A subset of rats will have a third survival surgery for virus delivery to a specific point in the brain.
An additional rat protocol involves multiple survival surgeries. A second procedure is done 72 hours after the lateral fluid percussion injury surgery in order to allow time for the post-injury brain swelling to peak and begin to abate, as well as to minimize the stress on the animal from prolonged surgery/anesthesia.

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.

Two protocols have studies in which some mice are provided a limited diet of 4g either regular chow or Western diet (higher caloric content) daily. In a previous study, food was weighed daily to determine typical mouse consumption and they found on average, a mouse consumes less than 4 g of food per day. These studies also require an overnight or short-term fast for glucose monitoring and/or lipid analysis. These animals will be monitored and weighed daily. If any mouse shows signs of distress or weight loss of greater than 10%, it will be removed from the study and returned to full ad libitum food portions.
A rat protocol involves food restriction until they reach 85-90% of starting weight to increase motivation for a food reward for the whisker conditioning paradigm. The same protocol will put rats on water deprivation for 12-14 hours to increase motivation for a water reward for the auditory conditioning behavioral testing. Rats will be weighed daily during food deprivation and monitored closely before, during and after both restrictions to ensure the animals resumes normal eating/drinking after the testing is complete.

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.

According the IACUC SOPs, researchers must use pharmaceutical grade drugs if available. If they must use a non-pharmaceutical grade agent, the ACORP requests justification and procedures used in preparing the drugs to make them suitable for administration. Drugs must be sterile filtered and pH requirements must be considered prior to dosing the animal.

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.

Not applicable

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

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

The institution and IACUC encourages the reuse of animals if the animal's welfare is not compromised.

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.

Canines are approved to be transferred to an acute protocol after completion of a chronic protocol.
Canines are approved to be transferred to another protocol that involves only minor (Category C) procedures to study anesthetic regimens. The canines are transferred back to the original protocol after completing several anesthetic regimens in a defined time period. Canines are closely monitored throughout this process by the Animal Health Technician and Veterinarian.

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.

This facility supports adoption or re-homing of research animals. The current protocols involve final procedures that harvest organs for additional tests. Should an animal arrive that cannot be used in an approved protocol due to size or other impediment, the investigator should pursue adoption after approval from the ACOS/R, Veterinarian, VMU Supervisor and CVMO. The animal must be spayed/neutered, vaccinated, all devices removed and have a temperament suitable for adoption.

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 must review the conduct of all animal protocols no less than annually regardless of species per VHA Handbook. All investigators must complete the IACUC Continuing Review every 12 months. Prior to the third anniversary, the IACUC must conduct a de novo of the protocol. This will be accomplished by reviewing a new ACORP form as well as the Continuing Review Form from the investigator noting any changes that have emerged since the previous review.
Annual and Triennial Review will evaluate animal protocols for the following elements.

1. Proper training of involved personnel.
2. Any issues involving animal welfare
3. A review of the number of animals used over the previous period to ensure that the number of animals requested is not exceeded.

Investigators that fail to submit annual and triennial reviews as directed will first be sent a warning letter, re-requesting the required information. If after this request, no

response is sent to the IACUC, the committee may suspend the protocol. Any contingent stipulations from the committee must be answered within one month.

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

Every six months the IACUC reviews the program of animal care and use as part of the semi-annual review process. The committee reviews changes at a regularly scheduled meeting. The institutional official and research administrator are involved in this review and discuss any changes or problems that have occurred over the last 6 months.

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 conducts a facility and laboratory inspection every six months as part of the semiannual review. All IACUC members are invited to participate and it occurs after a regular convened meeting. The members inspect the entire Animal Research Facility and all research laboratories that conduct survival or non-survival procedures in the laboratory. The VA IACUC Semi-Annual Self-Review forms are used as a guideline for committee review of the facilities. We do not use contract facilities or satellite holding facilities.

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.

In March 2019, AAALAC, International conducted the triennial full program site visit. After a thorough review of the entire animal care and use program, the site visitors had no suggestions for improvement or deficiencies. No post site visit response was required. The site visitors recommended continued full accreditation. The council met in July 2019 and granted continued full accreditation.

In July 2018, AAALAC, International conducted an interim focused site visit for the canine program per VHA request. After a thorough review of the canine program, they suggested the Standard Operating Procedure document's anesthesia section and euthanasia section be revised to only include agents/techniques that are or will be

approved at this facility. No deficiencies were noted. The SOPs were revised to address this suggestion for improvement and reviewed/approved by the IACUC in August 2018. A post site visit report was submitted for council review. The council met in October 2018 and granted continued full accreditation.
In January 2018, the Office of Laboratory Animal Welfare (OLAW NIH) conducted a site visit of the entire program. After a thorough review, they required the rat protocols be amended to expand the justification of single housing of the rats. Several rats were noted to be single housed without adequate justification. This amendment was submitted and approved at the March IACUC meeting. The final report was submitted in April to address this concern. No other deficiencies were noted on this site visit.

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

The Animal Health Technician conducts post approval monitoring of all active protocols on a regular basis. All protocols will have PAM review upon initiation. Those protocols that use USDA regulated species will be monitored on an annual basis and the protocols that utilize non- USDA regulated species will be reviewed on a triennial basis. The review will entail a thorough examination of the research protocol, procedures, techniques and records. The Animal Health Technician will provide a report to the IACUC after each PAM review which will detail any suggestions for improvement, teaching moments or potentially reportable situations. The IACUC, Veterinarian or Animal Facility Supervisor can request additional PAM reviews at any time. The IACUC conducts an annual review of every protocol using a Continuing review form to monitor animal usage, new procedures and any animal welfare concerns. Any adverse events (anticipated or unexpected) are reported to the VMU Supervisor and Veterinarian. These events and any follow up recommendations from the Veterinarian are reported to the IACUC via a VMU event report at every convened meeting. The committee can determine if these events warrant an action plan or modified ACORP.

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

Animal welfare concerns must be reported to the ACOS of Research or IACUC within 5 days. Personnel can report concerns to any member of the IACUC, Institutional official, Chief of Staff, VMU Supervisor or ACOS of Research anonymously and without reprisal or discrimination. Anonymous reports can be left in the (b)(7)(F) or in the Research administration office (b)(7)(F). Once reported, the IACUC will review the incident at the next convened meeting or an emergency meeting can be called in the event there is significant risk to animal/human safety. The IACUC Chairman will investigate the incident and gather information for the IACUC. The IACUC will determine if the event is

a reportable incident and what remedial actions are necessary. If reportable, the IACUC submits a report to the Facility Director within 5 days who sends a report to the Office of Research Oversight, OLAW, AAALAC and CVMO within 5 days.

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.

The Animal Facility disaster plan details specific situations and responses to those situations. All personnel involved with animal research would be called upon to participate in the event of an emergency but it would be coordinated by the VMU Supervisor, Veterinarian, ACOS/Research and AO of Research. The animal research facility is connected to the hospital's emergency generator power. In the event of a power failure, emergency heaters or air conditioners can be brought in by the facility safety office. Additionally, the facility has several battery-powered flashlights and emergency battery powered radios for use. The facility maintains at least two weeks' worth of food for all species always.
Should the facility require evacuating, there are portable stainless steel cages and minivans which will be available for our use to transport large animals. Directions to two nearby facilities are printed and readily available in the front office of the ARF and an MOU exists between Durham VAMC and the Richmond VAMC to assist in evacuations. An evacuation drill was simulated in 2014.

II. Animal Environment, Housing and Management

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

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 entire facility is indoors, self-contained, heated and fully air conditioned; 3,900 square feet of the facility involves animal rooms. (See Appendix 10 for specific HVAC information) Temperature is monitored in individual rooms with a Johnson Controls temperature alarm system that sounds in the Engineering control room of the Utility Plant if a room is above or below set limits (set limits are 66F and 78F with the alarm sounding at 65F and 79F) This is monitored 24 hours a day and 7 days a week. Additionally, each room has an individual thermostat and a digital monitor displaying temperature and humidity which is logged daily by animal caretakers and monitored by the VMU Supervisor. The housing boxes in (b)(7)(F) have a temperature/humidity monitor for visual reading and recording when animals are being housed there. The HVAC system (ducting, valve, controllers, piping) was completely replaced in 2018 providing more even and accurate temperature controls in each room.

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]

All animal rooms (mouse, rat, and large animal) are maintained at an average of 72 degrees F with individual thermostats. This will fluctuate by 2 degrees in either direction regularly but any fluctuations greater than that are reported to the VMU Supervisor. The alarm set points with the Engineering control room are 65F and 79F. If above or below these set limits, Engineering comes to repair the system immediately. Relative humidity is considered normal between 30-70% and if it goes above or below this any changes in animal health is reported immediately to the Veterinarian. The VMU received a new HVAC system during the Summer of 2018 which has provided tighter control of the temperature and humidity.

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]

All mice are provided with nesting material to ensure thermoregulation. A new HVAC system was installed in Summer of 2018. When humidity levels fall outside of the Guide's recommendations, the Veterinarian is notified. The animals are monitored closely for signs of illness associated with humidity changes. If any illness/adverse effects are noted, they are presented to the IACUC during a convened meeting to determine if changes need to be made. To date, no adverse effects have been noted.

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 ventilation room rates and pressure are assessed by Engineering every three years to ensure air changes are 10-15 per hour. The source is 100% fresh air with no recycling of room air.

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

   Most mice and rats are housed in individually ventilated caging from Tecniplast. The system uses room air that is HEPA filtered with a max air speed at cage level of 0.05 m/s. The exhaust hose is connected to the room exhaust duct to prevent recirculation. Each cage receives 70 air changes per hour.

   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.

   Our supply is 100% fresh air.

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).

   Not applicable

   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).

   Not applicable

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.

The facility has design features to reduce noise such as masonry walls and sound retardant doors. Ear protection is provided for employees for use in noisy areas. The individually ventilated caging has a noise level below 50 dBA as documented by Tecniplast.

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.

We follow the standards set by the Guide to verify adequacy of space provided for our research animals

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]

We have no space exceptions.

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).

Large animals are housed in chain link runs. This enables the large animals to interact by sight, smell and touch through the fence and eliminates most territorial behavior. Rodents can forage in the contact bedding and climb on the wire bar lid for enrichment.

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).

Dogs are allowed to exercise in a separate room with another compatible dog while their runs are being sanitized for approximately 15 minutes a day if the protocol allows. Otherwise, they are allowed to play alone in the separate room that contains toys and bones or allowed to run outside their run/interacting with the caretaker and other dogs. Dogs are provided with chew toys and Nylabones to encourage gnawing and Kong toys filled with peanut butter, canned food or baby food to provide activity. These toys and Kongs are rotated often to prevent boredom. Dogs have interaction with handlers and are given treats daily, which are rotated often. Additionally, the dogs are provided with a variety of enrichment that is rotated that includes music and DVDs.
Swine and sheep are allowed to move outside of their run and interact with caretakers and other cohorts once a day. Swine and sheep are provided enrichment items (chains, Kong toys, scratch mats, music etc.) as well as human interaction throughout the day. The enrichment items are rotated often to prevent boredom.
All mice are provided with nesting material. Breeding pairs are given a plastic shelter.
All rodents are provided with periodic foraging material such as foraging crumbles, certified mealworms or sugar treats.
Rats are provided with small, certified "nylabone" style chew toys for gnawing.

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

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

The institution expects all animals should be social housed whenever possible.

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.

There are several protocols with justification for single housing. Certain strains of male mice are known to fight and will be singly housed if not from the same litter. All animals are housed singly after surgical procedures or when fed special diets. Breeding male rats are single housed if another male rat of comparable size is not available for social housing. Dogs and swine are housed singly due to surgical procedures and monitoring protocols, however there are no solid dividers between the runs so they can see/smell/ each other at all times. Sheep will be single housed post operatively while incisions heal.

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

environmental enrichment, etc.).

Dogs, sheep and swine are provided extensive human interactions on a daily basis by caretakers and research technicians. They typically are removed from their runs during cleaning and for a variety of conscious and painless manipulations (ultrasounds, treadmill exercise, etc.). They are also given a variety of enrichment items and treats on a daily basis.
Rodents are provided with several enrichment items regardless of social housing status. They all receive nesting material and foraging crumbles. Rats are given Nyla bones and foraging treats.

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 VMU Supervisor and Animal Health Technician regularly review enrichment programs. New enrichment items are introduced periodically and those that are 'well-received' are put into circulation.
During the three year review of all protocols, the social housing is reviewed by the IACUC to ensure it is still beneficial to the well-being of the animal.

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.

Dogs, sheep and swine are introduced slowly to each other and to new people. Dogs found to be compatible are housed in the same room and allowed to play together daily. Cleaning schedules and animal caretakers are static to allow the animals to have a routine.
Any new procedure is introduced slowly to all the animals. If a new apparatus is to be used, the animal is placed in it for only a few minutes with no procedure done until they are comfortable with the process. The length of time is increased. The VMU Supervisor and Veterinarian can be consulted to help investigators with this process.

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).

Not applicable.

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.).

Not applicable.

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.

Not applicable.

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).

Not applicable.

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

Not applicable.

iii. Describe how animals are captured.

Not applicable

C. Animal Facility Management

1. Husbandry

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

i. List type and source of food stuffs.

We procure Teklad Lab Dog diet, Teklad Miniswine diet, Teklad Ruminant diet, Global 18% rodent diet, sterilizable Global 18% rodent diet, Global 19% extruded Rodent diet from Envigo. Enrichment edible treats (fruit, cookies, dog bones, etc) and canned soft foods are procured from a local store.
Special diets including certified diets, powdered chows, Helicobacter clearing diets or other special feeds are occasionally ordered at investigators request for specific protocols.
Enrichment treats (meal worms, foraging crumbles) are ordered from Bio-Serv.
Canned dog food or meat baby food, which is procured from a local stores or online markets, can be offered post-operatively to dogs if it will not interfere with

the research protocol.

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

The vendors, Envigo and Bio-serv, commercially contract vermin control. The food storage areas of all vendors are temperature controlled. Diets are delivered in climate controlled vehicles from Envigo.
Diets are stored in an animal facility feed storage room at room temperature. Enrichment items are stored in a refrigerated room at 4C. The animal facility contracts vermin control through an outside company. A pest control representative visits the facility weekly to change traps and check for vermin. All feed is stored in plastic bags in covered containers outside of each animal holding room. Feed is not stored in the animal rooms.

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).

Not applicable.

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

Food is provided ad libitum to rodents in stainless steel feeders unless reduced quantities are requested by the investigator after IACUC approval. Dogs are given food according to their weight in stainless steel pails. On average, a dog will receive 2 ½ -3 cups of food per day in the morning with 1-2 treats per day. This amount is adjusted according to the dog's weight and energy level to maintain optimum health. Dog food can be supplemented with canned dog food if their weight declines.
Swine are fed approximately 1000g (or 2% body weight) once per day to ensure proper weight. This amount is formulated by the vendor for Yucatan swine. This can be adjusted according to their weight to maintain optimum health.
Sheep are fed according to the Teklad diet to ensure proper weight. They are supplemented with hay pellets.

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

All food is discarded 6 months after the mill date. The mill date is written on the food bin when the bag is emptied. Animal care staff carefully monitor mill dates of all feed. When new bags arrive, the oldest mill dates are moved forward to be used first.
Envigo ensures optimum nutritional quality of their feeds and all enrichment products are purchased certified.

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).

The City of Richmond supplies our water. Water is tested by the city and certified to meet quality acceptable standards.
Water is provided to the animals in pails and water bottle assemblies. Fresh water is provided to all rodents at cage change and when water bottles are low between cage changes. Large animal buckets and waterers are dumped and refilled daily
Water bottles, sipper tubes and stoppers are sanitized at least once per week.
Rodents housed in sterile caging are provided autoclaved deionized water.
Automatic watering is not used.

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

Quality is controlled through daily change of water and sanitation of all small animal water assemblies. Fresh water supply to large animals is provided at least daily and containers are sanitized on a weekly basis

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

Not applicable

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

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

Corn cob bedding is used in shoebox cages for rodents as direct contact bedding. Rodents are housed routinely in contact bedding. Dogs, sheep and swine are housed in kennel runs with vinyl coated expanded metal flooring. Dogs have sheepskin pads or crate pads to lie on directly.

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

Bedding is stored in a temperature controlled room within the animal facility. Vermin control measures are monitored through Orkin.

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

Our quality control concerns are satisfied by the condition of the merchandise on arrival. Visual and olfactory inspection of contents, as a spot check measure, is performed

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.

If animals are transported to/from the local university, they are transported in a government motor pool vehicle. The vehicles are maintained by the VA physical plant and climate control is verified to be in working order prior to leaving the facility.

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.).

High-pressure sprayer connected to a Midland sanitizing station is used for sanitation of rooms but is not used in the presence of animals. HEPA filtered vacuum cleaners are used in pre-operative areas to vacuum hair clipped prior to surgical procedures. An electric power washer is available for monthly cleaning of the chain link or spot cleaning of the floor grates.

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.

Rodent contact bedding is changed at least weekly. Large animal runs are cleaned daily.

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

Not applicable

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 in room (b)(7)(F) (soiled cage room). Clean bedding is placed in cages in room (b)(7)(F) (clean cage room).

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.

Not applicable.

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).

The effectiveness of the cage sanitation program is through monitoring of the cage washer temperature, visual inspections and performance efficiency of our staff. Cage washer has a final rinse guarantee of 180 degrees and temperature tapes are used to monitor water temperature monthly. Bottles, sippers, cages and large animal runs can be spot monitored using ATP testing. Levels below 200 are considered satisfactory. Levels are recorded and maintained by the VMU supervisor.
Autoclave is monitored by steam sterilization tape on each load and monthly by test strips and biological indicators.
Sanitation of equipment is only a part of the prevention of cross contamination effort and control of infection. All research personnel involved in animal studies work together to achieve our goal of no infection outbreaks.

b) Describe preventive maintenance programs for mechanical washers.

The mechanical cage washer goes through preventative maintenance every 6 months by Engineering Service.

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.

All waste is double bagged in plastic bags in compliance with institutional policies and disposal procedures. Bags are tightly closed, identified, where applicable, and placed in designated holding area for appropriate disposal.

Soiled bedding and refuse are held in (b)(7)(F) and incinerated three times a week by Environmental Management Service.

ii. Animal carcasses.

Animal carcasses are held in the Cold Room, (b)(7)(F) or in chest freezer, (b)(7)(F) and incinerated weekly by Environmental Management Service.

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).

Environmental Management Service contracts an outside commercial pest control company which provides vermin control and monitoring on a weekly basis. We have adopted an integrated pest management approach to our pest elimination program, including but not limited to: the use of pest monitors, exclusionary practices and visual inspection on a regular basis to determine the need for judicial use of control practices. (i.e. the use of physical removal, environmental modification and sanitation.) Pesticides will be used at outside access doors only. Corridor areas are treated every 6 months on a preventative basis if needed. The food and bedding holding area, (b)(7)(F) is treated every 6 months if needed. Door thresholds that lead to outdoors loading dock areas are treated. Large animal run areas are not treated due to the frequent sanitizing and washing of these areas. No pesticides are used in the presence of animals. Animals are removed at least 24

hours from rooms treated with pesticides. Animal rooms are only treated at drains and door thresholds and room is empty of research animals. Flying insect attractant lights with glue boards are positioned near exit and loading dock doors.

Pesticides commonly used are:

PT 565 Plus XLO contact insecticide, PT 388B Advance Ant Gel Bait, PT Advance Cockroach Gel bait reservoir, Contrac all weather blox (rats/mice). All products are residual insecticides with broad-spectrum use. Applied every 6 months on a rotating basis has been working well to prevent vermin and insect resistance to pesticides used.

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.

The investigator is made aware of insecticides used through verbal communication. No pesticides are applied in the presence of animals. Rooms are vacated for 24-48 hours after being treated and investigators are notified of the room changes during pesticide spraying. Pesticides are not sprayed all over the room but at designated areas such as floor drains and door thresholds. Pesticides are residual and are not applied more often than once every 3-6 months unless a problem is noted and more frequent applications are recommended by Orkin

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.

Routine animal care is provided by at least one animal caretaker from regular staff every weekend and holiday. Their duties include cleaning large animal runs, providing food/water to each animal, observing all animals and report any abnormality to the VMU Supervisor, Veterinarian or investigator. Additionally, the regular staff can administer pain medications, antibiotics or pre-prepared medications if prescribed.

Specialized care of animals involving fluid administration, special feedings, metabolic studies with intake and output measurements, pain management, major wound care, maintaining weight logs, etc. is the responsibility of the investigator and their staff. This is monitored by the VMU Supervisor, Animal Health Technician and Veterinarian.

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

Weekend/holiday staff is regular staff.

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

Problems with animals are reported to the VMU Supervisor, Animal Health Technician and Veterinarian by the animal caretaker on duty or research staff in need of assistance. The problem is assessed through the supervisor and/or the consultant veterinarian, and in cooperation with the investigator, proper steps are taken for its management. Emergency numbers for VMU Supervisor, Animal Health Technician, Veterinarian and back up Veterinarian are posted prominently throughout the facility for assistance.

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).

Each animal housing unit is identified with a cage tag with information pertaining to the animal(s).
Dogs - Neckbands with facility ID numbers are placed on admission. Dogs arrive with tattoos from the vendor in their ear and this information is written on the cage card and admission book.
Swine and Sheep- Swine and sheep arrive with ear tags from the vendor with USDA number. Both are assigned a facility number upon arrival and this information is written on the cage card and admission book.
Rodents- the facility has a Somark tattoo machine for tail tattooing if approved in the protocol. Ear tags are available for use as well.
All animals have a cage card assigned upon arrival. The information on the cage card includes source of procurement, date of arrival, species, sex, admission weight, USDA numbers (where applicable), facility ID numbers, investigator's name, special information (i.e., birth date, surgical or procedural date, and type of procedure, etc.) and IACUC protocol number.

b. Breeding, Genetics, and Nomenclature

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

Investigators are encouraged to call the Veterinarian consultant for information and guidance on the subject

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.

Investigators are encouraged to call the Veterinarian consultant for information and guidance on the subject.

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

Each research group is responsible for maintaining and managing the genetic authenticity of the breeding colonies. To assess authenticity, several protocols are approved for tail snipping for genotyping. The process must be reviewed and approved by the IACUC. Breeding colony numbers are maintained in a record book in the ARF office. Genotyping results are maintained by the research staff.

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."

The ACORP requests specific information on abnormal characteristics or behavior associated with genotypes. The IACUC reviews this information and determines an appropriate course of action. The Veterinarian can monitor these animals closely and report any issues to the IACUC. At this time, we do not have any generated genotypes with phenotypes that negatively impact the animals' health or well-being.

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.).

Source evaluation is based on experience with quality of animals received from each USDA licensed source, reliability of animal supplier and cooperative attitude in

management of complaints we may have related to animal health, shipment methods, etc. We often consult with the professional staff at the Virginia Commonwealth University Central Animal Facility prior to establishing a new source for animal procurement.

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).

Licensed animal suppliers in species appropriate containers and in comfortable temperature controlled vehicles transport animals to the facility from commercial vendors. If transferred locally, a government vehicle is used and the animals are transported in appropriate containers with filter lids. The vehicle is thoroughly cleaned after transport. Within the facility, covered transport cages are used to transport animals to research labs or home cages.

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.

A Rodent Health Surveillance protocol has been reviewed and approved by the IACUC for mice and rats. In the rodent rooms, the IVC plenums are swabbed or a Tecniplast Interceptor filter is placed above the pre-filter for five weeks. These samples are sent to Charles River Diagnostics or IDEXX Bioanalytics for testing. If further testing/confirmation testing needs to be conducted, mouse or rat sentinel animals can be ordered and used per approved protocol or colony mice can be tested.

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

Within the past year, our animal facility has tested positive for Helicobacter and MNV in one room. To prevent spread to other rooms, all personnel are required to put on shoe covers prior to entering any animal room and remove those shoe covers prior to leaving any animal room. This prevents the spread of infectious agents via shoes throughout the facility. This applies to contractors, maintenance workers, housekeepers and researchers. If any researcher is going to remove or work with the animals, they are required to wear gowns, masks and gloves as well as shoe covers prior to removing a cage from the IVC rack.

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

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

For USDA regulated species, an intake form is complete on each animal upon arrival. This form notes physical characteristics (ears/eyes/scars etc.) and health status upon arrival. The Animal Health Technician (LVT) provides a preliminary physical exam upon arrival. Vaccine history is verified. Animals showing any signs of illness are isolated and the Veterinarian is consulted and the VMU Supervisor is notified. All USDA species records are maintained electronically using the IDEXX NEO system. Non- USDA regulated species are checked for physical injury and health status. If any issues are found, the VMU Supervisor and Veterinarian are notified.

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.

Procedure during quarantine period is to evaluate animals closely, daily, for early disease symptoms (i.e., general condition, amount of intake and quality of output, presence of internal or external parasites, behavioral changes, etc.) as applicable to species.
Rodents are quarantined in (b)(7)(F) (b)(7)(F) and (b)(7)(F) which is a group of rooms separate from the other animal holding rooms. These rooms are cleaned last in the rotation and no animals return to these rooms after being put in regular holding rooms. Rodents are moved to the regular holding room after the required quarantine period. If any animal shows signs of illness, they remain in the quarantine for Veterinarian consultation.
Canines, sheep and swine are held in chain link runs and are only housed with animals from the same shipment during the quarantine period. Newly arrived animals do not interact nor are they housed with animals that have been in the facility. All species are held in separate rooms. Procedure during quarantine period includes daily close inspection for early detection of disease symptoms, diagnosis and treatment (same as for purpose bred animals). Conditioned dogs are routinely dewormed and flea/tick treatment can be applied if needed. Once the required stabilization/quarantine period is complete, the Veterinarian or LVT releases the animals from quarantine and signs the intake form to clear them to begin research.
All rodents, canines and swine held in this facility are purpose bred. Sheep are purchased from a USDA registered Class B dealer and they are tested for OPP, Orf, Q fever and TB prior to shipment.

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

Rodents are quarantined/stabilized for 5-7 days before being moved into animal holding rooms for use by the research staff. Dogs, sheep and swine are stabilized for 4-7 days before use.

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.

All animals are separated by species such that no room contain more than one species. Animals may be housed together from mixed sources but all have the same health status and rodents are housed in individually ventilated caging with 0.2μ filter tops after quarantine. Large animals (Canine, Sheep, swine) are housed in separate rooms at all times.

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

We do not house multiple species in the same room, area or enclosure.

   c. Describe isolation procedures and related facilities for animals.

Sick animals are immediately separated from the rest of the colony and placed in a quarantine room. Any diagnostic tests deemed necessary by the Veterinarian are performed to aid in diagnosis and treatment, provided this is experimentally acceptable, otherwise animals must be euthanized.
Small animal isolation is achieved through removal of the sick animals into separate rooms or on to a separate row on the IVC rack.

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.

Animals are observed multiple times throughout the day for illness and abnormal behavior by the animal care staff. The Animal Health Technician makes daily rounds to observe the overall well-being of the animals and the Veterinarian review charts and observes all animals weekly with the Animal Health Technician. Each rodent cage is inspected to ensure all animals are healthy by the animal caretakers and Animal Health

Technician. A daily record is maintained with each animal holding room that logs the daily checks and any comments by the caretakers. The treatment book in the ARF office is used for daily notes from the caretakers on overall health and wellbeing of the animals. These records are reviewed by the VMU Supervisor, Animal Health Technician and Veterinarian.
All USDA species have electronic records maintained through IDEXX NEO that is accessible remotely or in house by all approved users. Observations, weights and health notes are entered in this system. Alerts can be activated to notify of special treatment or situation.
The VMU Supervisor has more than (b)(6) in research animal and surgical care with an additional (b)(6) veterinary technician experience. Supervisor is (b)(6) certified and is responsible for the condition of all animals within the facility.
The Animal Health Technician has more than (b)(6) of experience in research animals and surgical care with more than (b)(6) of experience in private practice veterinary clinics. Animal Health Technician is a (b)(6) and is (b)(6) certified.
The animal care staff consists of one full time, one-part time employee and one relief employee. The full-time caretaker has more than (b)(6) of experience in animal husbandry and post-operative care. The part time and relief caretakers are equally trained in animal husbandry and post-operative care. All caretakers report any illness/abnormal behavior to the VMU Supervisor and/or the Veterinarian. This is also recorded in the daily animal care log book located in the front office. The caretakers record if all animals are healthy as well.
The consulting veterinarian consults with the Animal Health Technician and monitors every animal on his visits to the facility as well.

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

Emergency numbers for all animal care staff, Veterinarian and researchers are posted in the animal research facility. The Veterinarian and VMU Supervisor are available by cell phone always. Good communication exists between the research staff, veterinary staff and animal facility staff. An emergency "phone tree" was distributed to the Research administration containing after hours' phone numbers for all research staff involved in animal research.

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.

On-the-job training of employees, including prevention of cross-contamination and isolation techniques, has been very effective. The quality of animals we use, as well as the availability of space and equipment, facilitate control of disease. All dogs and swine are purchased from a USDA Class A facility and have received all vaccinations

prior to arrival. Vendor provides documentation of canine vaccinations. Sheep are purchased from reputable USDA registered Class B vendors and are tested negative for OPP, Orf, Q Fever and TB prior to shipment. Rats and mice are obtained from reputable commercial dealers. Rodents are purchased viral antibody free and colony health status reports are available to us on request. If an investigator requests that animals be transferred from another research facility (i.e. VCU), the most current health status report is sent to the Supervisor for approval. The VMU Supervisor has the right to block transfer due to results found in this health status report. Health monitoring/surveillance are done through quarterly testing described in the IACUC approved health surveillance protocol. Dogs have toe nails trimmed and swine and sheep have hooves trimmed as needed by animal care staff or research technicians. Dogs are treated with flea/tick treatment if fleas and/or ticks are noted upon arrival. Dogs are given deworming medicine if they will be in the facility longer than 2 weeks.

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.

All emergency numbers for VMU Supervisor, Veterinarian and research technicians are posted in the Animal Research Facility. VMU Supervisor, Animal Health Technician and Veterinarian are available 24 hours a day, 7 days a week by pager or cell phone. The Emergency plan also provides emergency numbers for other research administrators.

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

The Veterinarian has absolute authority to treat all animals in emergency situations. Every effort will be made to contact the investigator or research staff. The animal's welfare and well-being are paramount.

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.

Individual records are maintained on all USDA regulated species using the electronic system, IDEXX NEO. These medical records that arrive with the animals are maintained in a central location in the Animal Facility and uploaded to the electronic files. The electronic records contain all records related to test results, weights, diagnoses, treatments, daily notes, medical progress reports and veterinary staff notes.

An animal caretaker and treatment binder is located in the front office of the Animal Facility. Researchers and veterinary staff can request treatments and progress report requests for the animal caretakers each day. These requests are transcribed in to the individual animal records as well. If orders are given by phone or email, this is noted in the records.
Non USDA regulated species records are maintained in the individual investigator laboratories. All treatments, weight logs and medical progress notes are maintained in these logs. These logs are reviewed by the Veterinarian on semi-annual review.

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.

The electronic record system can be accessed by Veterinarian, Animal Health Technician, research technicians, Surgical Technician, VMU Supervisor, investigators and other staff upon request. This system can be accessed via internet from anywhere. The VMU Supervisor maintains sole control of who has access to IDEXX NEO. All personnel information is de-identified. Once the animal has completed the protocol, the electronic records are printed to be filed as hardcopy in investigator's laboratory and an electronic copy remains in the system.
The VMU Supervisor maintains all treatment book records in the animal facility. Investigative staff keeps separate detailed records in their laboratories. The IACUC and veterinary staff have access to these records upon request.

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

The Attending Veterinarian reviews all animal medical records on a weekly basis or more often if required. After review, the Veterinarian makes notes in the electronic system. When the Veterinarian is contacted via phone or email, he can access IDEXX NEO remotely to input his notes. Mouse records are reviewed by the IACUC during semi-annual reviews.

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

a. In-house diagnostic laboratory capabilities.

The hospital's clinical laboratory can run CBC and blood chemistry panels upon request.
Binocular microscope for identification of internal or external parasites is available within the facility.
One PI owns an ultrasound unit which can be used for imaging of organs.

b. Commercially provided diagnostic laboratory services.

We are currently using Charles River Laboratories and IDEXX Bioanalytics for the health monitoring diagnostic services. IDEXX can be used for diagnostic testing such as bacterial cultures..

c. Necropsy facilities and histopathology capabilities.

We have no histopathology capabilities within the Animal Research Facility. The institutional Histopathology Lab and the VCU Central Animal Facility histopathology and parasitological lab provide the needed assistance in this diagnostic area. When necessary, we also send specimens to the State Veterinary Laboratory for analysis. The VMU has a dedicated necropsy room with a necropsy table, instruments and freezer.

d. Radiology and other imaging capabilities.

The VMU has a C-arm fluoroscope in the leaded room. Three investigators, one technician and the VMU Supervisor are approved and badged to work in this room. The C arm is approved for use in two protocols but can be used for some diagnostics, if needed.

5. Drug Storage and Control

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

Controlled drugs are kept in an Omnicell medication management unit outside of room (b)(7)(F) in Animal Facility and other non-controlled drugs are in the medication cabinet in (b)(7)(F) All controlled drugs are procured through the Pharmacy Service. Pharmacy service purchases and stocks the Omnicell unit on a regular basis. Non-controlled drugs are purchased through the animal facility or individual investigator through a veterinary supply vendor. These drugs are maintained in a locked cabinet in the animal facility. Keys are held by the animal caretakers and in a locked key box.

b. Describe record keeping procedures for controlled substances.

Pharmacy service conducts random and unannounced narcotics inspections at least monthly. Records of medications given to animals are maintained within the Omnicell unit and in the investigator's animal records. If a controlled substance is used up or expired, Pharmacy service will replace it automatically. The VMU staff also conducts weekly inventory cycle counts.

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.

All major surgery is performed by professional medical staff, trained by the principal investigator in the preparation of the experimental animal specific model. Experience of staff is outlined in each animal protocol form which is approved by the IACUC prior to conducting the study. The Veterinarian is consulted prior to initiation of any new procedure and will assist/observe the procedures to ensure proper procedures are being followed.
The Animal Facility has a surgical technician on staff that is able to assist investigators in planning and conducting surgical procedures. The investigators may also provide their own surgical technicians and support staff. The ARF surgical technician is available to train all researchers in surgical techniques. The Animal Health Technician can provide veterinary assistance for pre- and post-operative care as well as procedural training.
The VMU Supervisor and Animal Health Technician are responsible for the management and proper use of the surgical units and monitors animal use including anesthetic agents, techniques and supplies used.

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.

The animal surgical suite, consisting of (b)(7)(F) is in an area separate from the animal housing areas. This area has a dedicated surgical steam sterilizer, scrub sink and instrument preparation area. An animal prep room is available in the animal facility adjacent to the main surgical room. Canines are recovered in a (b)(7)(F) or (b)(7)(F) and rodents are recovered in their home cage. Swine and sheep are recovered in the sling and then returned to their home run.
(b)(7)(F) is used for survival and non-survival large animal surgical procedures as well as any emergency procedures required. This room is used heavily and has a gas anesthesia

machine, respirator, physiological monitor, cardiac defibrillator, central oxygen and air supply, IV fluid warmer, surgical lights and operating table.
(b)(7)(F) is used for survival major and minor surgeries on rats and mice and is used on a moderate basis. It has an anesthesia machine, surgical overhead lights, an operating table and microscope.
(b)(7)(F) is mainly used as a recovery room for rodent surgeries being conducted in (b)(7)(F) on a moderate basis. This room may be used for survival and non-survival major rodent surgeries, if needed, but is currently a support area only. This room has two warming incubators for recovery.
(b)(7)(F) is a leaded room used for survival and non-survival large animal surgeries involving the fluoroscope C-arm. It contains an anesthesia machine, respirator, physiological monitor, cardiac defibrillator, central oxygen and air supply, C-arm and surgical table. The use of this area changes with protocol need and is currently being used heavily.
Outside of the Animal facility, there are laboratories on third floor that are approved for surgical procedures.
(b)(7)(F) performs survival major surgery on rats and mice on a moderate basis.
(b)(7)(F) is used on a moderate basis for non-survival rodent surgery.
(b)(7)(F) performs minor survival surgery on rats on a heavy basis.
(b)(7)(F) have anesthesia machines and surgical tables.
(b)(7)(F) is used for non-survival surgery on mice and rats on a moderate basis.
(b)(7)(F) is used on a moderate basis for non-survival rodent surgery.
(b)(7)(F) is used on a moderate basis for non-survival rodent surgery.
(b)(7)(F) is used on a moderate basis for survival and non-survival rodent surgery

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).

Major procedures are defined as those which invade a body cavity and/or cause a permanent physical impairment in an animal. Minor procedures do not enter body cavity nor cause impairment. Survival procedures involve those in which an animal is placed under anesthesia, operated and allowed to recover from anesthesia.

b. How is non-survival surgery defined?

Non-survival procedures are those which the animal is euthanatized following the operation and never regains consciousness after the procedures.

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

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

All major surgery is performed by professional medical staff, trained by the principal investigator in the preparation of the experimental animal specific model. Experience of staff is outlined in each animal protocol form which is approved by the IACUC prior to conducting the study.
Patient preparations include but are not limited to: clipping and shaving the surgical area, preparation of the area with appropriate skin disinfectants, use of sterile instruments and drapes, IV catheter placement and intubation. Surgeon preparations include but are not limited to: caps, masks, shoe covers, sterile gowns and sterile gloves. Support staff wear caps, masks, shoe covers, gowns and gloves.
Additional equipment is available to maintain appropriate supportive care as well as monitoring equipment to maintain the patient anesthesia, respiration, hydration, body temperature, and healthy physiological state under sterile surgical conditions. A hand scrubbing sink is provided outside of the surgical suite and a steam sterilizer is available.

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.

Steam autoclaving is used for most items and chemical sterilization with Glutaraldehyde can be used depending on the item to be sterilized. All autoclaves are checked monthly using temperature indicator papers and biological indicators to ensure effective autoclave performance. Glutaraldehyde sterilization is done according to manufacturer's instructions with a 12-hour exposure time prior to use. Instruments must be washed and steam sterilized prior to use during serial surgeries. Several investigators utilize the Ethylene Oxide sterilization unit at Virginia Commonwealth University for items that cannot be steam sterilized. A glass bead sterilizer is available in the VMU for use as well.

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

A bead sterilizer is available to re-sterilize instruments between rodent surgeries. The steam sterilizer is adjacent to the canine surgical rooms and is used to re-sterilize items if serial surgeries are planned. If more than one large animal survival surgery is planned in one day, the instruments are re-sterilized in the autoclave or different sterile surgical packs are used

d. Indicate how effectiveness of sterilization is monitored.

Additionally, during each use temperature sensitive autoclave tape is placed on the interior (if possible) and exterior of the item(s) to be steam sterilized to indicate complete sterilization.

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

Dressing areas are located just outside the operating room suite in (b)(7)(F) (men's locker room) and (b)(7)(F) (women's locker room). (b)(7)(F) is the location of the surgeons' scrub sinks and (b)(7)(F) contains the autoclave for sterilizing instruments, linen packs, etc. (b)(7)(F) also contains sink and instrument washers for instrument cleaning prior to sterilization and after use.

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.

An intraoperative recording sheet and post-operative monitoring form must be completed on all USDA regulated species undergoing survival surgery within the IDEXX NEO Software. The intra-operative recording sheet includes a full description of the procedure, all pre-medications and length of surgery. Additional information is recorded detailing vital signs recorded every 15 minutes during procedure, recovery record and complications before, during and after procedure. The post-operative monitoring form includes all pertinent contact information, care requests for animal care staff., all treatments/analgesics given and daily observations of vital signs, attitude, posture, appetite, weight, incisions and temperature. All USDA species records are maintained in the IDEXX NEO online software. Once an animal has completed the protocol, the medical history/surgical forms are printed out to be filed in hardcopy and they remain online.
All records for non-survival surgeries and rodent surgeries are maintained with the investigator and research staff. The IACUC reviews these records during semi-annual inspections. Procedure description, vitals recording, anesthetic used, complications and analgesics used must be recorded as well as anesthesia monitoring during the procedure.

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.

The post-surgical care program is managed in accordance with investigative directives and specific animal needs. Veterinary staff provide routine care (daily inspection, food and water, sanitation, exercise, etc.), minor wound care and administer prescribed antibiotics and analgesia. It is the responsibility of the investigative staff to coordinate with the Animal Health Technician and provide the animal with special care such as administering fluid, major wound care, and maintenance of indwelling catheters. The investigative staff is also responsible for the management of emergencies (i.e., wound dehiscence, secondary closures, respiratory or neurological problems, etc.) as well as notifying veterinary staff of these procedures. Animals housed chronically are physically and physiologically monitored by animal research staff to ensure their well-being and freedom from disease during rehabilitative care. For USDA species, all records (post-operative care notes, surgical notes, wound care, daily notes) are maintained on IDEXX NEO online software. In addition, the investigator keeps research specific records. The consultant veterinarian oversees this program. Non- USDA species records are maintained by the individual

investigator and their staff.

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

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

Initially, the principal investigator determines the anticipated pain level and submits it on his protocol form to the IACUC. The committee reviews the protocol and discusses the pain and distress level and decides if the correct pain level has been selected and if alleviation methods are adequate. Methods to further relieve pain and distress to the animals are suggested if necessary. If the committee is unsure what level of pain and distress is involved in the protocol, the Attending Veterinarian will be asked to observe a small pilot study.

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

All personnel must complete the species-specific CITI training module which details species specific behavioral manifestations of pain and distress. This is reviewed by the IACUC prior to approval to start animal procedures. All procedures which cause pain in humans should be assumed to cause pain and distress to animals. This is stressed in the annual Animal Handler training completed by the VMU Supervisor.

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.

The protocols involving dogs with survival surgery uses Acepromazine, Pentobarbital, Sodium Thiopental or Methohexital for pre-anesthesia and Isoflurane for anesthesia and Buprenorphine, Buprenorphine SR, Meloxicam, Meloxicam SR or Carprofen for post-operative analgesia. We have one study that is trying to determine the best anesthetic to use in canine survival surgeries which in addition to the agents listed above uses: Ketamine, Propofol, Alfaxalone, Midazolam and Fentanyl. The protocols involving swine and sheep uses Acepromazine, Ketamine, Propofol, Atropine and Lidocaine for pre-anesthesia with Isoflurane for anesthesia. Swine and sheep are given Buprenorphine, Buprenorphine SR, Meloxicam and Meloxicam SR for analgesia. Rodent studies use Pentobarbital or Isoflurane for anesthesia and Buprenorphine (SR LAB), Acetaminophen or aspirin for post-operative analgesia.

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

(b)(6) Consultant Veterinarian, edits and maintains the listings of recommended species-specific methods for anesthesia, analgesia and sedation in the Animal Research Facility Standard Operating Procedure document which is made available to each investigator and approved by the IACUC annually. (b)(6) pre-reviews all initial submissions and advises researchers on their anesthetic and analgesic choices at that time. Additionally, pain moderation is reviewed by the IACUC prior to initiating the study. (b)(6) and the LVT are also available for further consultation when necessary.

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.

The use of anesthetics and analgesics is monitored by the Principal Investigator, VMU Supervisor and the Consultant Veterinarian. Animals are evaluated post-operatively by Principle investigator, Animal Health Technician, VMU Supervisor and Veterinarian. Post-operative notes are recorded in the books maintained by the investigator or in the electronic system. If any discomfort is noted, new strategies are implemented after consulting with the Veterinarian.

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 can only be used in conjunction with another appropriate anesthetic agent to achieve a surgical plane of anesthesia. Use of these agents must be justified in the animal component protocol with a specific plan to monitor anesthesia levels to ensure no pain is felt and approved by the IACUC.

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

The isoflurane vaporizers are returned to Surgi-vet as required by the manufacturer for service and maintenance. This is done by the VMU Supervisor.

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.

Barbiturate overdose is an approved for dogs, sheep and swine (IV), rodents (IP) and

neonates (IP). Carbon dioxide overdose is approved for rodents (adults) using the TBJ Model REM-1 euthanasia system in the Animal Facility which follows the parameters set by the AVMA Guidelines for Euthanasia. We have protocols approved for heart removal under deep anesthesia in rats, mice, swine, sheep and canines and exsanguinations under deep anesthesia prior to perfusion in mice and rats. Additionally, Isoflurane overdose is approved for mice and guillotine for rats. All procedures must be done outside of the animal housing rooms.

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

The carbon dioxide tank is maintained by the Animal Facility staff. The research personnel are required to physically check the sharpness of the guillotine blade prior to each use. The VMU Supervisor has it professionally sharpened as needed.

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

The standard operating procedures for the use of the CO2 chamber requires animals to remain in the chamber for 3-5 minutes. Death must then be confirmed by cessation of vital signs, thoracotomy or cervical dislocation. Overdose of barbiturates requires visual observation for 3-5 minutes and death is confirmed by cessation of vital signs.

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 animal facility and surgical suite are (b)(7)(F) (b)(7)(F) All animal housing and use facilities are contained in these two areas exclusively.

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 Animal facility is arranged with a single corridor bidirectional circulation pattern. The Cage washing area is central to the facility and dual sided with a clean/dirty pass through. All animal holding rooms open directly into the double loaded corridor. The quarantine suite is located adjacent (b)(7)(F) to prevent contamination of the facility. The surgical suite is separated from the animal holding area by two double doors and a corridor.

(b)(7)(F)

Mice and rats are housed in conventional caging during quarantine and are transferred to individually ventilated caging after quarantine. There is one mouse room dedicated to aseptic housing/immune-deficient mice/re-derived mice from other facilities.
Radioactive studies will use either disposable conventional caging (short term studies) or conventional caging with filter tops (long term studies)
Infectious and chemical containment occurs in IVC or conventional caging.
Canines, sheep and swine are housed in chain link runs that are two to five per room.

The animal facility flooring is epoxy painted concrete with floor level drains. The facility floors were repainted with high traffic rexthane paint with 'sharkskin' to improve traction in 2019. The large animal runs have plastic coated walls to prevent paint chipping. The large animal runs have plastisol coated grates for raised flooring. All doors are painted and sanitized. All surfaces can be sanitized.

The Infectious disease suite has isolation chambers within the room and a pass-through steam sterilizer. The HVAC contains a HEPA filter and negative air flow.

The Animal facility is secured (b)(7)(F)

(b)(7)(F)

No windows are in animal rooms. (b)(7)(F)

(b)(7)(F)

(b)(7)(F)

(b)(7)(F)

(b)(7)(F)

(b)(7)(F)

(b)(7)(F)

(b)(7)(F)

The facility has a chemical storage room that is on an opposite corridor from the animal holding rooms. Cage wash chemicals are used and stored in the dirty side of the cage wash room that also contains the emergency shower and eye wash. Small amounts (less than 5G) of sterilizing chemical are contained in secondary containment in each large animal room. The chemical container is fastened to the wall with a stainless steel bracket and not within reach of animals within their runs.

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.

Any area approved by the IACUC to house animals longer than 12 hours to satisfy a scientific aim of a protocol is determined to be a Satellite Animal Housing Area.

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.

The investigator must provide justification in the ACORP to house animals outside of the centrally maintained facility. The satellite facility must be inspected to ensure compliance with the Guide prior to starting any housing. Sanitation records are maintained by the lab and the HVAC is tested in concert with the centrally maintained facility. The IACUC inspects this area during all semi-annual inspections. The Veterinarian has access at all times. The satellite animal housing area (b)(7)(F)

(b)(7)(F)

(b)(7)(F)

(b)(7)(F)

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 lighting is available to entire animal facility. Emergency power is available to limited areas of the facility. Operating rooms and all red plug outlets operate during emergency generator usage. The ventilated cage systems are powered by an emergency 'red plug' outlet to prevent complete power failure during an emergency.
Emergency flashlights are available in the event of a power outage. We requested and received emergency lighting with our renovations in December 1989 through February 1990. Hurricane Irene caused a hospital wide power failure during the summer of 2011 for approximately 8 hours. The air temperature was monitored during this time and never went above 72F since this power outage occurred at night and the outside temperatures were cooler.

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).

We have never had an animal loss or animal health problem due to power failures. During the installation of the new HVAC system in the VMU in the Summer of 2018, the HVAC system had to be completely shut down while switching to the new system. The shutdown lasted 11 hours. Animal facility staff were on site for the duration of the shutdown monitoring temperatures every hour. Portable A/C and dehumidifier units were put in every animal room and throughout the hallways. Temperatures did not exceed 72 degrees. The humidity did increase to above 90% in all rooms but there was no impact to animal welfare. This IACUC was notified of this event and that no animal health problems resulted.

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.

Not applicable

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

Not applicable

Appendix 1: Glossary of Abbreviations and Acronyms

Please provide a Table defining abbreviations and acronyms used in this Program Description.

Abbreviation/Acronym	Definition
ACORP	Animal Component of Research Protocol
VMU	Veterinary Medical Unit- also known as Animal Research Facility
IACUC	Institutional Animal Care and Use Committee
SRS	Subcommittee on Research Safety
IBC	Institutional Biosafety Committee
HVAC	Heating, Ventilation and Air Conditioning
PIV	Personal Identity Verification- identification card used at VA
VA	Veterans Affairs
CITI	Collaborative Institutional Training Initiative
LVT	Licensed Veterinary Technician
R&Dor RDC	Research and Development Committee
CHO	Chemical Hygiene Officer
VAIRRS	VA Innovation and Research Review System (IRBnet)

Appendix 2: Summary of Animal Housing and Support Sites

Briefly summarize in the following Table the animal facility or facilities, noting the number of areas in which animals are housed (buildings, floors, farms, etc.), the total square footage/metres (or acreage) for animal care and use, and the total square footage/metres (or acreage) for necessary support of the animal care and use program covered by this Description (water treatment plant/area if housing aquatic or amphibian species, cagewashing facilities, service corridors, etc. and additional areas to be considered are enumerated in the *Guide*). If more than one facility/site, note the approximate distance (yards/miles or meters/kilometers) to each facility from a reference point such as from the largest animal facility. A campus/site map (with a distance scale) may be included as an additional Appendix (Appendix 2.1) to provide this information. See Instructions, Addendum A - Animal Facility Square Footage/Meters Compilation Form for guidance in calculating the size of your animal care and use program.

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**
(b)(7)(F)	(b)(7)(F)	3900	6100	Dogs	15	(b)(6)
				Rats	100	
				Mice	600	
				Swine	4	
				Sheep	0	

Totals:		
Total animal housing and support space:	**10,000ft²** **(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

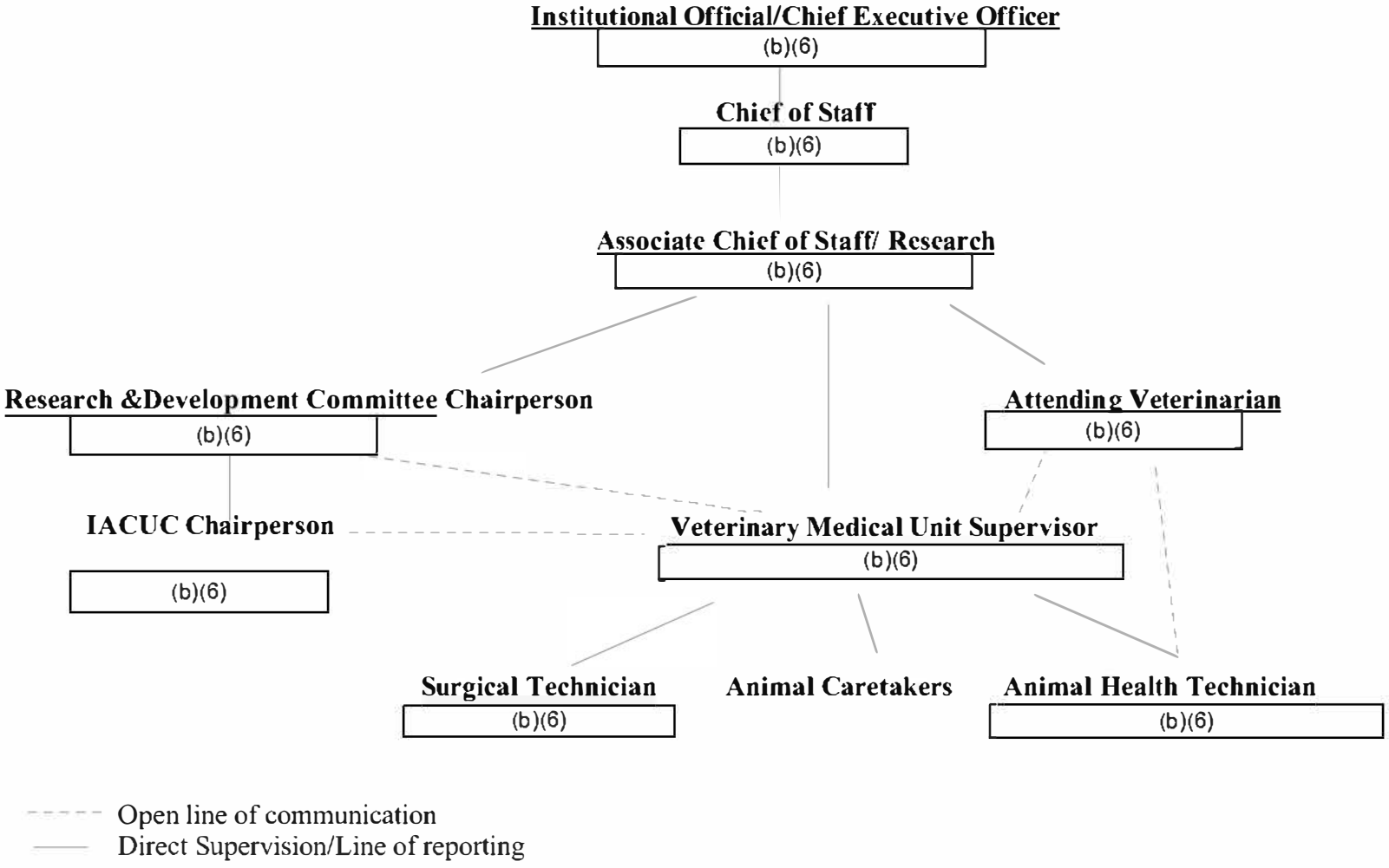
Provide floor plans of each centralized animal housing facility. Plans should be provided on 8.5" x 11" or A4 paper. Ensure that the drawings are legible, including room numbers if used, and the use of each room is indicated (animal housing, procedure room, clean cage storage, hazardous waste storage, etc.) either directly on the drawing or in a Key/Table.

MAP OF ANIMAL RESEARCH FACILITY

(b)(7)(F)

Appendix 4: Organizational Chart(s)

Provide an accurate, current, and detailed organization chart or charts that detail the lines of authority from the Institutional Official to the Attending Veterinarian, the IACUC/OB, and personnel providing animal care. If applicable, include personnel responsible for managing satellite housing areas/locations and depict the reporting relationship between the Attending Veterinarian and other(s) having a direct role in providing veterinary care.



Appendix 5: Animal Usage

In order to assist the site visitors in their evaluation of the animal care and use program, please provide the information requested below. Information should be provided for all animals approved for use in research, teaching or testing, including those which may be used or housed in laboratories outside the animal care facility. Of particular interest is information on those animals which are used in research projects involving recovery surgical procedures, behavioral or other testing requiring chairing or other forms of restraint, or exposure to potentially hazardous materials. An alternate format is acceptable as long as the information requested is provided.

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)
Testing of Noninvasive TMS in rat brain for treatment of movement disorders	02418	(b)(6)	Rat	264	D	✓			✓		✓
Advancement and Application of a Novel Basal Ganglia Thalamocortical Circuitry Model in Dystonic Rats	02206	(b)(6)	Rat	581	D/E	✓	✓		✓	✓	✓
Sphingolipids in Obesity	02385	(b)(6)	Mouse	336	C						✓
Attentuating microglial-dependent axonal pathology in EAE	02493	(b)(6)	Mice	2361	D/E					✓	
The Roles of Microglial Neurofascin in Inflammatory	02445	(b)(6)	Mice	7500	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)
Disease											
The Role of Sulfatide in Alzheimer's Disease	02446	(b)(6)	Mice	2400	D/E						
Lymphoma development in elderly perturbed post-transcriptional regulation	02492	(b)(6)	Mice	10000	D					✓	
Cholesterol Regulation of Macrophage Inflammation and Vascular Disease	01939	(b)(6)	Mice	600	C			✓			
The effect of optical and electrical stimulation of NBM on cognition and memory in rats	02288	(b)(6)	Rats	130	D	✓	✓		✓	✓	✓
Mechanistic Insight of PVC induced cardiomyopathy	02232	(b)(6)	Dog	54	D	✓	✓				
Validation of a Premature Ventricular Contraction-induced Cardiomyopathy on a Swine Model	02480	(b)(6)	Swine	56	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)
Optimizing Echocardiographic Imaging In a Cardiomyopathy Swing Model	02494	(b)(6)	Swine	10	D	✓					
Validation of a Premature Ventricular Contraction Induced Cardiomyopathy on a Sheep Model	02499	(b)(6)	Sheep	54	D	✓	✓		✓		
Evaluation of ablation lesions in a swine model	02384	(b)(6)	Swine	6	D	✓					
Epileptogenesis and Network Dysfunction of TBI	02450	(b)(6)	Rats	133	D	✓					
Aging Heart: Basis of Increased Ischemic/Reflow Injury	01499	(b)(6)	Rats	200	D						✓
Reduction of cardiac injury by targeting damaged mitochondria during reperfusion	01552	(b)(6)	Mice	2400	D						✓
Reduction of cardiac injury by targeting damaged	01715	(b)(6)	Mice	1500	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)
mitochondria during reperfusion (in vivo surgery)											
Myocardial Infarction in the Aging Heart	●2156	(b)(6)	Mice	24●0	D	✓					
High Dose Acetaminophen for the Treatment of Malignancies	●2444	(b)(6)	Mice	28●0	D	✓				✓	
Cholesterol, Its Metabolites, and Nonalcoholic Steatohepatitis	●1595	(b)(6)	Mice	75●	D	✓		✓		✓	✓
Inhibition of IGF-1R: A Therapeutic Strategy for Colon Cancer Stem-Like Cells (MR2)	●214●	(b)(6)	Mice	21●0	D					✓	
STARD5 regulates colon cancer stem cell growth	●2241	(b)(6)	Mice	96	D					✓	
Development of a Selective Non-Saccharide Glycosaminoglycan Mimetic for Colon	●2529	(b)(6)	Mice	30●0	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)
Cancer											
StarD5, a protein that translocates cholesterol to the plasma membrane, is a novel target for Colon Cancer	02541	(b)(6)	Mouse	1100	D					✓	
Unique Non-Saccharide Mimetics of Sulfated Glycosaminoglycan Target Colon Cancer Stem Cells	02544	(b)(6)	Mouse	630	D					✓	
Mitochondrial metabolic modulation to minimize ischemic damage in donor heart	02253	(b)(6)	Rats	318	D	✓	✓				✓
Study the Role of Oxysterol Sulfates in NAFLD Development	01426	(b)(6)	Mice	200	D	✓		✓			
A comparison of Canine Anesthetic Regimens to Optimize Hemodynamic	02289	(b)(6)	Canine	8	C						

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)
Stability and Quality of EP Data Acquisition											
A Novel Controller/Regulator of Intracellular Cholesterol Distribution and Efflux	1756	(b)(6)	Mice	550	C						
CRTAM-CADM-1 A T Cell and Tumor Cell Interaction: Defining its role in Tumor Regression and its Clinical Implications	2470	(b)(6)	Mice	500	D						
StarD5, a Cholesterol Transporter Protein, is a Critical Regulator of Colon Cancer Stem Cells	2483	(b)(6)	Mice	310	D					✓	
Richmond VAMC Rodent Health Surveillance	1958	(b)(6)	Mice	48	D						
Richmond VAMC Rodent Health Surveillance	2046	(b)(6)	Rats	18	D						
Autonomic Nerve	2002	(b)(6)	Dogs	34	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)
Activity and Cardiac Arrhythmias											
Nanoparticle Injection into GNP	02235	(b)(6)	Dog	20	D	✓	✓			✓	
Validation of Swine as a Suitable animal Model for Testing a Novel Therapy for Postoperative Atrial Fibrillation using Nanoformulated Calcium Chloride to Suppress Cardiac Ganglionated Plexi	02511	(b)(6)	Swine	52	D	✓	✓		✓	✓	
Innate Pattern Recognition Receptors Acetaminophen-Induced Liver Injury	02053	(b)(6)	Mouse	1200	B/D/E					✓	✓
Mechanisms of Berberine for the treatment of NAFLD	02345	(b)(6)	Mouse	240	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)

Appendix 5: Animal Usage

(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:

We use the USDA Pain/Distress Category system for all species.

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

Animal Type or Species	Approximate Annual Use
Mouse	2000
Rat	200
Dog	25

Animal Type or Species	Approximate Annual Use
Swine	15
Sheep	

[Create additional rows by pressing TAB in the bottom-right box.]

Appendix 6: Personnel Medical Evaluation Form

Provide a ***blank*** copy of form(s) used by medically-trained personnel to review individual health assessment, individual risk assessment, health history evaluation, health questionnaire, periodic medical evaluation, etc. If form(s) are not used, include a description of how such evaluations are performed in the Program Description (Section 2.I.A.2.b.ii.1).d), Section 2 (Description). I (Animal Care and Use Program). A (Program Management). 2 (Personnel Management). b (Occupational Health and Safety or Personnel). ii (Standard Working Conditions and Baseline Precautions). 1) (Medical Evaluation and Preventive Medicine for Personnel). d).

Confidential Medical Information
Significant Biological Agent or Animal Contact Health Surveillance Questionnaire

Return to: Medical Director, Occupational Health Services
(b)(6)
Phone: 804 675 5000 ext (b)(6) Fax (b)(6)

*Please complete **ALL** of the following information:*

Name:_____Birth date: _____

SSN #_____

Department: _____ E-mail:_____

Phone: _____

Status: ☐ Faculty ☐ Veterinarian ☐ Research Technician
☐ Student ☐ Biologist ☐ Microbiologist
☐ Animal Handler ☐ Pathologist ☐ Other _____

Work history: Indicate the type/s of species of animals you will be handling (Check all that apply):

☐ Dogs ☐ Cats ☐ Cattle ☐ Horses ☐ Guinea Pigs ☐ Hogs
☐ Primates ☐ Rabbits ☐ Goats ☐ Sheep ☐ Rats or Mice
☐ Ferrets ☐ Opossums ☐ Frogs ☐ Birds ☐ Other (list):_____

For use with **live animals** only, any work with:

A) **Recombinant DNA**	☐ Yes	☐ No	
B) **Infectious Agents**	☐ Yes	☐ No	please list: _____
C) **Blood borne Pathogens**	☐ Yes	☐ No	
D) **Human Cell lines**	☐ Yes	☐ No	
E) **Extremely Hazardous Agents**	☐ Yes	☐ No	please list: _____
F) **Radiation**	☐ Yes	☐ No	please list: _____
G) **Lasers** (Class 3b, 4a)	☐ Yes	☐ No	please list: _____
H) **Toxins**	☐ Yes	☐ No	please list: _____

Appendix 6: Personnel Medical Evaluation Form

Medical History:
Have you ever contracted a disease from animals, or experienced an animal related injury (including bites, scratches, needle sticks, etc.)? ☐ Yes ☐ No If yes, please explain below:

Have you been told by a physician that you have an immune compromising medical condition or are you taking medications that impair your immune system (steroids, immunosuppressive drugs, or chemotherapy)? ☐ Yes ☐ No If yes, explain below:

Are you currently taking any medications? ☐ Yes ☐ No If yes, list below:

For Women: Are you pregnant, or planning to be pregnant in the next year? ☐ Yes ☐ No

Do you have any ongoing medical problems? If yes, explain.
Have you had (check all that apply)?:

☐ Pneumonia	☐ Recurrent Bronchitis	☐ Tuberculosis
☐ Heart Disease	☐ Rheumatic Fever	☐ Heart murmur & Valve Disease
☐ Diabetes	☐ Kidney Disease	☐ Gastrointestinal Disorder
☐ Cancer	☐ Liver Disease	☐ Loss of Consciousness
☐ Seizures	☐ Arthritis	☐ Chronic Back or Joint Pain

Allergy History:
List any allergies to medications: _____

Do you have any of the following symptoms (Check all that apply)?:

☐ Chronic cough	☐ Asthma	☐ Itchy, irritated eyes
☐ Hay fever	☐ Skin rash	☐ Chronic allergies (food, pollens, dust)

Are you allergic to (Check all that apply)?

☐ Dog	☐ Cat	☐ Cattle	☐ Horse	☐ Bird (feathers)
☐ Hog	☐ Primates	☐ Rabbit	☐ Goat	☐ Sheep (wool)
☐ Rat or mice	☐ Guinea Pig	☐ Alfalfa	☐ Weeds	☐ Trees
☐ Chemicals	☐ Latex	☐ Wood	☐ Grasses	☐ Other (list):

Immunizations: (Complete **IF NOT** previously evaluated at Employee Health)
Indicate date of most recent vaccination (or blood test to document immunity). Mark "X" if you do not recall the date. Mark "?" or leave blank if you are unsure.

Measles _____ Mumps _____ Rubella _____ Hepatitis A _____
Hepatitis B _____ Rabies _____ CMV _____ Toxoplasmosis _____
"Q" Fever _____ Yellow Fever _____ Vaccinia ("smallpox") _____
Tuberculosis vaccine (BCG) _____ Place of birth _____
Primary Language _____

Appendix 6: Personnel Medical Evaluation Form

Date of last tetanus booster: _____
Date of last rabies booster: _____
Date of last rabies titer: _____
Date of last serum sample: _____
Tuberculosis Skin Testing: _____
Date of last PPD skin test: _____ ☐ Positive, ☐ Negative
If POSITIVE, date of last Chest X-ray: _____
If POSITIVE in the past, are you having any of the following symptoms (check box)?

☐ Fever ☐ Chronic cough ☐ Bloody sputum ☐ Weight loss ☐ Shortness of breath

Appendix 7: IACUC/OB Membership Roster

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

Member Name	Specialty	Term Exp.
(b)(6) (Chairperson)	Neuroscientist	1/1/2021
(b)(6) D.V.M., M.S.	Veterinarian Vice Chairperson	8/27/2020
(b)(6)	Cardiologist/Scientist	12/01/2021
(b)(6)	Director, Animal Research Facility	3/1/20122
(b)(6)	Safety Committee (CHO), R&D	
(b)(6)	Non-affiliated Non-Scientist Member	06/25/2021
(b)(6)	Non-affiliated Member	05/01/2022
Ex Officio Non-Voting Members		
(b)(6)	Animal Health Technician	N/A
Alternate Voting Members		
(b)(6)	Non-affiliated Non-Scientist	5/1/2023
(b)(6)	Non-affiliated Non-Scientist	8/31/2019

Appendix 8: IACUC/OB Minutes

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

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.
For Initial reviews:

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
      ►

Appendix 9: IACUC/OB Protocol Form

(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 briefly summarize 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.
►

Appendix 9: IACUC/OB Protocol Form

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

Appendix 9: IACUC/OB Protocol Form

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.**

Appendix 9: IACUC/OB Protocol Form

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	Year4	Year 5	**Category B TOTAL**

Appendix 9: IACUC/OB Protocol Form

USDA Category C

Procedures▶						
Species / Experimental Group / Procedure(s)	Year 1	Year 2	Year 3	Year4	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	Year4	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.

Appendix 9: IACUC/OB Protocol Form

► ( ) 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

Appendix 9: IACUC/OB Protocol Form

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.

►

Appendix 9: IACUC/OB Protocol Form

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
		( )	( )
		( )	( )
		( )	( )

Appendix 9: IACUC/OB Protocol Form

► ( ) 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.

Appendix 9: IACUC/OB Protocol Form

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.

Appendix 9: IACUC/OB Protocol Form

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 maybe 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►		( )	( )	( )

Appendix 9: IACUC/OB Protocol Form

( )	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►

Appendix 9: IACUC/OB Protocol Form

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.

Appendix 9: IACUC/OB Protocol Form

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 covered by the search	Potentially painful or distressing procedures addressed	Key words and/or search strategy used	Indicate which mandate each search 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.
   ►

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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?

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► ( ) 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

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	Title	ID	Date
C.2.c			
M.1			
M.2			
U.4.a			
U.4.b			
V			

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:

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- 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

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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

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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

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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

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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

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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

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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.

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ACORP Appendix 1

ADDITIONAL LOCAL INFORMATION

VERSION 4

(This appendix may be used to collect additional information required by the local IACUC. See ACORP App. 1 Instructions, for more detailed explanations of the information requested.)

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ACORP Appendix 2

Antibody Production

Version 4

See ACORP App. 2 Instructions, for more detailed explanations of the information requested.

1. **Immunization.** Provide the information requested below for any animals to be used for raising antibodies specifically for use in this protocol.

   a. Describe the immunization protocol in the table below, using a separate row for each day on which any agent (including primer, antigen, and/or adjuvant) will be administered. (Make sure that each primer, antigen, and adjuvant is also included in Appendix 3.)

Immunization day (e.g. day -7, 0, 7, 30, etc.)	Antigen		Adjuvant – give name, concentration, and volume (ml)	Total injection volume (ml) per animal (antigen plus adjuvant)	Divided among how many injection sites?	Injection route and location of injection site(s) on body
	Name	Total amount (mg) and volume (ml)				

   b. Describe how each antigen will be screened to make sure that it does not harbor infectious agents that could infect other laboratory animals or people after injection.
   ▶

   c. List possible adverse effects that might be observed in animals receiving the proposed primer, antigen, and/or adjuvant injections, and describe the measures that will be taken if these adverse effects occur:
   ▶

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d. Give the justification for using any primer or adjuvant that is expected to cause pain or distress in the animals.
►

2. **Survival Blood Collection.** Will blood be collected as a survival procedure for the production and harvesting of antibodies on this protocol?

► ( ) No, the production and harvest of antibodies on this protocol does not involve survival collection of blood.

► ( ) Yes, this protocol requires the collection of blood in a survival procedure, before (as a "pre-bleed") and/or after immunization. Make sure this is included in Item R of the ACORP, and complete items 2.a, 2.b, and 2.c, below.

a. Describe each survival collection of blood in the table below, including any "pre-bleeds" prior to immunizations:

Site of Blood Collection	Amount of Blood Collected at any one time, expressed as volume (ml) and as % of body weight (assume 1 ml = 1 gram)	Number of Blood Collections	Time Interval(s) Between Successive Collections	Volume Replace-ment? (yes/no)

b. Will anesthetics, tranquilizers, or analgesics be administered for blood collection?

► ( ) No anesthetics, tranquilizers, or analgesics will be administered for blood collection.
Explain why it is appropriate or necessary NOT to administer pain-relieving agents:

►

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► ( ) Yes. Describe the administration of pain-relieving agents, including the name of each agent, and its dose (mg/kg), volume (ml), and route and frequency/duration of administration (Make sure this information is also included in Appendix 3):

►

c. Will volume replacement be provided for blood that is collected?

► ( ) Volume will NOT be replaced for some of the blood collection listed. For each collection listed in Item 2.a, above, for which volume will NOT be replaced, explain why not.

►

► ( ) Volume WILL be replaced for some of the blood collection listed. For each collection listed in Item 2.a, above, for which volume WILL be replaced, describe the replacement(s) that will be provided (including the composition of the replacement(s), volume, and route of administration).

►

3. **Terminal Blood Collection.** Will animals be euthanatized by exsanguination, for harvest of antibodies?

► ( ) No, this protocol does NOT involve terminal blood collection for harvest of antibodies.

► ( ) Yes, this protocol DOES require terminal blood collection for the harvest of antibodies. Make sure this is included in Item R of the ACORP, and complete Items 3.a., 3. b., and 3.c., below:

a. Describe the method(s) to be used for euthanasia and exsanguination:
►

b. Will anesthetics, tranquilizers, or analgesics be administered for exsanguination?

► ( ) No anesthetics, tranquilizers, or analgesics will be administered for the exsanguination(s). Explain why it is appropriate or necessary NOT to administer pain-relieving agents:

►

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► ( ) Yes. Describe the administration of pain-relieving agents including the name of each agent, and its dose (mg/kg), volume (ml), and route and frequency/duration of administration (Make sure this information is also included in Appendix 3):

►

c. Describe how you will make sure that the animals are dead after collection of the blood:
►

4. **Harvesting Feeder Cells.** Describe the exact procedures (including administration of pain-relieving agents) that will be used on any donor animals from which feeder cells will be collected for this protocol, and estimate the number of animals needed for this purpose. Make sure that these animals are included in Item I of the ACORP, and that the harvesting of feeder cells is included in Item R of the ACORP.
►

5. **Expansion of Hybridoma Cell Line(s) *in vivo*.** Will any animals be used to expand hybridoma cell lines so that antibody can be harvested from ascites fluid?

► ( ) No animals will be used on this protocol for *in vivo* expansion of hybridoma cell lines.

► ( ) Yes, this protocol requires use of some animals for *in vivo* expansion of hybridoma cell lines. Make sure that the animals used for this are included in Item I of the ACORP, the priming agent and the hybridoma cells are documented in Appendix 3, and the collection of ascites fluid is included in Item R of the ACORP. Complete items 5.a, 5.b, and 5.c, below.

a. Explain why alternate research methods that do not require the use of additional animals (e.g., *in vitro* cell culture systems for harvesting monoclonal antibodies) are not adequate to meet the research objectives of this project.
►

b. Complete the following table to summarize the procedures to be performed in expanding the hybridoma cell lines and collecting ascites fluid:

Hybridoma cell line designation	Number of animals to be used for ascites production	Priming agent and volume	Number and timing of priming injections	Volume of injected hybridoma cells	Number of abdominal taps before euthanasia

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c. Describe the exact procedures (including administration of pain-relieving agents) that will be used for the abdominal taps to be performed on this protocol
▶

d. List the criteria for euthanasia of animals prior to the last planned abdominal tap.
▶

(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.)

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ACORP APPENDIX 3
BIOSAFETY
VERSION 4

See ACORP App. 3 Instructions, for more detailed explanations of the information requested.

1. **Summary of <u>All</u> Materials Administered to Animals on this Protocol.** Complete the table below for <u>all</u> materials to be administered to any animal on this protocol, indicating the nature of the material by marking EVERY box that applies, and indicating the BSL number for any infectious agents:

Material (Identify the specific agent, device, strain, construct, isotope, etc.)	**Source** (Identify the vendor or colleague, or specify which animals on this protocol will serve as donors)	**Nature of Material**						
		Toxic Agent (Item 4)	Infectious Agent (Item 5) -- Enter the CDC Biosafety Level (BSL 1, 2, 3, or 4)	Biological Agent (Item 6)	Radioactive Agent (Item 7)	Contains Recombinant Nucleic Acid (Item 8)	Routine Pre- or Post-Procedural ☐Drug	Euthanasia agent
		( )	( )BSL_	( )	( )	( )	( )	( )
		( )	( )BSL_	( )	( )	( )	( )	( )
		( )	( )BSL_	( )	( )	( )	( )	( )
		( )	( )BSL_	( )	( )	( )	( )	( )
		( )	( )BSL_	( )	( )	( )	( )	( )
		( )	( )BSL_	( )	( )	( )	( )	( )

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2. **Summary of How Materials will be Administered.** Complete the table below for each of the materials shown in the table in Item 1 above:

Material* (Identify the specific agent, device, strain, construct, isotope, etc.)	**Dose** (e.g., mg/kg, CFU, PFU, number of cells, mCi) and **Volume** (ml)	**Diluent* or Vehicle***	**Route** of admin	**Frequency or duration** of admin	**Reason** for Administration and **Expected Effects**	Location of **Further Details** in this ACORP (specify "Main Body" or "App #", and identify the Item)	Administration Under **Anesthesia, sedation, or tranquilization (Y/N)**

*Each material, diluent, or vehicle that is listed as FDA approved or is labeled "USP" is pharmaceutical grade. Check on-line for formulations that are FDA approved for administration to humans (http://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm) or animals (http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/UCM042847). Designate with a * each material and each diluent or vehicle to be used that is not pharmaceutical grade. For each of these, explain here why the use of a non-pharmaceutical grade formulation is necessary, and describe how it will be ensured that the material is suitable for use. (See ACORP App. 3 Instructions, for specifics about the level of detail required.)

►

3. **Anesthesia, Sedation, or Tranquilization.** Complete 3.a. and 3.b. below:

a. For each material with "Y" entered in the last column of the table in Item 2 above, describe the anesthesia, sedation, or tranquilization to be used, identifying the anesthetic, sedative, or chemical tranquilizer, and detailing the dose, volume, and route of administration (Make sure that these agents are also included in Item 1 of this appendix, as materials to be administered):
►

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b. For each material with "N" entered in the last column of the table in Item 2 above, explain why no anesthesia, sedation, or tranquilization is necessary, or can be provided, and describe any alternate methods of restraint that will be used.
▶

4. **Toxic Agents.** Complete the table below for each of the materials listed as a "toxic agent" in the table in Item 1 above, checking the all of the properties that apply (see ACORP App. 3 Instructions, for details).

Name of Toxic Agent	a. Mutagen	b. Carcinogen	c. Teratogen	d. Select Agent?			e. Other – specify toxic properties
				Not a Select Agent	Select Agent Used in Sub-threshold Quantities	Select Agent that Requires Registration/Approval	
	( )	( )	( )	( )	( )	( )*	( )▶
	( )	( )	( )	( )	( )	( )*	( )▶
	( )	( )	( )	( )	( )	( )*	( )▶
	( )	( )	( )	( )	( )	( )*	( )▶
	( )	( )	( )	( )	( )	( )*	( )▶
	( )	( )	( )	( )	( )	( )*	( )▶

*For each "select agent" that requires registration/approval (copy the lines below for each agent):

Name of agent ▶

Registered with CDC or USDA ▶

Registration Number ▶

Registration Date ▶

Expiration Date of Registration ▶

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Name of official who granted approval on behalf of VACO►

Date of approval►

5. **Infectious Agents.** Complete the table below for each of the materials listed as an "infectious agent" in the table in Item 1 above (see ACORP App. 3 Instructions, for details).

Name and BSL Number of Infectious Agent	a. ABSL Number *	b. Drug Sensitivity Panel Available? (Describe)	c. Select Agent?		
			Not a Select Agent	Select Agent used in Sub-threshold quantities	Select Agent that Requires Registration/Approval
		(Yes/No)	( )	( )	( )**
		(Yes/No)	( )	( )	( )**
		(Yes/No)	( )	( )	( )**
		(Yes/No)	( )	( )	( )**
		(Yes/No)	( )	( )	( )**
		(Yes/No)	( )	( )	( )**

*Complete the following for each agent for which the ABSL Number given is less than the BSL Number shown (copy the lines below for each agent):

Name of agent ►

Justification for applying ABSL measures that are less protective than those recommended ►

**For each "select agent" that requires registration/approval (copy the lines below for each agent):

Name of agent ►

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Registered with CDC or USDA ►

Registration Number ►

Registration Date ►

Expiration Date of Registration ►

Name of official who granted approval on behalf of VACO►

Date of approval►

6. **Biological Agents.** Complete the table below for each of the materials listed as a "biological agent" in the table in Item 1 above (see ACORP App. 3 Instructions, for details).

Name of Biological Agent	Screening for Infectious Agents

7. **Radioactive Agents.** Complete the table below for each of the agents listed as a "radioactive agent" in the table in Item 1 above (see ACORP App. 3 Instructions, for details).

Name of Radioactive Agent (specify the isotope)	Authorized Individual	Approving Committee or Official

8. **Agents Containing Recombinant Nucleic Acid.** For each of the materials checked in the table in Item 1, above, as "contains recombinant nucleic acid", indicate which of the conditions applies (see ACORP App. 3 Instructions, for details).

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Name of Agent that Contains Recombinant Nucleic Acid	Subject to the *NIH Guidelines for Research Involving Recombinant DNA Molecules*	Exempt
	( )	( )
	( )	( )
	( )	( )
	( )	( )
	( )	( )
	( )	( )

9. **Potential for Pain or Distress.** Complete the table below for each of the agents listed in Item 1, above, that is expected to have potentially painful or distressing effects on the animals (see ACORP App. 3 Instructions, for details).

Name of Agent	Nature of Potential Pain/Distress	Measures to Alleviate Pain/Distress

10. **Protection of Animal Facility Staff from Hazardous Materials.** Complete Items 10.a and 10.b, below, for each of the agents listed in the table in Item 1, above, as "toxic", "infectious", "biological", "radioactive", or "contains recombinant nucleic acid" (detailed in Items 4 – 8). This item specifically addresses members of the animal facility staff; protection of the research staff from each of these agents must be addressed in Item G of the main body of the ACORP. See ACORP App.3 Instructions, for details.

a. Complete the table below.

Name of Hazardous Agent	Approving Committee or Official	Institution (VA or affiliate)	Names of Animal Facility Staff Members at Risk

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b. Detail how the individuals listed in the table above (Item 10.a.) have been (or will be) informed of the possible risks of exposure, and have been (or will be) trained to avoid exposure to these agents.
▶

11. **Signatures.** Provide the applicable signatures on the signature pages (Item Z.3) of the main body of this ACORP.

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ACORP Appendix 4
ANTEMORTEM SPECIMEN COLLECTION

VERSION 4

See ACORP App. 4 Instructions, for more detailed explanations of the information requested.

1. **Summary.** Complete the table below for each specimen to be collected from a live animal on this protocol (see ACORP App. 4 Instructions, for details).

Specimen Collected	Site and Method of Collection	Anesthesia (Yes/No)	Amount Collected Each Time	Volume Replacement (Yes/No/NA)	Total Number of Collections per Animal	Time Intervals Between Successive Collections

2. **Use of Anesthetics, Tranquilizers, or Analgesics**.

   a. For each specimen described in Item 1, above, as being collected WITHOUT anesthesia, complete Items 2.a(1) and 2.a(2), below:

      (1) Explain why no measures will be taken to prevent pain (e.g., because of scientific requirements described here, or because the collection method involves no more than minor or momentary pain).
      ▶

      (2) Completely describe any method of physical restraint that may be used.
      ▶

   b. For each specimen described in Item 1, above, as being collected WITH anesthesia, complete the following table:

Anesthetic, tranquilizer, or analgesic agent	Dose (mg/kg) and volume (ml)	Route of administration	Frequency of administration

Appendix 9: IACUC/OB Protocol Form

3. **Volume Replacement for Fluid Collections.**

   a. For each fluid specimen described in Item 1, above, for which NO volume replacement will be provided, explain why not.
   ►

   b. For each fluid specimen described in Item 1, above, for which volume replacement WILL be provided, describe the replacement fluids that will be administered (including their composition, volume, and route of administration).
   ►

4. **Monitoring the animals.** Detail how the animals will be monitored after collection of specimens to ensure that they recover appropriately (see ACORP App. 4 Instructions, for details).
   ►

Appendix 9: IACUC/OB Protocol Form

ACORP Appendix 5
SURGERY

VERSION 4

See ACORP App. 5 Instructions, for more detailed explanations of the information requested.

1. **Surgery Classification.** Complete the table below for each surgery included in this protocol, and indicate how it is classified (terminal, minor survival, major survival, one of multiple survival). See ACORP App. 5 Instructions, for details.

Surgery		Terminal	Survival		
#	Description (specify the species, if ACORP covers more than one)		Minor	Major	One of Multiple*
1		( )	( )	( )	( )*
2		( )	( )	( )	( )*
3		( )	( )	( )	( )*
4		( )	( )	( )	( )*

*If survival surgery (including major surgeries and any minor surgeries that may induce substantial post-procedural pain or impairment) will be performed as part of this protocol in addition to any other such surgery (on this or another protocol) on the same individual animal, complete items 1.a and 1.b, below:

a. Provide a complete scientific justification for performing the multiple survival surgeries on an individual animal:
▶

b. Give the interval(s) between successive surgeries, and the rationale for choosing the interval(s):
▶

2. **Description of Surgeries.** Describe each surgery listed in Item 1, providing enough detail to make it clear what the effects on the animal will be. (Pre-operative preparation, anesthesia, and post-operative recovery will be covered in items 5, 6, and 7, below.)

Surgery 1 ▶

Appendix 9: IACUC/OB Protocol Form

Surgery 2 ▶

Surgery 3 ▶

Surgery 4 ▶

3. **Personnel.** Complete the table below for each individual who **will** be involved in any of the surgeries on this protocol.

Name	Surgery #(s) (see Item 1)	Role in Surgery			
		Surgeon	Assistant	Manage Anesthesia	Other (describe)
		( )	( )	( )	( )
		( )	( )	( )	( )
		( )	( )	( )	( )
		( )	( )	( )	( )
		( )	( )	( )	( )

4. **Location of surgery.** Complete the table below for each location where surgery on this protocol will be performed.

Building	Room Number	Surgery #(s) (see Item 1)	Type of Space		
			Dedicated Surgical Facility	Other Dedicated Surgical Space	Other Space not Dedicated to Surgery
			( )	( )*	( )*
			( )	(*)	( )*
			( )	( )*	( )*
			( )	( )*	( )*

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*For each space that is not in a dedicated surgical facility, provide the justification for using this space for surgery on this protocol

►

5. **Pre-operative protocol.**

a. **Pre-operative procedures.** Complete the table below for each pre-operative procedure that will be performed to prepare the animal(s) for surgery.

Surgery #(s) (see Item 1)	Fast (Specify Duration)	Withhold Water (Specify Duration)	Place Intravenous Catheter(s) (Specify Site(s))	Other – Describe
1	( ) --	( ) --	( ) --	( ) --
2	( ) --	( ) --	( ) --	( ) --
3	( ) --	( ) --	( ) --	( ) --
4	( ) --	( ) --	( ) --	( ) --

b. **Pre-operative medications.** Complete the table below. Include agent(s) for induction of anesthesia, as well as any other pre-treatments that will be administered prior to preparation of the surgical site on the animal.

Agent	Surgery #(s) (see Item 1)	Dose (mg/kg) & volume (ml)	Route of administration	Frequency of administration (e.g., times/day)	Pre-operative period of treatment (e.g., immediate, or # of days)

c. **Pre-operative preparation of the surgical site.** For each surgery, identify each surgical site on the animals, and describe how it will be prepared prior to surgery.

Surgery 1 ►

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Surgery 2 ▶

Surgery 3 ▶

Surgery 4 ▶

6. **Intra-operative management.**

   a. **Intra-operative medications.** Complete the table below for each agent that will be administered to the animal during surgery.

Agent	Paralytic*	Surgery #(s) (see Item 1)	Dose (mg/kg) & volume (ml)	Route of administration	Frequency of dosing
	( )*				
	( )*				
	( )*				

   * For each agent shown above as a paralytic, explain why its use is necessary, and describe how the animals will be monitored to ensure that the depth of anesthesia is sufficient to prevent pain.

   ▶

   b. **Intra-operative physical support.** For each surgery, describe any physical support that will be provided for the animals during surgery (e.g., warming, cushioning, etc.).
   ▶

   c. **Intra-operative monitoring.** Describe the methods that will be used to monitor and respond to changes in the state of anesthesia and the general well-being of the animal during surgery.
   ▶

7. **Survival surgery considerations.** For each survival surgical procedure indicated in Item 1 and described in Item 2, complete Items 7.a. – 7.g.

Appendix 9: IACUC/OB Protocol Form

a. Complete the table below for each survival surgery listed in Item 1, above.

Surgery # (see Item 1)	Survival Period	Measures for Maintaining Sterility							
		Sterile Instruments	Surgical Cap	Sterile Gloves	Surgical Scrub	Sterile Drapes	Sterile Gown	Face Mask	Other*
		( )	( )	( )	( )	( )	( )	( )	( )*
		( )	( )	( )	( )	( )	( )	( )	( )*
		( )	( )	( )	( )	( )	( )	( )	( )*
		( )	( )	( )	( )	( )	( )	( )	( )*

* Describe any "other" measures to be taken to maintain sterility during surgery.

►

b. For each surgery, describe the immediate post-operative support to be provided to the animals.

Surgery 1 ►

Surgery 2 ►

Surgery 3 ►

Surgery 4 ►

c. Post-operative analgesia. Complete the table below for each surgery listed in item 1, above.

Surgery # (see Item 1)	Agent*	Dose (mg/kg) & Volume (ml)	Route of Administration	Frequency of Dosing (e.g., times/day)	Period of treatment (e.g. days)

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1					
2					
3					
4					

*For each surgery for which NO post-operative analgesic will be provided, enter "none" in the "Agent" column, and explain here why this is justified:

►

d. Other post-operative medications. Complete the following table to describe all other medications that will be administered as part of post-operative care.

Surgery # (see Item 1)	Medication	Dose (mg/kg) & Volume (ml)	Route of Administration	Frequency of dosing (e.g. times/day)	Period of treatment (e.g. days)

e. Post-operative monitoring. <u>After-hours contact information for the personnel listed must be provided to the veterinary staff for use in case of an emergency.</u>

(1) Immediate post-operative monitoring

Surgery # (see Item 1)	Frequency of Monitoring	Duration at this Frequency	Name(s) of Responsible Individual(s)

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(2) Post-operative monitoring after the immediate post-operative period

Surgery # (see Item 1)	Frequency of Monitoring	Duration at this Frequency	Name(s) of Responsible Individual(s)

f. Post-operative consequences and complications.

(1) For each surgery, describe any common or expected post-operative consequences or complications that may arise and what will be done to address them.

Surgery 1 ▶

Surgery 2 ▶

Surgery 3 ▶

Surgery 4 ▶

(2) List the criteria for euthanasia related specifically to post-operative complications:

Surgery 1 ▶

Surgery 2 ▶

Surgery 3 ▶

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Surgery 4 ▶

(3) In case an emergency medical situation arises and none of the research personnel on the ACORP can be reached, identify any drugs or classes of drugs that should be avoided because of the scientific requirements of the project. (If the condition of the animal requires one of these drugs, the animal will be euthanatized instead.)
▶

g. Maintenance of post-surgical medical records. Complete the table below for each surgery, specifying where the records will held, and identifying at least one individual who will be assigned to maintain accurate, daily, written post-surgical medical records. Indicate whether the named individuals are research personnel involved in this project, or members of the veterinary staff.

Surgery # (see Item 1)	Location of Records	Name(s) of Individual(s) Responsible for Maintaining Written Records	Research Personnel	Veterinary Staff
1			( )	( )
2			( )	( )
3			( )	( )
4			( )	( )

8. **Certification.** The PI must sign the certification statement in Item Z.5 of the main body of the ACORP.

Appendix 9: IACUC/OB Protocol Form

ACORP APPENDIX 6
SPECIAL HUSBANDRY AND PROCEDURES

VERSION 4

See ACORP App. 6 Instructions, for more detailed explanations of the information requested.

1. **Description of Procedures.** Complete the table below for each procedure listed in Item V of the main body of the ACORP that is not detailed in a SOP or in another item or Appendix of the ACORP. For each special procedure, check all features that apply.

Special Procedure		Features							
Number	Brief Description	Husbandry	Restraint	Noxious Stimuli	Exercise	Behavioral Conditioning	Irradiation	Imaging	Other**
1		( )	( )	( )	( )	( )	( )	( )	( )
2		( )	( )	( )	( )	( )	( )	( )	( )
3		( )	( )	( )	( )	( )	( )	( )	( )
4		( )	( )	( )	( )	( )	( )	( )	( )

*Husbandry refers to all aspects of care related to the maintenance of the animals, including (but not limited to) provision of an appropriate diet, access to water, control of environmental conditions, and the selection of primary and secondary enclosures.

**Describe any "Other" features that are involved.

►

a. Provide a complete description of each special procedure listed above, including the duration of the procedure, how frequently it will be repeated in any one animal, and any effects it is expected to have on the animal:

Special Procedure 1 ►

Special Procedure 2 ►

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Special Procedure 3 ▶

Special Procedure 4 ▶

b. Explain why each of these special procedures is necessary:

Special Procedure 1 ▶

Special Procedure 2 ▶

Special Procedure 3 ▶

Special Procedure 4 ▶

2. **Personnel.** Complete the table below for each special procedure listed in Item 1, above. Identify the individual(s) who will be responsible for carrying out the procedures, and those who will be responsible for monitoring the condition of the animals during and after the procedures. After-hours contact information for the personnel listed must be provided to the veterinary staff for use in case of an emergency.

Procedure Number (see Item 1)	Responsible Individual(s)	
	Carrying Out Procedure	Monitoring the Animals
1		
2		
3		
4		

3. **Potential Pain or Distress.** Complete the table below for each special procedure identified in Item 1, above, indicating for each procedure, whether potential pain and/or distress is expected, and, if so, describing the potential pain and/or distress and indicating whether any measures are to be taken to prevent or alleviate it.

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Procedure Number (see Item 1)	Expected Potential Pain and/or Distress			
	No	Yes		
		Description	To Be Relieved	Not to Be Relieved
1	( )		( )[a]	( )[b]
2	( )		( )[a]	( )[b]
3	( )		( )[a]	( )[b]
4	( )		( )[a]	( )[b]

a. For each procedure for which potential pain and/or distress is expected, but WILL be prevented or alleviated by administration of the analgesic(s) or stress-relieving agents, complete the table below:

Procedure Number (see Item 1)	Agent	Dose (mg/kg) & vol (ml)	Route of admin	Freq of admin (times/day)	Duration of admin (days post-procedure)
1					
2					
3					
4					

Describe any non-pharmacological measures to be taken to address the potential pain and/or distress:

Special Procedure 1 ▶

Special Procedure 2 ▶

Special Procedure 3 ▶

Special Procedure 4 ▶

b. For each procedure for which potential pain and/or distress is expected and will NOT be prevented or alleviated, provide the scientific justification for this:

Special Procedure 1 ▶

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Special Procedure 2 ▶

Special Procedure 3 ▶

Special Procedure 4 ▶

4. **Monitoring.** Describe how the condition of the animals will be monitored during and after each of the special procedures, and list the criteria that will be used to determine when individual animals will be removed from groups undergoing these procedures, because of pain or distress (see ACORP App. 6 Instructions, for details):

Procedure Number (see Item 1)	Monitoring Methods	Endpoint Criteria
1		
2		
3		
4		

Appendix 9: IACUC/OB Protocol Form

ACORP APPENDIX 7

USE OF PATIENT CARE EQUIPMENT AND/OR AREAS

FOR ANIMAL STUDIES

Version 4

See ACORP App. 7 Instructions, for more detailed explanations of the information requested.

1. **Full Name(s) of Principal Investigator(s)** ►

2. **Equipment to be Used.**

   a. Identify the equipment ►

   b. Procedure(s) to be performed with this equipment ►

   c. Describe how contamination of the human patient care equipment will be prevented and how the equipment will be cleaned/sanitized before its subsequent use for human patients. ►

3. **Human Patient Care Procedural Areas to be Used.**

   a. Location(s) ►

   b. Animal species to be studied or treated ►

   c. Number of individual animals to be studied or treated ►

   d. Date(s) ►

   e. Time(s) of day ►

   f. Procedure(s) to be performed on the animals in these areas ►

   g. Protection and cleaning of patient care room surfaces ►

   h. Benefits to VA patients. Briefly describe how this use of the human patient care areas for research on animal subjects potentially benefits VA patients. ►

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i. Necessity for use of human patient care areas. Explain why this work on animal subjects cannot be performed within the animal facility or a research laboratory area.
►

j. Animal transport. Describe how the animals will be transported back and forth between the animal housing area and the human patient care areas.
►

k. Preventing human patients and patient care personnel from being affected by the presence of the animals. Provide detailed descriptions of the measures to be taken to address noises and odors, allergens, and zoonotic pathogens associated with the animals.
►

4. **Signatures.** Provide the signatures required on the signature pages (Item Z.7) of the main body of this ACORP.

Appendix 9: IACUC/OB Protocol Form

ACORP Appendix 8

Use of Explosive Agent(s) within the VMU or in Animals

Version 4

See ACORP App. 8 Instructions, for more detailed explanations of the information requested.

1. **Full name(s) of Principal Investigator(s) ►**

2. **Explosive agents to be used.**

   a. Identify the explosive agents. Complete the table below.

Agent Number	Name(s) Used to Refer to the Agent in This ACORP	Name Shown for this Agent on the MSDS on File	CAS number	Location of the MSDS on File
1				
2				
3				
4				

   b. Locations where the explosive agents will be used. Complete the table below.

Agent Number	Location Where Agent Will Be Used			
	Building	Room Number	Within the VMU	Outside of VMU
1			( )	( )
2			( )	( )
3			( )	( )
4			( )	( )

   c. Procedure(s) to be performed. Briefly describe the use of each of the explosive agents on this protocol and explain why it is necessary to use these agents (why non-explosive replacements cannot be used instead).
   ►

Appendix 9: IACUC/OB Protocol Form

d. Precautions to be taken to prevent explosions. Describe the measures to be taken to store, use, and dispose of safely each explosive agent and any materials contaminated with it, and to prevent the generation of sparks in its presence. See ACORP App. 8 Instructions, for a list of commonly used precautions.
►

e. Period of use.
Beginning no earlier than (date) ►

Ending no later than (date) ►

f. Animals that will be administered explosive agents:
Species ►

Approximate weights of individual animals ►

Approximate number of animals ►

3. **Personnel.** Complete the table below for each individual who **will** handle any of the explosive agents as part of this protocol.

Name of Individual	Explosive Agent(s) to be Handled	Training and Experience Pertinent to Handling Explosive Agents

4. **Signatures.** Provide the signatures required on the signature pages (Item Z.8) of the main body of this ACORP.

Appendix 9: IACUC/OB Protocol Form

ACORP Appendix 9

DEPARTURES FROM "MUST" AND "SHOULD" STANDARDS IN THE *GUIDE (2011)*

VERSION 4

See ACORP App. 9 Instructions, for more detailed explanations of the information requested.

For each IACUC-approved "departure" of this protocol from a "Must" or "Should" standard in the *Guide*, provide the following information. (Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.):

Copy the lines below for each departure.

Briefly summarize the "Must" or "Should" standard, and provide the number(s) of the page(s) on which it appears in the *Guide*

▶

Describe the specific alternate standard(s) that will be met on this protocol, and how they will be monitored.

▶

Provide the scientific, veterinary medical, or animal welfare considerations that justify this departure

▶

Appendix 9: IACUC/OB Protocol Form

For Annual Reviews:

IACUC CONTINUING REVIEW SUBMISSION FORM

Date: IACUC No:

Principal Investigator: Telephone:

E-mail:

Protocol Title: Funding Source:

Annual Review ☐ Three-Year Renewal ☐ (Requires new ACORP submission)

The IACUC must review the conduct of all animal protocols annually. Failure to comply will result in suspension or termination. The current copy of the proposed protocol must accompany this submission. Modifications to protocols require a Protocol Amendment Form. For Three-Year Renewals, a new ACORP must accompany this form. Please provide the following information.

1. Have there been any alterations in the protocol since the last review? ☐YES ☐NO

   If **YES**, please explain:

2. Did you obtain approval from the IACUC prior to any changes in the protocol?

   ☐YES ☐NO ☐N/A

   If **NO**, please explain:

3. Please list the number and species of all animals used during the past year:

	Species	Number	# Category B	# Category C	#Category D	#Category E
a.						

4. Are there any changes in personnel involved with this protocol since last review?

   ☐ YES ☐NO

Appendix 9: IACUC/OB Protocol Form

If **YES**, please list new personnel or personnel no longer involved:

5. Have all research personnel received appropriate training on the animal species used in this protocol? ☐ YES ☐ NO

6. Have there been any unanticipated problems that have affected animal use, welfare, morbidity, or mortality? ☐ YES ☐ NO

   If **YES**, please explain:

7. Since the last IACUC approval, have alterations to the use of animals become available that could be substituted to achieve your specific project aims? ☐ YES ☐ NO

   If **YES**, explain why the alternative to animal use is not feasible for your project.

8. Since the last IACUC approval, have alternatives that are potentially less painful or distressful to the animals become available that could be used and that would allow you to continue to achieve your specific aims?

   ☐ Not Applicable

   ☐ NO, the following sources were consulted to search if alternatives exist with the following results:

Database	Date of search	Years covered	Key words	Alternatives Found
Medline www.ncbi.nlm.nih.gov/entrez/query.fcgi				
USDA Alternatives http://awic.nal.usda.gov/alternatives				
ALTWEB http://altweb.jhsph.edu/resources/searchalt/index.html				
Other				

   ☐ YES, state how your study has been modified to include alternatives or explain why it is not feasible:

Appendix 9: IACUC/OB Protocol Form

9. Please indicate the future status of this project:

☐ No changes planned and the project will continue as previously approved

☐ Currently inactive but will become active within the next year

☐ Project to be terminated

☐ Project Active but requires minor modifications. (Protocol Amendment Form must be attached)

10. I certify that I will submit research results to the Research Office (b)(7)(F) Ext. (b)(6) and

I will upload notification of all publications/presentation to https://vaww.ord.portal.va.gov/sites/comm/PubTracker/Pages/default.aspx prior to submission or publication. I will include acknowledgement of VA support and employment in all presentations.

Yes ☐

This signature certifies that the Principal Investigator:

- Understands the requirements of the PHS Policy on Humane Care and Use of Laboratory Animals, applicable USDA regulations, the Guide for the Care and USE of Laboratory Animals and the VHA guidelines (VHA HANDBOOK 1200.7, USE OF ANIMALS IN RESEARCH) governing the use of vertebrate animals for research, testing, teaching or demonstration projects.
- Is responsible for all aspects of this project, including assurance that all research staff involved in handling animals in this project are qualified and appropriately trained in conducting those animal procedures.
- Assures the activities of this project remain in compliance with the requirements that there must not be any unnecessary duplication of experiments.
- Will continue to conduct the project in full compliance with the aforementioned requirements.

_____ _____

PRINCIPAL INVESTIGATOR SIGNATURE DATE

(Only the Principal Investigator is authorized to sign)

Appendix 10: IACUC/OB Periodic Report

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

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

Summarize the heating, ventilation and air conditioning (HVAC) systems for each animal facility, ***including all satellite facilities***. Include ***all animal holding rooms*** (including satellite holding rooms), surgical facilities, procedure rooms, and support spaces integral to animal facilities (e.g., cage wash, cage and feed storage areas, necropsy, treatment).

Location/Building/Facility:	**McGuire VAMC/Building (b)(7) Veterinary Medical Unit**

In the text box below, provide a general description of the mechanical systems used to provide temperature, humidity and air pressure control. Include details such as:

- the source(s) of air and air recirculation rates if other than 100% fresh air
- treatment of air (filters, absorbers, *etc.*)
- design features such as centralized chilled water, re-heat coils (steam or hot water), individual room vs. zonal temperature and relative humidity control, the use of variable air volume (VAV) systems and other key features of HVAC systems affecting performance
- features that minimize the potential for adverse consequences to animal well-being (such as re-heat coils that fail closed or that are equipped with high-temperature cut-off systems), and
- how room temperature, ventilation, and critical air pressures are monitored and maintained in the event of a system or component failure, including notifying appropriate personnel in the event of a significant failure that occurs outside of regular working hours and/or other management systems used to respond to alerts or failures.

The entire facility is indoors and has 100% fresh air. The system is zonal with steam re-heat coils and uses a Johnson Control VAV system. The reheat coils fail to off and each room has a Johnson Control alarm system that sounds in the Engineering physical plant office when temperatures are above 78F or below 60F. The room temperatures are monitored daily by the animal caretakers and monitored for alarms by the Engineering physical plant. The Engineering physical plant staff and Facility Safety office has the VMU Supervisor's emergency numbers and all contact numbers are posted prominently through the facility. The Facility's HVAC system was replaced in its entirety during the Summer of 2018. All ducting, piping, valves, vents, controllers and thermostats were replaced as well as the main air handler unit.

In the Table below, provide room-specific information requested. For each room within this location, indicate use, including the species for animal housing rooms. *Measurement of air exchange rates and verification of relative pressure within animal housing rooms (excluding rooms housing aquatic species only) and cage washing facilities must be completed* ***within the 12 months preceding completion of this Program Description.*** Air exchange rates may be important to maintain air quality in other areas; *however,*

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

measurements may be left at the discretion of the institution. Information may be provided in another format, providing all requested data is included. **[*Note*: Please remove the examples provided in the Table below.]**

Room No.	Specific Use	Temperature Set-Point (F)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (F)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified / Measured
		(settings to be verified)					(values to be measured)	
(b)(7)(F)	Housing Large box	72	Y	66F/78F	Y	-	34.29	3/2019
	Holding Room	72	Y	66F/78F	Y	-	21.72	3/2019
	Holding Room	72	Y	66F/78F	Y	-	21.89	3/2019
	Procedure room	72	Y	66F/78F	Y	-	19.34	3/2019
	Procedure room	72	Y	66F/78F	Y	-	19.33	3/2019
	Holding room	72	Y	66F/78F	Y	-	23.09	3/2019
	Holding room	72	Y	66F/78F	Y	-	17.76	3/2019
	Holding room	72	Y	66F/78F	Y	-	19.59	3/2019
	Holding Room	72	Y	66F/78F	Y	-	17.59	3/2019
	Holding room	72	Y	66F/78F	Y	-	19.08	3/2019
	Holding Room	72	Y	66F/78F	Y	-	17.27	3/2019
	Holding Room	72	Y	66F/78F	Y	-	11.96	3/2019
	Holding room	72	Y	66F/78F	Y	-	17.65	3/2019
	Holding Room	72	Y	66F/78F	Y	-	13.12	3/2019
	Holding room	72	Y	66F/78F	Y	-	12.57	3/2019
	Infectious disease suite	72	Y	66F/78F	Y	-	9.01	3/2019

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

Room No.	Specific Use	Temperature Set-Point (F)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (F)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified / Measured
		(settings to be verified)					(values to be measured)	
(b)(7)(F)	Holding room	72	Y	66F/78F	Y	-	12.92	3/2019
	Necropsy room	72	Y	66F/78F	Y	-	25.72	3/2019
	Cage Wash	72	Y	66F/78F	Y	-	30.52	3/2019
	Cage Wash	72	Y	66F/78F	Y	+	6.14	3/2019
	Receiving room	72	Y	66F/78F	Y	-	12.99	3/2019
	Quarantine	72	Y	66F/78F	Y	-	15.62	3/2019
	Quarantine	72	Y	66F/78F	Y	-	21.22	3/2019
	Quarantine	72	Y	66F/78F	Y	-	20.33	3/2019
	Surgery/C-arm	72	Y	66F/78F	Y	+	14.29	3/2019
	Surgery	72	Y	66F/78F	Y	+	18.3	3/2019
	Surgery	72	Y	66F/78F	Y	+	19.29	3/2019
	Surgery	72	Y	66F/78F	Y	+	10.43	3/2019
	Surgery	72	Y	66F/78F	Y	+	19.75	3/2019

Copy and repeat the Description and Table for each location, including all satellite housing locations.

Appendix 12: Aquatic Systems Summary – Part I

Please summarize water management and monitoring information programs for each animal facility, including all satellite facilities, rooms, enclosures. The following key will assist you in completing the form:

(1) List location of aquaria, including outdoor enclosures (ponds or outdoor tanks). If indoors, list building and room number. Note that all species housed at the same location and maintained via the same design and monitoring may be listed in the same row.
(2) Please indicate if embryonic (E), larval (L), juvenile (J) or Adult (A)
(3) Group tanks (ponds, outdoor tanks, multiple aquaria) are arranged as arrays with shared water supply; individual aquaria have exclusive water handling systems.
(4) Indicate water type, e.g., fresh, brackish, or marine.
(5) Indicate water pre-treatment, e.g., dechlorination, rough filters.
(6) Indicate water circulation, e.g., static, re-circulated, constant flow, or some combination of these. If applicable, indicate water exchange frequency and amount (percentage).
(7) Provide a key word for filtration employed, e.g., biological, chemical, mechanical, and type (e.g., mechanical-bead filter). A diagram may be provided showing the flow of water, filtration, source of "make-up" water and amount replaced daily.

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)
Not applicable							

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

[Create additional rows by pressing TAB in the bottom-right box.]

Appendix 12: Aquatic Systems Summary – Part II

The following key will assist you in completing this form:

(1) In these columns, please indicate monitoring frequency, e.g. daily, weekly, monthly or other point sampling frequency; continuous/real time, or none, if applicable. Also indicate method of control (heaters versus room HVAC, hand versus auto dosing, etc.).

(2) Indicate other parameters and their monitoring frequency, e.g., alkalinity, total hardness, conductivity, chlorine/chloramine.

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):**
Not applicable									

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

[Create additional rows by pressing TAB in the bottom-right box.]

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**
Dog Swine Sheep	4' X 10'X 6'	1 (<30kg) 1 (<100kg) 5 (>50kg)	The Guide	Galvanized chain link
Dog Swine Sheep	3' X 6' X 6'	1 (<30kg) 1 (<50kg) 5 (>50kg)	The Guide	Galvanized chain link
Dog	51"X 37"X 36"	1 (<30kg)	The Guide	Stainless Steel post operative recovery cage
Rabbit	30"X 24"X 20	1 (<5.4kg)	The Guide	Stainless Steel
Rat	10" X 18"X 7"	2(<500 g)	The Guide	Polycarbonate static micro isolator
Rat	13" X 14.5" X 7"	>500g	The Guide	IVCS
Rat	18 X16 X 16	>500g	The Guide	Double Decker IVCS
Rat	8" X 10" diameter	2 (<300g) 1 (>300g)	The Guide	Polycarbonate metabolic caging with wire floor
Mouse	7" X 11.5" X 5"	4 (<25g) 3 (>25g)	The Guide	Polycarbonate static micro isolator

Appendix 13: Primary Enclosures and Animal Space Provisions

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**
Mouse	7" X 14.5" X 5"	5 (<25g) 4(>25 g)	The Guide	IVCS
Mouse	7.5" X 9" diameter	4 (<25g) 3 (>25g)	The Guide	Polycarbonate metabolic caging with wire floor

*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	LabGuard 126	
Solid-bottom cages (IVC)	Mechanical washer	weekly	LabGuard 126	Autoclaved, if necessary
Suspended wire-bottom or slotted floor cages	Hand washing	weekly	LabGuard 126	
Cage lids	Mechanical washing	Weekly	LabGuard 126	
Filter tops	Mechanical washing	Weekly	LabGuard 126	
Cage racks and shelves	Mechanical washing	monthly	LabGuard 126	
Cage pans under suspended cages	Mechanical washing	3 times weekly	LabGuard 126and Citric Acid	
Play pens, floor pens, stalls, etc.	High pressure sprayer	Daily/Sanitized weekly	F-204	
Corrals for primates or outdoor paddocks for livestock	NA	NA	NA	
Aquatic, amphibian, and reptile tanks and enclosures	NA	NA	NA	
Feeders	Mechanical washing	Weekly	LabGuard 126	

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)
Watering devices	Mechanical washing	Weekly	LabGuard 126	
Exercise devices and manipulanda used in environmental enrichment programs, etc.	Mechanical washing or hand washing	Weekly	LabGuard 126or Peridox RTU	
Transport cages	Mechanical Washing	After each use	LabGuard 126	
Operant conditioning & recording chambers, mechanical restraint devices (chairs, slings, etc.)	Hand washing	After each use	Peridox RTU	
Euthanasia chambers	Hand washing	After each use	Peridox RTU	
Macro-Environment				
Animal Housing Rooms:				
Floors	Mopped	Daily	Scrubbed with Alkaline foam cleanser (F-204) for cleaning and LabGuard 256 for sanitation	Runs: sprayed daily, sanitized weekly. Rodent rooms: swept/mopped daily, sanitized monthly
Walls	Hosed	monthly	Scrubbed with F204 and/or LabGuard 256	

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)
Ceilings	Hosed	Monthly	Scrubbed with F204 and/or LabGuard 256	
Ducts/Pipes	Hosed	Monthly	Scrubbed with F204 and/or LabGuard 256	
Fixtures	Hosed	Monthly	Scrubbed with F204 and/or LabGuard 256	
Corridors:				
Floors	Mopped	Daily	Scrubbed with Virex 256	
Walls	Hand washed	Monthly/as needed	Scrubbed with Virex 256	
Ceilings	Hand washed	Monthly/as needed	Scrubbed with Virex 256	
Ducts/Pipes	NA	NA	NA	
Fixtures	Hand washed	Monthly/as needed	Scrubbed with Virex 256	
Support Areas (e.g., surgery, procedure rooms, etc.); complete for each area:				
Floors	Mopped	After use	Scrubbed with Virex 256	
Walls	Hand washed	After use	Scrubbed with Virex 256	
Ceilings	Hand wiped	Monthly/as needed	Scrubbed with Virex 256	
Ducts/Pipes	NA	NA	NA	
Fixtures	Hand wiped	After use	Scrubbed with Virex 256	

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)
Implements (note whether or not shared): Shared within the facility but not shared outside of facility				
Mops	Laundered	After use		Laundered in facility Washer
Mop buckets	Hand washed	Daily	Virex 256	
Aquaria nets	NA	NA	NA	
Other	NA	NA	NA	
Other:				
Vehicle(s)	Hand washed by Facility	After use/regular schedule by Motor Pool		The facility Motor Pool takes care of sanitizing the vehicles after use. All animals are transported in sealed containers with filter lids.
Other transport equipment (list) Carts	Mechanical washer	Daily	LabGuard 126	

*Please provide chemical, not trade name.

Appendix 15: Facilities and Equipment for Sanitizing Materials

In the Tables below, summarize the facilities and equipment used to sanitize animal related equipment (tunnel washer, bottle washer, rack washer, bulk autoclave, hand-washing area, bedding dispensing unit, *etc.*). Note that some descriptions may be combined if all share identical features (e.g., all rack washers).

Building	Room No.	Equipment Type	Safety Feature(s)	Methods of Monitoring Effectiveness
(b)(7)(F)	(b)(7)(F)	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; ATP testing done annually
(b)(7)(F)	(b)(7)(F)	Bulk autoclave	Emergency "off" button; lock-out key	Biological testing monthly, Temperature strips monthly, ATP-based luminescence swabs performed as needed
(b)(7)(F)	(b)(7)(F)	Bulk autoclave	Emergency "off" button; lock-out key	Biological Testing monthly, temperature strips monthly, ATP-based luminescence swabs performed as needed
(b)(7)(F)	(b)(7)(F)	None – hand-washing area	Limited to PPE	Visual assessment

[Create additional rows by pressing TAB in the bottom-right box.]

Appendix 16: Lighting Summary

Using the Table below, summarize the lighting system(s) for the animal housing facility(ies). For each species or holding room type, list light intensity (range), construction features (e.g., water resistance), photoperiod (light:dark) and control (e.g., automatic versus manual, phasing). For systems automatically controlling photoperiod, describe override mechanisms (including alarms, if applicable).

Location: McGuire VAMC Building (b)(7)(Veterinary Medical Unit on (b)(7)(F) and (b)(7)(F)

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	330-540 lux	Surface mounted, water resistant, LED Bulbs	12:12	Automatic via wall-mounted timer box	Timer has an override button that resets at next light change to prevent constant on/off
Large Animal Holding Rooms	500-670 lux	Surface mounted, water resistant, LED bulbs	12:12	Automatic via wall-mounted timer box	Timer has an override button that resets at next light change to prevent constant on/off
Surgery	530-1198 lux	Recessed, water resistant; arm-mounted, water resistant, LED Bulbs	NA	NA	NA
Necropsy	815 lux	Recessed, water resistant; arm-mounted, water resistant, LED bulbs	NA	NA	NA
Cage-Washing Room	330-480 lux	Recessed, water proof, LED Bulbs	NA	NA	NA
Rodent housing boxes (b)(7)(F)	170 lux	Surface mounted, LED Bulbs	12:12	Automatic via wall-mounted timer box	Timer has an override button that resets at next light change to prevent constant on/off

[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.

Repeat Location and Table as necessary for each location, including satellite housing locations.

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 each of these must also be 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
(b)(7)(F)	(b)(7)(F)	(b)(6)	Mice	15 ft2	48 hours	overnight injection	Fully enclosed wood box with epoxy paint and dedicated HVAC/lighting system.

[Create additional rows by pressing TAB in the bottom-right box.]