Program Description

Animal Care and Use Program

Veterinary Medical Unit (VMU)

New Mexico VA Health Care System (NMVAHCS)

1501 San Pedro Dr. S.E.
Albuquerque, NM 87108

March 31, 2017

For

AAALAC International

Table of Contents

Appendices

Program Description

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

Section 1. Introduction

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

VMU, NMVAHCS, Albuquerque, New Mexico

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 NMVAHCS is a leader in the provision of rural health care, opening its first VA-staffed community based outpatient clinic (CBOC) in Farmington, New Mexico, followed by clinics in Artesia, Gallup, Raton, Silver City, Rio Rancho and Santa Fe. In recent years, the NMVAHCS has contracted with Health Net Federal Services and Ben Archer Health Center to provide Veterans access to clinics throughout New Mexico and southwest Colorado. The goal of NMVAHCS's Research Service is to continuously improve care of our nation's Veterans. By encouraging Research, the NMVAHCS is striving to achieve high quality, prompt, and seamless service to the Veterans we serve. The VMU is a support unit of the Research Service developed to help research investigators in the use of laboratory animal in Biomedical Research.

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.

We use the standards of the Guide, PHS Policy, and the Animal Welfare Act for all animals. In addition, we are guided by VHA Handbooks 1200.07 'Use of Animals in Research', 1200.08 'Safety of personnel Engaged in Research', and 1058.01 'Research Compliance Reporting Requirements."

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

The VMU staff report to the Veterinary Medical Consultant (VMC) and the Chief, Research Administration. The VMC reports to the Chief of Research Administration, is a member of the IACUC, and has direct access to the Institutional Official (IO) for semi-annual reporting and any significant non-compliance issues. The Institutional Animal Care and Use Committee (IACUC) is a subcommittee of the Research & Development Committee (R&DC) and has the same direct access to the IO as the VMC. The R&DC reports to the Associate Chief of Staff for Research (ACOS/R) and the Chief of Staff (COS). The COS reports to the Medical Center Director (MCD). The MCD is the IO.

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.

[redacted], MHA, FACHE, Medical Center Director, IO (01)
[redacted] FACS, Chief of Staff (11)
[redacted] PhD, IACUC Chairperson (151)
[redacted], D.V.M., DACLAM, Veterinary Medical Consultant
[redacted] LATG, Supervisor, Veterinary Medical Unit (151)
[redacted], Research Safety Coordinator (151)
[redacted], M.D., PhD, Associate Chief of Staff for Research (151)
[redacted], Chief of Research Administration (151)
[redacted], Public Affairs Specialist (135)

[redacted], Chief, Engineering Service (138)
[redacted], Industrial Hygienist (138)
[redacted], Emergency Management Coordinator (138)
[redacted], Physical Security Specialist (07B)
[redacted], Acting Chief, Police Service (07B)
[redacted], RN, Employee Health (115)

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.

Major types of research include enteric infectious disease, diabetic retinopathy, Gulf War Syndrome models, addiction genetics, and Orofacial Pain model. Currently nine separate research projects using animals and two breeding protocols (seven principal investigators) are approved.

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

1) Federal grants from the VA; 2) start-up money and private donations managed by the [redacted]), a non-profit organization.

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.

N/A

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.

N/A

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

Although we currently have no protocols using rabbits, there is a very slight possibility that a rabbit protocol will be approved before the site visit. That is why you will see references to rabbits throughout this document and the appendices.

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.

At least twice a year, after a majority of all voting IACUC members approve/sign the semiannual report, the VMC, IACUC Chair, and ACOS/R discuss the report with the IO. Other IACUC members may also attend. The IO must sign the report indicating that he/she has reviewed it. Written recommendations are included as part of the semiannual report to the IO. Other recommendations are sent in writing as part of the IACUC minutes to the R&DC. The R&DC will, in turn, act appropriately, note this action in the Committee's minutes, and forward them to the IO for final approval. However, the IACUC may at any time provide a recommendation if a significant deficiency is noted. If any committee member expresses a concern regarding the program or facilities, it will be discussed at the next convened meeting. If an immediate concern arises, any member of the IACUC or staff can discuss the concerns with the ACOS/R and IO.

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.

The VMC has direct program authority and responsibility for the Institution's animal care and use program including access to all animals. [redacted] is contracted to spend 10% of [redacted] time contributing to our program. [redacted] makes weekly visits to

inspect animal and facility conditions. [redacted] provides programmatic support by review of IACUC protocols (ACORPs), operational procedures, and other Animal Care and Use Program documents on site and remotely. When not on station, [redacted] is available on-call for emergencies and the VMU supervisor and Research faculty and staff consult him regularly.

When Dr. [redacted] is unavailable, in order to ensure adequate veterinary care, emergency veterinary services are provided through an arrangement with the veterinarian(s) at of the [redacted], Albuquerque [redacted]. They will always be accompanied by one of the VMU staff if they are called to campus.

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.

During the time that Dr. [redacted] is not on station, [redacted], VMU supervisor is responsible for daily animal care and facility management. It is [redacted] responsibility to contact Dr. [redacted] if a problem arises that [redacted] cannot resolve. If the problem cannot be resolved by phone or electronic consultation with Dr. [redacted], [redacted] comes on site to resolve the problem.

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.

N/A

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.

All training is documented electronically and is retrievable by Research Administration. The effectiveness of the training is evaluated through Post-Approval

Monitoring (PAM).

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.

[redacted], D.V.M., DACLAM: 34 years of experience in laboratory animal medicine; graduated from Oklahoma State University in 1980 with a D.V.M.; completed a Laboratory Animal Medicine Residency 1983-87; board-certified by ACLAM in 1987. Continuing education activities: routinely attends CE meetings, reads journals, AAALAC updates, ACLAM newsletter; discussions with colleagues, ethicists, etc.

[redacted], D.V.M.: MS., DVM., DACZM: 15 years' experience caring for a wide variety of exotic species including the laboratory rodent and rabbit species housed at the VA. She completed her veterinary degree in 2002 at the Ohio State University and worked in an exotic animal practice for three years prior to completing a two-year residency in [redacted] at the [redacted]. Since 2008, she has practiced zoo animal medicine and is currently the head veterinarian at the [redacted] where she is responsible for providing the clinical care for a wide variety of species. In 2012, she completed Board Certification in the American College of Zoological Medicine.

[redacted] LATG: 38 years of experience in laboratory animal care; completed LATG certification in 1984; worked at the University of New Mexico, University of Kentucky and Lovelace Respiratory Research Institute. Continuing education activities: reads journals, AAALAC updates; attends webinars.

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

1) Indicate the number of animal care personnel.

1

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.

LAT certified technician/surgical technician: 29 years of experience in laboratory animal care; regularly reviews pertinent journals and literature and

has the opportunity to take continuing education courses and webinars provided by the NMVAHCS.

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 personnel are required to complete courses through the CitiProgram.org website. VMU staff randomly query those performing live vertebrate animal work within the VMU to see if they know specifically where certain procedures are in the protocol and can tell how they perform these particular procedures. Training specific to protocols, conducted by VMU staff, Veterinary Medical Consultant or the PI is documented.

a) Briefly describe the content of any required training.

The basic courses include:
• Species specific training (e.g. Working With Mice, Rats, and Rabbits in Research Settings);
• Humane methods of animal maintenance and experimentation;
• Detecting, monitoring, and alleviating animal pain and distress;
• Research and testing methods that minimize the number of animals required to obtain valid results and minimize animal distress;
• Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility;
• Occupational health issues.

Completion requires a passing grade on the exams.

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

Training must be completed prior to working with live animals, their tissue or blood. CitiProgram courses must be retaken every three years.

c) Describe continuing education opportunities offered.

Hands-on bio-methodology training is provided throughout the year to individuals who need it by the VMC, the VMU Supervisor, or other professionals with specified expertise. Examples of this training may include:
• Handling, restraint, anesthesia and euthanasia of the species with which the person is working;

• Techniques of injection or blood collection as needed;
• Techniques of aseptic and survival surgery and post-surgical care if this is to be done;
• Other techniques as determined by the IACUC.

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 VMC provides hands-on training for all surgical procedures and/or monitors the personnel. He reports to the IACUC which determines that personnel are qualified and trained.

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

The VMC or VMU staff provides hands-on training for all anesthesia procedures and/or monitors the personnel. They report to the IACUC which determines that personnel are qualified and trained.

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

VMU staff provides hands-on training for all euthanasia procedures and/or monitors the personnel. They report to the IACUC which determines that personnel are qualified and trained.

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 Facility Director is responsible for developing and implementing an OHS Plan for personal hygiene, protective safety measures, safe use of hazardous materials, and preventive medicine for personnel engaged in the care and use of research animals.
- Employee Health Service operates the Occupational Health Program and provides pre-placement and periodic post-employment medical evaluations when called for by a change in risk factors, and ensures that required immunizations are current.
- The Employee Health Nurse reviews each employee's Animal Contact Health Surveillance Questionnaire annually.
- The Employee Health Physician provides guidance to Research Service in developing and maintaining this policy. The Employee Health Physician also does follow-up exams as indicated.
- Research Service provides OHS training annually and as required.
- The Industrial Hygienist (IH), Radiation Safety Officer (RSO), and Subcommittee on Research Safety, Biosafety and Security (SRSBS) provide information, monitoring, and assistance, as needed, for any work involving hazardous biological, chemical, and physical agents.

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.].

The Principal Investigator (PI) is required to identify hazards associated with his/her research protocol and enforce the appropriate safeguards for those working in the project, based upon recommendations from the SRSBS and Institutional Biosafety Committee (IBC). All work with hazardous agents must be cleared through the SRSBS. Evaluation of animal specific hazards, protocol hazards, and potential for exposure to hazardous agents is conducted jointly by the PI, VMC, animal care personnel, SRSBS, and IBC. An approved copy of the Research Protocol Safety Survey (RPSS), with the signature of the Facility Safety Officer, needs to be on file in the Research Office.

The IH, RSO, SRSBS and IBC provide information, monitoring, and assistance, as needed, for any work involving hazardous biological, chemical, and physical agents. The occupational health program is tailored by Employee

Health accordingly for personnel potentially exposed to hazardous agents. This is evaluated on a case-by case basis and may include more frequent physical examinations and/or more inclusive clinical pathology work-ups as it relates to the hazardous agent.

The IACUC reviews all protocols, including those involving the use of hazardous agents. The project PI must submit a written Standard Operating Procedure (SOP) for handling potentially hazardous animals, and a safety plan to the SRSBS and the IACUC that describes the hazardous agents to be used and the safety precautions to be followed by the animal care personnel. The VMC and/or VMU supervisor reviews these precautions with the VMU tech, and these are posted as an SOP in the animal facility. The SRSBS and VMU staff jointly monitors the program.

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

Certified hazard assessments are conducted at least every 3 years to determine the need for, and appropriate types of, PPE. New hazards are identified on the annual animal contact questionnaires and during IACUC and SRSBS annual project reviews.

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]

Employee reports all injuries, exposures, accidents, etc. to his/her immediate supervisor. The supervisor used the Veterans Health Information Systems and Technology Architecture (VISTA) to track these items. The supervisor reports exposures to Employee Health as detailed in Medical Center Memorandum 05-18, Management of Office of Workers' Compensation Program (OWCP). Potential hazards are reported to the SRSBS and the hospital Environment of Care (safety) committee (EOC). The SRSBS does follow-up with the assistance of the EOC, as needed.

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.

Each year PI's, research technicians, animal technicians and IACUC members must fill out the Annual Medical Clearance Questionnaire. VA Police who could have need to enter the VMU in an emergency, and engineering personnel who enter the VMU intermittently, are also required to complete this form annually. Individuals with isolated one-time animal contact are exempt. There are no exemptions for anyone working directly with animals in the VMU.

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.

Personnel may decline to receive services not required by the VA facility to protect the health of the animals or other personnel (e.g. TB testing or chest radiography). Personnel who decline optional services are considered to be enrolled in the OHSP as long as the VA facility documents that they were given the opportunity to receive these services. The annual survey itself is not optional.

c) Describe provisions for assuring confidentiality of medical information.

All medical information is maintained only at the Employee Health Service, which operates the OHP and provides pre-placement and periodic post-employment medical evaluations when called for by a change in risk factors, and ensures that required immunizations are current. Employees fill out their own forms and take or email them directly to the Employee Health Nurse.

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

Individuals with incidental exposure to animal care and use, while exempt from a medical evaluation, are informed of safety issues such as allergens.

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.

All new employees must have a pre-placement evaluation conducted by either their primary employer or the NMVAHCS. This will consist of an assessment of medical and allergy history, physical examination if indicated, and diagnostic tests and immunizations as needed. Annual medical questionnaires are filled out covering animal exposure, allergy history and immunization history.

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.

N/A

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.

General education program for allergies, zoonosis, and personal hygiene is provided through CitiProgram.org. The VA Talent Management System (TMS) provides training on waste anesthetic gas, chemical spill kits, PPE, ergonomics, infection control and prevention. Refresher training is required annually.

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.

Clean uniforms consisting of scrubs are furnished to all VMU animal care personnel on a daily basis by the hospital laundry. The uniforms are provided by the VMU. Shoes are also provided for the VMU animal care personnel. Lab coats, respirators, protective smocks, gloves, masks, caps, and shoe covers are also provided for work with hazardous agents as required.

b) Describe arrangements for laundering work clothing.

All work clothing is laundered by the institution.

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.

Sinks, soap and paper towels are available in animal rooms, laboratories, procedure rooms, lavatories, and the employee lounge for washing hands. Personnel are required to wash hands upon exiting animal rooms. Instant hand sanitizer is provided in the hallways. Showers, lockers, and changing facilities are available for animal care personnel in the VMU. At a minimum, the animal care technicians change uniforms daily. Work uniforms are restricted to use only in the VMU. The animal care staff may leave the VMU to go outside, to the canteen, etc., if they wear a lab coat or similar covering over their uniforms. If they leave the NMVAHCS campus, they must change into their personal clothing.

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

Eating and drinking is restricted to the administration area of the animal facility which is separated from the animal housing and procedure area by a door. Smoking is not allowed in the animal facility or any building on the

VA campus.

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).

Bulk chemicals are stored in the cage wash area and are piped to the cage washing equipment through tubing in the ceiling. A hydraulic drum dolly is provided to move bulk chemicals from the loading dock to the storage area. A portable hydraulic lift table cart is available for moving heavy equipment. A hydraulic scissors lift is available at the loading dock. Employees also work in pairs when moving or lifting awkward, bulky or heavy items.

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

Proteins in urine, hair follicles and dander as well as in saliva are the likely sources of allergens. Administrative areas are separated from animal housing and procedural areas. Mice are housed in individually ventilated caging systems (IVCS) hooked to the building exhaust system. Mice are changed under animal changing stations or biological safety cabinets. Air is 100% intake and exhaust with no recirculation.

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

The most likely source of zoonoses would be from mice experimentally infected with *Clostridium difficile*. Mice are housed in a negative IVCS and changed under a biological safety cabinet (BSC) in a BSL-2 room. Dirty cages from the BSL-2 mouse room are red bagged and autoclaved before being washed.

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

BSC's and the animal changing station are certified annually. Autoclaves are monitored at least every 40 hours of operation with AccuFast Biological Indicators and each load is monitored with temperature tape.

e) Respiratory Protection

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

3M N-95 disposable respirators are available for use when changing, dumping or bedding cages.

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

The hospital has a Respiratory Protection Program that complies with the Occupational Safety Health Administration (OSHA) Protection Standard (29 CFR 1910.134) and all VHA guidance. Employees are identified as "at risk" for potential exposure upon assignment (during orientation) or when their assignment changes to include at risk activities. After the Employee Health Physician evaluates the employee, the employee takes online training on respirator use and maintenance. The hospital industrial hygienist then does the fit/testing and provides further training on how respirators are donned and worn. Fit-testing and training are annual requirements.

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

The hospital industrial hygienist selects employee respirators. We currently use only N95 respirators that are inspected each time prior to donning. If used in a BSL-2 or ABSL-2 area, they are disposed of after each use. If used as protection from dust and dander they are disposed of at the end of the day.

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).

Rack washer, cage/bottle washer, pass-through autoclave, and small autoclave. Staff is trained annually on rack washer safety. There are signs on the equipment denoting safety features and specific safety

features are described in Appendix 15.

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.

N/A

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.

N/A

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

Oxygen is piped to the procedure rooms and surgical suite. Isoflurane is the only volatile anesthetic used in the VMU. It is scavenged by two systems: 1) exhaust hood in procedure rooms; 2) F-Air charcoal canisters.

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.

BSL-2: Enteropathic Escherichia coli, Clostridium difficile, Campylobacter jejuni

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

Streptozotocin, tamoxifen

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

N/A

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.

All investigators conducting research involving animals must complete ACORP with the signature of the Chair of the IACUC indicating that the investigator has provided an appropriate plan for the safe handling of the animals, caging, and animal waste. All investigators must also complete the Research Protocol Safety Survey (RPSS) with the signature of the Chair of the SRSBS indicating what hazards are involved with each protocol.

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 specific safety measures needed are dependent on the risk to human and animal health represented by the agent, and the difficulty involved in containing the agent. Procedures are developed with input from the PI, VMC, and VMU technicians. These procedures are reviewed by the IACUC and the SRSBS.

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.

Contamination with infectious agents requires that bedding be sterilized before being dumped in the regular waste stream. If soiled bedding

containing infectious material cannot be rendered harmless prior to being dumped, it will be bagged, or double bagged, and placed in the Regulated Medical Waste (RMW) stream. Bedding containing chemical waste is also bagged and placed in the RMW stream. Upon completion of the necessary work with contaminated carcasses, they are placed in red biohazard bags, tagged with an "Incinerate Only" sticker and disposed of as RMW. If carcasses need to be held, they are bagged with hazards clearly identified and refrigerated, or placed in the freezer reserved for carcass disposal. Needles and syringes are disposed of by dropping them into puncture-proof containers that are located in every room in which sharps are used and disposed of as RMW. An Environmental Management Service (EMS) employee picks up RMW when called and takes it to a central location adjacent to the hospital for disposal by a hazardous waste contractor.

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

Animal care personnel engaged in working with biohazardous agent-inoculated animals, as well as all laboratory personnel working with these animals, will be offered pre-exposure immunization by Employee Health if available unless it is not conducive to the individual.

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.

Personnel who work with animals exposed to hazardous agents will be trained in proper procedures to work with the animals and related waste and equipment. Specific training will be supervised by the Principal Investigator. Documentation of such training needs to be made before employees manipulate experimental animals treated with hazardous agents. This training is repeated annually.

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.

Room [redacted] is an ABSL-2 room used to house mice exposed to biohazardous agents. Rooms [redacted] and [redacted] are designed to house rodents and rabbits exposed to biohazardous agents, but are not currently used for this purpose.

These three rooms have inward directional airflow. Room [redacted] occasionally houses rats injected with Streptozotocin. Room [redacted], an SPF mouse room with outward directional airflow, occasionally houses mice injected with Tamoxifen. However, these filtered cages are only opened inside of a BSC and the exhaust from the BSC is connected to the building exhaust.

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.

When Tamoxifen is used, it is administered to the animals in a BSC. A lab coat or disposable gown, safety glasses/goggles, and nitrile exam gloves are used for handling live animals, carcasses or animal waste/dirty bedding. After administration of Tamoxifen, the Principal Investigator (PI) lab member shall place the mice into a clean disposable cage with a full size blue cage card placed in front of the regular cage card, which clearly states the chemical hazard, relevant lab and contact name, date of each drug injection, special handling until date (3 days after the last injection). These cages are kept on a separate shelf from animals not on Tamoxifen.

When Streptozotocin is used in rats, a lab coat or disposable gown, safety glasses/goggles, and nitrile exam gloves are used for handling live animals, carcasses or animal waste/dirty bedding. Animals are appropriately restrained prior to administering injections. Needles are disposed of in approved sharps containers immediately following use. All potentially contaminated carcasses, bedding, and other materials are disposed of as Regulated Medical Waste (RMW) through incineration.

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

BSC are certified annually; autoclaves are monitored at least every 40 hours of operation with AccuFast Biological Indicators and each load is monitored with temperature tape.

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

PPE used are disposable gowns, gloves, shoe covers, bonnets, masks, and eye protection. Procedures are performed and cages are changed under BSCs. If BSCs cannot be used for procedures where there is a risk of biohazardous

aerosols, N-95 respirators are used instead of masks.

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.

N/A

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.

N/A

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.

Members are appointed in writing by the Medical Center Director, IO. The letter from the IO must include the length of the appointments. The Chair is appointed for a one year renewable term. The all other members are rotating members assigned to the subcommittee for 3 year renewable terms. For continuity of the subcommittee, rotation of the non-permanent members should be staggered. At least one member of the IACUC needs to be a member of the R&D Committee. One IACUC member should also be a member of the Subcommittee on Research Safety, Biosafety, and Security.

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

The IACUC meets at least quarterly with additional meetings as necessary to conduct

mandatory business.

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

New IACUC members are required to complete the www.CitiProgram.org "Essentials for IACUC Members" course. This course is repeated by all IACUC members every three years. In addition, new IACUC members receive a copy of the "Guide", current PHS Animal Welfare Assurance, VHA Handbook 1200.07, "Use of Animals in Research", and an integrated summary of the regulatory requirements applicable to VA Animal Research, "Nuts and Bolts of Regulatory Requirements for Use of Animals in Research." Continuing education via 'training scenarios' provided by the Chief Veterinary Medical Officer's (CVMO) office is presented throughout the year at convened IACUC meetings. Members may also participate in webinars held at the University of New Mexico.

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.

New Protocols including protocols that do not involve a formal grant proposal, Three Year Re-writes and Major Amendments:
The PI sends a completed electronic copy of the Animal Component of Research Protocol (ACORP) to the Veterinary Medical Consultant (VMC) for pre-review and comments. If the PI wants a face-to-face or phone consultation with the VMC before the pre-review, that can be arranged. The PI finalizes the ACORP and submits it electronically to the Research Office. All protocols, regardless of funding source (including pilot and internally funded studies) are submitted through electronic submission. The ACORP is then sent electronically to all IACUC members along with the meeting agenda.

A quorum of the IACUC must be present before conduct of business under full committee review (FCR). The committee may invite the PI to attend a convened meeting to summarize or answer questions about the protocol, especially relating to procedures having the potential to cause pain or distress to animals, the justification of group sizes, and the total numbers of animals requested. Once all questions are answered, the PI leaves the room while the IACUC members discuss and vote on motions associated with the protocol. Approval of a motion requires affirmative vote of the majority of the quorum present. No member may participate in the IACUC review or approval of a research project in which the member has a conflicting interest, except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum. The IACUC may invite consultants to assist in the review of complex issues. Consultants may not approve or withhold approval of an activity or vote with the IACUC unless they are also members of the IACUC.

Protocols that have a potential to cause significant pain or distress are reviewed through a similar process as described below except protocol questions relating to category D, alleviated pain and category E, unalleviated pain studies, require additional information, searches for alternatives, justification, and description of endpoints and monitoring procedures. Based upon justification provided for such studies, the committee considers whether the potential scientific benefits justify the harm. (See para c.i.2) for additional detail on expectation when painful or distressful alternatives are not available. The ACORP also has a section that requires the PI to use non-technical language to describe how the 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 the protocol.

Following discussion at the convened meeting, possible committee decisions include: Approval: The protocol is approved as written. However, the R&D Committee may disapprove a project that the IACUC has approved.

Withhold approval: The IACUC shall include in its electronic notification a statement of the reasons for its decision and give the PI an opportunity to respond in person or in writing. The Research and Development (R&D) Committee may not overturn this decision.

Require modifications to secure approval: When substantive information is lacking from a protocol, the committee may have questions requiring a response from the PI. The committee may decide by unanimous decision to have the revised research protocol reviewed and approved by designated member review (DMR). When multiple reviewers are assigned for DMR, all decisions must be unanimous. However, if not unanimous then the protocol must return to a convened meeting for action. Currently all members of the IACUC have signed approval of this DMR process (described below) following a convened meeting in compliance with OLAW

guidance.

Tabling the protocol:
The PI is informed of the outcome of the protocol review process electronically from the IACUC following the convened meeting.

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.

Proposed changes to an approved ACORP may be submitted to the IACUC as an amendment if there is a definite and clear link to the hypothesis presented in the original protocol and if the proposed change(s) are easily interpretable as a change or outgrowth of the original protocol.

The IACUC requires that all changes (Minor or Major amendments) to an approved protocol be submitted electronically to the Research Office. The VMC and the IACUC Chair have been designated by the VA IACUC to determine if proposed modifications represent minor or major changes to the existing protocol. Decisions are based upon PHS policy, OLAW guidance and VHA Handbook 1200.07.

Minor Amendments: The VMC and the IACUC Chair review and approve minor modifications to existing protocols. The reviewers can request additional information in order to secure approval or, if acceptable, they can approve. Minor amendments for a change in personnel (other than a change in the PI) are reviewed and approved administratively by the IACUC Chair following confirmation that all training and occupational health requirements have been met. The minor amendment is listed on the agenda at the next convened meeting. If any IACUC member requests further review of minor modifications, a review will be conducted at the convened meeting.

Major Amendments (significant modifications): These modifications are processed and reviewed the same as original protocols (i.e. requiring approval either through designated member review or review during a convened committee meeting with a quorum). Change in the PI is a major change and is reviewed as such.

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.

In general, if humane endpoint criteria are met and there is timely provision for treatment, removal from the study, or euthanasia prior to conditions developing that are considered to be more than minor or momentary pain or distress, the respective animals are categorized as "D", alleviated pain. Under these circumstances, alternatives searches are required as well as selecting whether potential morbidities are expected and criteria that, if identified, will signify the humane endpoint. At times, clinical scoring sheets may be required to establish a more objective measure for the endpoint. In addition, interval of observations, the action required when reaching endpoint (e.g. treatment, euthanasia, etc.) must be defined under the respective observation criteria.

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).

In general, animals under these types of studies are category E, unalleviated pain or distress. Whenever an experimental protocol includes a significant potential for morbidity, unalleviated pain, and/or death as and endpoint, first and foremost the PI must consult with the VMC. A justification is required if alleviation of pain or distress cannot be provide within the goals of the research. Under these circumstances, the PI is expected to clearly delineate acceptable early endpoint criteria, when possible, and this is generally managed though implementation of clinical scoring criteria that provides objective measures or numerical scores that identify when animals can be treated or euthanized. Clinical scoring is based upon a number of measures including unprovoked and provoked behaviors, general body condition and appearance, and changes in body weight. Severity of outcomes for each of these general categories is scored from 0 for normal to increasing numbers with severity. Specific numerical values by category and/or sum of all categories are pre-defined as the endpoint criteria when treatment or euthanasia will be administered. Early endpoint decisions are designed to minimize pain or distress at the earliest point possible while supporting the goals of the research. Based upon justifications for unalleviated pain or death as an end-point or other sections in the protocol that capture expected morbidity and subsequent requirements for the PI to define methods of observation, interval for observation and/or more quantifiable scoring sheet methods for end-point determination, the committee consider harm to the animal model versus benefits to science when considering approvals or decisions to require more justification, other interventions, earlier end-points, more frequent observation, etc. Pilot studies are also encouraged by the IACUC to determine whether earlier or more humane end-points could be considered.

3) Identify personnel responsible for monitoring animals for potential pain and distress and describe any mechanisms in place to ensure that the

personnel have received appropriate species- and study-specific training.

The PI, research tech, or animal technicians are responsible for monitoring animals for potential pain and distress. VMU personnel are trained periodically and have access to the Handbook of Clinical Signs in Rodents and Rabbits. Protocols with potential morbidity define frequency and type of observations required by the PI labs and clinical signs, weight loss, etc. used for decision making. The PI and/or VMU technician provide training to staff for handling, procedures, and methods for observations as applicable.

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.

Expected outcomes are defined in the ACORP to inform associates of expectations and actions or end point measures that should be applied following adverse expected outcomes, if applicable. All protocol associates or members of the VMU are trained to report unexpected adverse outcomes either to the VMU supervisor, the veterinarian or the IACUC. Examples include outcomes that occur related to experimental procedures or physical plant or husbandry failures and also unexpected spontaneous disease or mortality that occurs with any species/strain to include genetically modified animals. The goal of early reporting is to enable rapid determination and mitigation of causal factors.

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."

Appendix 6 of the ACORP form requires that the PI specify if restraint is required. For more than momentary restraint, the committee expects habituation of the animals to the apparatus starting with short periods and increasing to longer periods, as long as such preconditioning will not compromise the goals of the science. If animals fail to habituate to the restraint, they are removed from the study. In addition, the PI must defines the frequency of monitoring and criteria for removal of individual animals if they fail to adapt to the restraint. No long-term restraint procedures are currently approved. However, any use of restraint devices, even for short-term procedures, requires description of the procedure. Restraint is considered short-term if it is brief minutes (e.g. tube restraint for mice or rats ~15 minutes or

less). Momentary hand restraint of an animal for an injection does not require completion of the restraint description but the committee does recommend habituation to manual restraint in most cases.

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.

We had one protocol where mice were restrained in a nose-only smoking apparatus ten minutes a day, five days a week, for eight weeks. To acclimate the mice before the experiment, they were placed in the restraint tubes five minutes a day for three consecutive days without any cigarette smoke exposure. The mice were monitored at all times during acclimation and experiments by the research technician.

iv. Multiple Survival Surgical Procedures [*Guide*, p. 30]
Note: One survival surgical procedure followed by a non-survival procedure is not included in this category.

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

The PI must discuss plans for such with the veterinarian and must also provide scientific justification. The IACUC considers the justification, risks to the animals associated with any multiple survival surgeries, and aftercare as part of the decision process.

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.

16-A214, *Peripheral and Central Pain Generators of Chronic Trigeminal Neuropathic Pain*, is the only protocol currently approved that involves multiple major survival surgical procedures. The first surgery is to produce the

Orofacial Pain Model. After this initial surgery, the rats have a second surgical procedure for 1) stereotaxic placement of pain relief drugs or inhibitors; or 2) Dual micro-cannula implant for drug injections.

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.

Clostridium difficile Colitis
Justification: to reduce the mass of intestinal lumen content at the time of bacterial inoculation.
Species: mouse
Length and type: fasted 6 hours prior to orogastric inoculation and 6 hours prior to being euthanized.
Mouse Model of Gulf War Syndrome
Justification: Metabolic cages: to find out the optimal time for running behavioral and intestinal transit motility procedures; Maze: to motivate mice to work for treats
Species: mouse
Length and type: 3 hour fast while in metabolic cages, 4 hours before each maze learning session
Rat Model of Gulf War Syndrome
Justification: Gavage: to reduce the mass of intestinal lumen content at the time of gavage; Metabolic cages: to collect accumulated air samples
Species: Rat
Length and type: 12 hour fast pre-gavage; 3 hour fast while in metabolic cages

Fasting is for short, limited periods; no monitoring is done, nutrition is adequate, and fluid is not restricted.

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.

As part of the protocol, the PI must explain why the use of a non-pharmaceutical grade formulation is necessary, and describe how purity, sterility, physiological characteristics will be assured so that the material is safe and supports scientific integrity. Generally the justification is because pharmaceutical grade products are not available. Cost alone cannot be used as the sole justification.

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.

N/A

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

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

Occasionally, animals that have been ordered but not used on a protocol will be transferred to the Procedures and Technique Training or other protocol for use but reuse is not the routine. The risk to animals would be evaluated by the veterinarian and the IACUC if this option were requested.

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.

N/A

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.

N/A

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).

Annual review: Ongoing reviews are considered compliant if they are completed within the same month as the anniversary date of the most recent previous approval. It is also acceptable for the review to be carried out up to 5 weeks before the anniversary date, with the approval effective on the anniversary date. A new 3-year ACORP must be submitted, reviewed, and approved by the IACUC prior to the third anniversary of the initial ACORP approval for vertebrate research to continue. Regardless of the dates of any annual renewals, the approval of each ACORP will expire on the date of the third anniversary of the initial approval.

The PI completes the annual review form and submits it electronically to the Research Office. Annual review forms will be reviewed by the IACUC Chair for category of stress, use of biohazards, and training status of all study personnel. The IACUC Chair will also verify that protocols using biohazards have an approved Research Protocol Safety Survey (RPSS) at the time of annual review.

The Annual renewal/review is approved by DMR when all questions and/or comments have been answered in a satisfactory manner. All annual reviews are placed on the agenda of the next convened full Committee meeting. Each member has full access to the protocols and they can request FCR of any protocol of concern.

3-year renewals: All existing protocols must be resubmitted for a complete de novo IACUC review/approval as described for new protocols every three years, regardless of funding source in order for research to continue.

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

ACUP Program Review: The IACUC conducts the semiannual review at least every 6 months, using the Guide, and the VA Semiannual Evaluation of the Institutional Animal Care and Use Program and Facilities Form. Each member is encouraged to participate in semiannual facility inspections, and the Program Review. No IACUC member wishing to participate in semiannual facility inspections and/or the program review is prevented from doing so. This review of institutional policies and responsibilities include: IACUC membership and functions, protocol review process, animal facility inspection process, provisions for reviewing and investigating concerns regarding animal care and use, IACUC record and reporting requirements, veterinary care program, personnel, emergency preparedness, post-approval monitoring, security, and other aspects of the program, according to Chapter one of the Guide. The program of veterinary medical care is evaluated to determine what is intended or expected from institutional policies, transportation procedures, surgery guidelines, pain, distress, analgesia, and anesthesia guidelines, euthanasia guidelines (AVMA Guidelines on

Euthanasia), and drug storage and control. The program review is completed every six months along with the facility inspection.

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**.

Facility Inspection: The IACUC inspects the animal facility every six months using the Guide as a basis for evaluation. IACUC procedures for semiannual facility inspections are as follows: At least three members of the IACUC physically inspect the VMU, noting any deficiencies or departures from the provisions of the Guide. This information is used when filling out the VA Semiannual Evaluation of the Institutional Animal Care and Use Program and Facilities Form, a checklist utilized when the IACUC conducts the semiannual facility inspections. This checklist is based on the examples of checklists found on the OLAW website, but is more extensive. This checklist covers:

a. All rooms and laboratories in which animals are housed or used > 12 hour;
b. Specialized spaces such as surgery, and support facilities such as storage, locker rooms, and cage wash areas;
c. All laboratories where survival and non-survival surgery and other procedures are performed.

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

The ORO Research Safety and Animal Welfare (RSAW) group conducted an On-Site Focused Review of the Animal Care and Use Program (ACUP) on June 21-23, 2016. ORO did not identify any programmatic regulatory concerns associated with the NMVAHCS ACUP, and no specific actions were required as a result of this review. Suggestions to further enhance our research oversight program, were implemented.

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

Post Approval Monitoring (PAM) program: Ongoing activities are also monitored

through a PAM program. A monitoring form is used by the IACUC Chair, VMU supervisor, and other IACUC members to randomly query those performing live vertebrate animal work within the VMU. During the PAM, the reviewer asks questions that are detailed in the approved protocol to determine whether activities are compliant. Training status and enrollment in the Occupational Health Program are also verified. The results of the PAM are sent to the PI for review and corrective action. If deficiencies are found the PI must provide a response to the IACUC describing how the deficiencies were or will be corrected and a subsequent PAM meeting will be scheduled with the PI within 6 months, or sooner depending on severity of the findings. The results and corrective actions will be reviewed by the IACUC at the next convened meeting.

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

Employees are encouraged to report any concerns immediately. A sign is posted in the animal facility listing the phone numbers of the IACUC chairperson, the veterinary medical consultant, the animal facility supervisor, and the hospital research compliance officer. Concerns are corrected at the lowest possible level by reporting them first to the Veterinary Medical Consultant through the VMU Supervisor on an informal basis. If a satisfactory response is not received, the concern is taken to the IACUC. Concerns reported to the IACUC are forwarded to the Chair of the IACUC promptly. The Chair of the IACUC (in consultation with the VMC or other members of the IACUC when appropriate) has the authority to initiate an investigation.

Procedures the IACUC uses to review reported concerns: The concern will be evaluated relative to the applicable provisions of the Animal Welfare Act and Animal Welfare Regulations (AWAR), the Guide, the Institutional Assurance, VHA Handbooks 1200.07 and 1058.01, and IV.C.1a-g of PHS Policy (Published Standards). Concerns raised will be discussed at the regularly scheduled meetings unless meeting specific criteria to warrant holding a special meeting. Seriousness of concern and need for a special meeting will be decided by the IACUC Chairperson.

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.

Analysis of the consequences of disasters (either natural or man-made) indicates that

failure of the physical plant to maintain security and a proper environment will be the focus of concern. The VMU supervisor will be notified in the event of a disaster that threatens the integrity of the building housing the VMU or its environmental controls [redacted] will assess the situation, using resources such as the VA engineering personnel and the VMC as indicated. A judgment will be made as to whether animals can continue to be safely housed in the VMU, moved to another facility, or euthanized.

II. Animal Environment, Housing and Management

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

A. Animal Environment

Note: Facility-specific details regarding mechanical system construction and operation is requested in Section IV.B.5. and **Appendix 11**; current (measured ***within the last 12 months***), detailed (by room) performance data must also be provided as indicated in **Appendix 11.**

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

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

The HVAC system to include fan controls, temperature and humidity is monitored and alarmed remotely by the energy plant 24/7. In addition, personnel in the VMU monitor and record the high/low temperatures and humidity in each animal room daily. No outdoor housing areas are used.

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]

Room temperatures (+/- 3° F): 74°F Mice, 72°F Rats, 68°F Rabbits. Humidity 18-40%

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]

Considering that the thermoneutral zone for mice is 80-86° we provide additional hutches and nesting material to enable the mice to manipulate their environment such as to thermoregulate. Rats are provided with small towels. We have a significant tradeoff between room temperature and humidity because for every degree increase in temperature, humidity goes down (based upon the temperature differential at the fan where the air is humidified and the room where the air is reheated to set point). Humidity: The Guide requires 30 – 70% humidity in the animal rooms. Due to very low ambient humidity conditions under desert environments, the humidity in the VMU can usually only be maintained between 18-30%. There are no rat breeding colonies that would be affected by lower humidity and the humidity levels do not fluctuate widely from day to day. The IACUC considers impact of low humidity below the range listed in the guide during semi-annual inspections to assure that the conditions are not causing clinical concerns. One value of lower humidity is that the cage bedding environment stays dryer and we have less ammonia production as compared to humid environments with the same cage change frequency.

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.

ABSL2 rooms are maintained -0.02 to -0.05 pressure gradient to the hallway while SPF rooms are either static or slightly positive to the hallway. The pressure is measured with sensors in the hallway.

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

We have two individually ventilated, high density mouse housing units whose design delivers low velocity HEPA filtered air to each cage while capturing cage effluent air. We also have one individually ventilated caging unit for mice that has variable airflow rates and selectable pressure modes that allows the unit to be maintained under either continual positive pressure or continual negative pressure. The exhaust air from the racks is connected to the building exhaust system to minimize rodent odors and risks from allergens.

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.

N/A

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).

   N/A

   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).

   N/A

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.

   Technicians are trained to perform necessary tasks with the minimum amount of noise. If building maintenance, construction, or remodeling in an animal room is likely to produce noise or vibration, then animals are moved to a quieter area. An A-frame sign is placed in the hall outside the mouse behavioral room when mice are being tested to remind people to be quiet.

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.

   The 8th Edition Guide and general assessment based upon performance standards (behavior, growth/productivity, ability to display normal species specific posture, etc.).

   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]

Rabbit cage height: Allow <2.5 kg NZW and DB rabbits to be housed in 14" high cages for short-term (<3 wks) experiments. NZW rabbits were observed during two experiments from 1/27/13 – 2/14/13 and 2/17/13 – 3/4/13. Animals weighed 1.6 – 2.1 kg 7 days after arrival and 1.4 – 2.3 kg on the last day of the experiment. Every rabbit was able to sit in a natural posture with 2 – 3" of space between ear tips and cage ceiling. They were also observed to lay stretched out without touching the cage sides.

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).

Mice: LifeSpan enrichment device from Lab Products; Rabbits: Dri-Dek resting boards.

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).

Mice: [redacted] manzanita wood gnawing sticks, certified mouse tunnels, certified wood gnawing blocks; [redacted] Specialty Papers Dome Shack, [redacted] nesting material; [redacted] Mouse House; [redacted] Enrichment unit.
Rats: [redacted] certified/irradiated Diamond Twists; certified wood gnawing blocks; [redacted] manzanita wood gnawing sticks, [redacted] nesting material; clean surgical towels.
Rabbits: [redacted] stainless steel rattles, certified [redacted]; [redacted] hay, canning jar lid rings.

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

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

All animals are housed in groups 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.

Male mice may be housed one per cage if they fight with their cage mates. Diabetic rats may be house singly if cages become too wet between daily cage changes. Rabbits are housed one per cage in infection studies to avoid cross-contamination.

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

Toys are provided to singly-housed animals. Employees interact with isolated rats and rabbits throughout the day. For rabbits that are singly housed we attempt to at least arrange cages so that they have visual contact and for long-term projects compatible rabbits are paired in the large exercise pens for part of the day.

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 enrichment program is described under a VMU SOP. Both the enrichment program and exceptions to social housing of social species are regularly reviewed during the semiannual program review.

d. Procedural Habituation and Training of Animals [*Guide*, pp. 64-65]
Describe how animals are habituated to routine husbandry or experimental procedures, when possible, to assist animals to better cope with their environment by reducing stress associated with novel procedures or people.

Rabbits and rats are handled and talked to daily by both animal technicians and the research technicians who will perform the experiments. Research technicians are encouraged to do the same with mice.

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).

N/A

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.).

N/A

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.

N/A

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).

N/A

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

N/A

iii. Describe how animals are captured.

N/A

C. Animal Facility Management

1. Husbandry

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

i. List type and source of food stuffs.

[redacted] 2920X Global Soy Protein-Free Extruded Irradiated Rodent Diet; [redacted] 8656 Sterilizable Rodent Diet (W); [redacted] [redacted] [redacted] [redacted] 2031; [redacted] – Grocery Store, [redacted] hay (autoclaved prior to feeding) – local pet store.

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

Primary Rodent and Rabbit diets ([redacted]) are delivered door to door via the Vendor's trucks or commercial freight [redacted]) and the diets are not stored at a local distribution center. The vendors manage their storage under strict temperature, sanitary and vermin control programs.

Feed is stored in the VMU in a cold room set at 43°F. Bags are rotated with the oldest feed used first. Feed is stored in the animal rooms in autoclaved mouse/rat cage bottoms with filter tops.

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).

N/A

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

Mice/Rats – Metal cage lid hoppers ad libitum, glass Petri dishes, modular diet system ad libitum; Rabbits - J-feeders - hand fed daily with appropriate amounts in order to monitor appetite and optimize normal growth rates.

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

Stock is rotated so that the oldest food is used first. Commercial food is used up to six months after manufacture. Torn or patched bags are refused on delivery. Diets are refrigerated. [redacted] hay is purchased irradiated.

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 NMVAHCS has its own well which is the primary source of water. The NMVAHCS has a secondary source "City Water" from the Albuquerque Bernalillo County Water Authority (ABCWUA). The NMVAHCS considers the water pumped from the well "Hard Water" because it is not softened when it first

comes out of the well. The “Hard Water” is then chlorinated at the Well House via a Mixed Oxidant (MIOX) System which in basic terms separates chlorine from salt. This “Hard Water” is then pumped to a 300,000-gallon “Hard Water” Storage Tank. The “Hard Water” is then pumped through a Water Softener and Charcoal Filters located in [redacted] The “Soft Water” is then treated via a MIOX System again since the “Hard Water” was stripped of the chlorine before it enters the Charcoal Filter and Water Softener. The “Soft Water” is then pumped to a 100,000-gallon “Soft Water” Storage Tank or directly to the facility if needed. The “Soft Water” is then pumped or via gravity flow to the facility buildings for use. The “City Water”, if required, goes thru the same process except it is already chlorinated and does not need to be chlorinated at the Well.

It is provided to the animals, autoclaved, in bottles with sipper tubes.

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

The NMVAHCS, as a public water system, is required by the EPA and State of New Mexico Environment Department (NMED) Drinking Water Bureau to test for specific contaminants once every three (3) years. We are required to test for lead and copper once per year. Water samples are sent monthly to the state lab; there is random weekly monitoring throughout the campus; water is tested for chlorine levels daily.

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

N/A

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

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

a) [redacted] bedding for direct bedding in mouse and rats.
b) Commercial screened, hardwood chip animal bedding [redacted]) mixed with [redacted] for direct bedding for diabetic rats and used as indirect bedding for rabbits.
c) 10-ply Omni pad, [redacted] as indirect bedding in rabbit cages.

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

N/A

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

Bedding that is wet, moldy, in torn bags, or otherwise contaminated is rejected. Analysis for pesticides, chemicals, heavy metals, etc. is provided by the manufacturer upon request. Bedding is also visually inspected for obvious contaminants when cages are filled. All mouse cages with bedding is autoclaved prior to use.

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.

N/A

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.).

Wet/dry HEPA filtered vacuum cleaner, clippers, class II type A2 BSC, bedding dump station, sterilizers, cage and rack washers.

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.

Contact bedding: Rat – twice a week, Mouse –IVCS– at least once every two weeks; more, if needed.
Non-contact bedding: twice a week.
All bedding is changed more frequently than scheduled if needed by the individual cage or required by experimental protocol due to high cage density or medical conditions (e.g. diabetes that results in increased urination).

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

There is an approved program-wide exception to the Guide to allow a ventilated rack sanitation interval of every two weeks. This is also performance based as our desert environment results in lower ambient and room humidity when compared to less arid regions. We have not detected high ammonia as reported by some institutions with [redacted] (JAALAS 53-2, Pp 146-151).

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

Non-hazardous Bedding: Dirty cages are transported to room [redacted] where soiled bedding is removed in a HEPA-filtered dump station. Cages are hand-rinsed in room [redacted] then taken to room [redacted] and washed in the rack washer or small cage washer. Clean bedding is placed into the cages and cages are stacked on covered carts in room [redacted] before being sterilized.
Hazardous Bedding from ABSL-2 rooms: Soiled non-contact bedding is removed in the animal room, bagged for autoclaving, and then removed to room [redacted] where it is autoclaved. Soiled contact bedding is left in the cage. The cage is wiped with bleach wipes or red-bagged before transport. The cage is taken to room [redacted] autoclaved, and then bedding is removed in room [redacted] in a HEPA-filtered dump station.

Cages are hand-rinsed in room [redacted] then taken to room [redacted] and washed in the rack washer or small cage washer. Clean bedding is placed into the cages and cages are stacked on covered carts in room [redacted] before being sterilized.

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.

N/A

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).

Thermostats in mechanical washers control rinse water temperatures at 180°F. Washers are monitored with 180°F temperature recording labels which are put on the first load run each day. RODAC plates are run approximately twice a year.

b) Describe preventive maintenance programs for mechanical washers.

Both washers are serviced several times a year by [redacted].

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.

Put in heavy-duty plastic bags and taken to outside dumpster daily; taken by a contractor to a landfill. Contaminated bedding and refuse is autoclaved, then processed in the Medical Center regulated medical waste stream.

ii. Animal carcasses.

Placed in plastic bags and stored in a freezer until incinerated by a hospital waste contractor of regulated medical waste. Environmental Management Service employees pick up the bags as frequently as needed.

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).

[redacted], weather-resistant boric acid bait, is used for vermin control around the outside perimeter of the building and in drains if needed. [redacted] Ant and [redacted] containing silicon dioxide from diatomaceous earth is used inside the building. Insect glue traps are used to monitor for vermin. Snap traps are set when loose animals are suspected. The Chief, Environmental Management Service, oversees this program and the insect/rodent control technician applies the agents as needed.

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.

N/A

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

Other than desiccants, pesticides are not used in the animal rooms.

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.

Regular animal care staff observes and cares for all animals, including administering medications, recording information and contacting responsible personnel when required. Animals are fed/watered and if required, housing units (soiled/wet cages, etc.) are cleaned/replaced.

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

N/A

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

First, the VMU Supervisor is notified. The VMU Supervisor calls the Veterinary Medical Consultant (VMC). If the Supervisor is not available, the VMC is contacted directly. The Principal Investigator is also informed of the situation as soon as possible. If animals need routine veterinary care on weekends or holidays, arrangements are made in advance with the VMC.

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).

Mice: cage cards, ear punch, tail tattoo; Rabbits: cage cards, ear tattoo; Rats: cage cards, Sharpie mark on tail, tail tattoo

b. Breeding, Genetics, and Nomenclature

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

Consultation is available through the Veterinary Medical Consultant (VMC), at any

time.

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.

Standardized nomenclature of both the strain and sub-strain, or the genetic background, of all animals is used for all rodents. This facility does not produce any new transgenic or genetically modified mice, thus the nomenclature is adopted from the originating vendor/institution and includes both the background strain and the gene nomenclature. Consultation is available through the VMC at any time.

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

Mice are genotyped. Mouse lines are crossed to wild-type mice every ten generations. Basic breeding records (matings and progeny) are kept in a binder in the animal room. More extensive records are kept by the PI's lab technician.

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."

Although no genetically engineered animals are produced at the VMU, information about phenotype is requested from the institution of origin or the PI during acquisition. This information is included in breeding protocols during the review/approval process. If unexpected morbidity occurs, it is reported to the veterinarian and diagnostic testing and literature review is conducted to determine cause of death or morbidity. Significant events are also reported to the IACUC.

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.).

Well-known commercial vendors that provide health reports assuring SPF status are used whenever possible. If rodents must come from a private lab, academic institution, or non-pre-approved vendor, the sender must provide a health report and obtain approval from the VMU Supervisor and VMC before the animals are shipped to us. Additional quarantine is required for non-commercial sources.

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).

Animals are trucked or flown in by the vendors. Between Research buildings mice and rats are transported in their cages covered with a towel or sheet, or in a box or bag.

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.

Animals are observed and checked daily by VMU personnel and weekly by the VMC. Dirty bedding sentinel animals are used to monitor the in-house mouse colonies and testing is conducted three times a year or more often if clinical signs or history suggest concern.

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

The preventive medicine program includes: vendor surveillance, quarantine and testing of animals from non-commercial sources, daily health and environmental surveillance, and proper animal husbandry and barrier practices (segregation by microbiological status; sequence of care from barrier to conventional; sanitation/sterilization; use of microisolator cages and opening SPF cages inside a BSC or clean bench) to reduce the potential of spread of contagious diseases. A balanced HVAC system and a quality assurance programs that includes periodic microbiological monitoring of animals also contributes to our program.

Non-commercial source rodents are quarantined, routinely treated for pinworms, and

monitored with a sentinel animal program prior to being released from quarantine. Some direct testing may be required for quarantined rodents rather than full reliance on sentinel testing.

Rabbits are obtained only from SPF sources, and the vendor provides health status information. Usually rabbits are held short term, all in all out, and so periodic colony testing is not completed under these circumstances.

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

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

Mice, rabbits, and rats– The shipping containers are inspected for damage or wetness; the outsides of the shipping containers are sprayed with a disinfectant; the animals are inspected and evaluated. If the animals appear healthy the order is accepted. One ill animal may cause rejection of the entire shipment. Since most commercial vendors will not accept animals back into their facilities, disposition is coordinated with the vendor. However, if a shipment is rejected due to potential infectious disease they will either be quarantined to rule out infections or euthanized to avoid introduction of diseases into our colony animals.

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.

Rodents are not quarantined if obtained from an approved commercial vendor. They are immediately housed in their designated room in IVCS. Rodents from non-approved and non-commercial sources are quarantined in a room isolated from colony housing. The quarantined rodents are routinely administered a fenbendazole treatment regimen, sentinel animals are set up for each shipment, and animals are held for a sufficient time to verify the SPF status. Health status is determined by serological tests, parasite analysis, and a comprehensive assessment, depending upon the source and available health status information supplied by the originating institution. Purpose-bred rabbits are not quarantined since only SPF rabbits procured from a single vendor are used.

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

Most animals are allowed one week for stabilization. During this time no invasive procedures or breeding of, the animals are allowed.

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.

No more than one species is housed per room. Mice, rats, and rabbits are purchased from reputable commercial vendors. Each barrier area has been screened and has the same health status as other room occupants from the same source. If animals from different sources must be housed in the same room, they are isolated on different rows within an IVCS. Animals in poor health are caged separately and removed from the room, if necessary.

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

N/A

c. Describe isolation procedures and related facilities for animals.

Animals are housed in an individual, separate area and standard quarantine procedures are closely observed with veterinary care available. Animals are evaluated before reintroduction into the original colony area. Animals that are not acceptable will be euthanized.

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

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

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

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

The animal technician observes animal populations daily for sick, injured or dead animals and report verbally to the VMU supervisor. For protocols with expected morbidity the approved protocol will be referenced for early end-point criteria and euthanasia or treatment will be managed accordingly. The VMU supervisor notifies investigators or technicians regarding the health status of the animals. The Veterinary Medical Consultant (VMC) decides if sick or injured animals are treated or euthanized. Technicians observing the animals have at least 29 years of experience.

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

Communication is by person, telephone, text or e-mail depending on the researchers'

preference.

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.

Mice, rabbits, rats: Vendor surveillance, daily health and environmental surveillance, proper animal husbandry. The preventive medicine program includes quarantine procedures, reliance upon approved vendor health surveillance reports and husbandry and management practices to reduce the potential of spread of contagious diseases and as stated above, the use of soiled bedding exposed sentinels for ongoing rodent colony surveillance. A balanced HVAC, sanitation practices, microbiological monitoring of animals and quality assurance programs contribute to preventive medicine programs.

Non-commercial source rodents are quarantined, routinely treated for pinworms, and monitored with a sentinel animal program, prior to being released from quarantine. Some direct testing may be required for quarantined rodents rather than full reliance on sentinel testing.

Rabbits are obtained only from SPF sources, and the vendor provides health status information.
Any rodent or rabbit that goes off its feed or is not thriving is checked for dental malocclusion; teeth are clipped and soft food provided, if necessary.

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.

When not on station, the VMC is available on-call for emergencies. When the VMC is unavailable, emergency veterinary services are provided through an arrangement with the veterinarian(s) at of the [redacted].

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

The VMC has complete authority relative to the emergency treatment of animals in the program.

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.

When a medical record is initiated it is kept updated, documented and maintained by the animal technician or the research technician in the animal room on a daily basis. Old records are filed in the VMU Offices.

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 VMU supervisor is responsible for making sure that medical records are maintained.

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

The VMC review records and adds observations and clinical orders as necessary.

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

a. In-house diagnostic laboratory capabilities.

The VMC provides gross necropsy examinations but otherwise no in-house clinical diagnostic capabilities exist.

b. Commercially provided diagnostic laboratory services.

Rodent sentinel, Health Surveillance Program specimens are routinely submitted to [redacted], [redacted] These specimens range from blood spot for serology to fecal, or cage/animal swabs for PCR/culture or whole animals for necropsy or histopathology. Complete laboratory and necropsy services including histopathology, microbiology, hematology, and clinical chemistry are available from the New Mexico [redacted] located on the [redacted] campus. The [redacted] is staffed by three full time veterinary pathologists who are also available for consultation as needed. This [redacted] is a full service veterinary pathology laboratory. [redacted] will also support histopathology. We use these services about three to five times a year.

c. Necropsy facilities and histopathology capabilities.

An ABSL2 procedure or necropsy room is available for euthanasia, gross examination and tissue or other specimen collections. We have no in-house histopathology capabilities.

d. Radiology and other imaging capabilities.

[redacted]

5. Drug Storage and Control

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

Controlled drugs are purchased from the VA hospital pharmacy and stored in either a double-locked cabinet or the safe in Room [redacted]. Non-controlled drugs are purchased and stored by either the VMU or the investigator.

b. Describe record keeping procedures for controlled substances.

Each controlled substance must be ordered through the VA hospital pharmacy where it is numbered and provided with a record sheet. When drugs are received they are entered as received in the hospital computer system. Every time any drug is used, it must be signed out on the "green" sheet. Once a month a drug inspector from the hospital checks the drug amount and reviews and signs the drug sheet. When the drug is used up, the drug number is entered into the hospital computer system and the "green" sheet is returned to the narcotics pharmacist.

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

1. Pre-Surgical Planning [*Guide*, p. 116]

Describe the process(es) used to ensure adequate pre-surgical planning, including: identifying personnel; locating equipment, supplies, veterinary involvement for selecting analgesic and anesthetic agents and facilities; planning; and pre- and post-operative care.

The VMC meets with the investigator to discuss the actual protocol. The VMU supervisor or surgical technician meets with the research technician to discuss equipment, supplies, and facilities. The investigator meets with operating support personnel such as the anesthetist and assistant surgeon. Pre- and post-operative care plans involve the veterinarian, investigator, research technician, and VMU supervisor. Having a "dry run" is encouraged.

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.

1) Building [redacted]: animal preparation, [redacted]: surgeon's scrub, [redacted]: postoperative recovery, [redacted] operating room; rabbits; major survival but currently there are none approved. Gas anesthesia machine with respirator, Pulse Oximeter Patient Monitor unit, electro-cautery unit, overhead adjustable operating room light, adjustable hydraulic heated operating room table, and recirculating warm water blanket.
2) Building [redacted]: aseptic surgery; rodent minor survival surgery; portable surgical lamps, microwavable gel heat pads and inhalant anesthesia systems are available. The amount of use is very light.

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 survival surgery penetrates and exposes a body cavity or produces substantial impairment of physical or physiological functions, while minor surgery does not. The veterinarian makes the final decision about what is a major or minor procedure. Both major and minor survival surgical procedures are performed aseptically. In non-survival surgery, the animal is euthanized before any recovery from anesthesia.

b. How is non-survival surgery defined?

The animal is not allowed to recover from anesthesia.

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

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

Surgeons wear head coverings, masks, sterile gowns, and sterile gloves. Surgical sites are clipped, washed three times with alternating Betadine and alcohol. The surgical site is sprayed with Betadine as a final prep after the animal is positioned on the operating room table. The animal is then draped with sterile towels.

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.

Gowns, drapes, instruments, and supplies are steam sterilized at 250°F.

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

The preferred method is to have as many steam sterilized packs as surgeries. However, we also use hot bead sterilizers between multiple rodent surgeries within same group as long as instruments are wiped down with alcohol, sterilized in the hot bead sterilizer for 15 seconds, and place back in the sterile field.

d. Indicate how effectiveness of sterilization is monitored.

Sterilization effectiveness is monitored with [redacted] strips in the packs and autoclave tape on outside of packs. [redacted] Biological Indicators are used every three weeks to monitor the sterilizer efficacy. This is much more frequent than every 40 hours of use, but this schedule was determined so that the Biological Indicators would not go out of date.

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

Pre-op, surgical prep, anesthesia and anesthesia monitoring, and post-operative care are provided by VMU staff.

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.

Anesthesia records must be maintained by PIs for survival and non-survival surgery procedures. Intra-operative monitoring sheets have been developed for each procedure, specific to the procedure, anesthetics employed, duration of the procedure, etc. VMC monitors the anesthesia program and it is subject to review by the IACUC. The VMU supervisor and the animal technicians observe research technicians and report to the VMC. The VMC makes unannounced spot checks to areas of use and checks records.

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 VMC is responsible for overseeing the post-surgical care program. Post-surgical care,

including thermal support, fluid therapy and the use of analgesics, is addressed at the time of initial protocol submission by the VMC, and must meet current standards of acceptable veterinary care. The attending veterinarian further evaluates individual cases as needed. The researcher, research technician, and animal care technicians provide the care. This is monitored on a daily basis by the VMU supervisor who reports to the VMC. Individual rabbit records are maintained in the animal room, and then filed in the VMU office. These records list the medication received, condition of animal, food intake, condition of surgical incision, and general comments.

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

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

The VMC in conjunction with the IACUC categorizes levels of pain and distress based on the assumption that procedures that cause pain in humans also cause pain in animals. The IACUC also requires the design and use of clinical observation scoring sheets for studies when outcomes of significant morbidity or mortality are expected.

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

CitiProgram.org provides training on species-specific behavioral manifestations as indicators of pain and distress. Further training may be provided depending on the experiment so that all observers have the same baseline when filling out observational sheets.

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.

Mice: Isoflurane, Buprenorphine; Ketamine/xylazine
Rabbits: Isoflurane, Ketamine, Xylazine, Buprenorphine, Droperidol, Fentanyl patch;
Rats: Isoflurane, Pentobarbitol, Buprenorphine, Lidocaine

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

Researchers must communicate with the VMC during the planning of their protocols if the procedure to be used has the potential to cause more than momentary or slight pain or distress. If modifications or amendments to protocols are proposed, the VMC will also discuss new procedures at that time.

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.

Rabbit anesthesia records must be maintained by PIs for survival and non-survival surgery procedures. Intra-operative monitoring sheets have been developed for each procedure, specific to the procedure, anesthetics employed, duration of the procedure, etc. The VMC monitors the anesthesia program and it is subject to review by the IACUC. The VMU supervisor and the animal technician observe research technicians and report to the VMC. The VMC makes unannounced spot checks to areas of use and checks records.

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.

N/A

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

Vaporizers are professionally cleaned and calibrated every three years.

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.

Mice: Carbon dioxide inhalation, isoflurane overdose; procedure rooms [redacted] and [redacted]
Rabbits: anesthetized with Ketamine and Xylazine, then injected via cardiac puncture with Euthasol; procedure rooms [redacted] and [redacted]
Rats: Carbon dioxide inhalation, isoflurane overdose; procedure rooms [redacted]

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

Visually inspected before each use.

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

a. There is no evidence of respiration.
b. There is no heartbeat present when examined by palpation.

c. There is no corneal reflex when the cornea is gently touched.
d. The animal does not respond if the foot is forcefully pinched.
e. Secondary mechanical means such as cervical dislocation, exsanguination, and thoracotomy are used to assure that animals do not recover following the primary euthanasia procedure.

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 VMU is located on the [redacted] There are two SPF mouse housing rooms, three ABSL-2 animal housing rooms, one quarantine room, and one flex-room currently being used as a mouse behavioral room. There are two procedure rooms, a surgical suite, food storage, dirty/clean cage washrooms, autoclave room, clean cage storage, sterile cage storage, and administration area with breakroom, restrooms, and offices. [redacted].

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).

1) Single corridor; 2) [redacted]; 3) Types of available housing space include conventional for rats, two quarantine cubicles for rodents, three ABSL2 rooms with ante-rooms for rodents and rabbits, one SPF room for mouse breeding colonies and one SPF room for experimental mice; 4) Floors are heavy-duty epoxy paint, resilient sheet goods with chemically welded seams, porcelain tile, vinyl composition tile, solid vinyl floor tile (breakroom), carpet (offices); Walls and doors are painted with water-based epoxy, ceilings are acoustical tiles or painted with water-based epoxy; 5) We have an ABSL 2 procedure/necropsy room; 6) Security features consist of a Cardkey system with key pads for randomly assigned PIN at VMU doors that controls access through exterior doors, and through the door between the animal housing and procedural areas and the administration area. There are motion sensors in the VMU hallways which are armed at specified times after hours. If someone enters the facility while the system is armed and fails to disarm using their PIN, then an alarm is sent to the VA police resulting in a police response. Cameras monitor all VMU doors, internal and external. There are glass-break detectors on the windows in the cage wash area; 7) Exterior windows are in the cage wash area; 8) Disinfectants are stored in room [redacted] cage-washing chemicals are stored in room [redacted] and are piped to the rack washer and cage washer. We do not store flammable materials other than quart-sized containers of 70% alcohol.

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.

N/A

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.

N/A

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.

The hallways and animal rooms have emergency lights. All animal rooms have emergency power receptacles and the IVCS are plugged into these. The HVAC system is also on emergency power. All power failures in the past three years have been minor, short-term disruptions. Emergency power was available to run the HVAC system and normal animal room temperatures were maintained.

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).

N/A

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.

Room [redacted] contains a [redacted]. IVIS Imaging System; Room [redacted] has a water maze and an elevated radial arm maze. Room [redacted] is the Mouse Behavioral Core. Equipment is wiped down with a disinfectant after every use.

2. Other Animal Program Support Facilities

Describe other facilities providing animal care and use support, such as feedmills, diagnostic laboratories, abattoirs, etc.

N/A

Intentionally left blank

Appendix 1: Glossary of Abbreviations and Acronyms

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

Abbreviation/Acronym	Definition
ABSL2	Animal Biosafety Level 2
ACORP	Animal Component of Research Protocol
ACOS/R	Associate Chief of Staff for Research
ACUP	Animal Care and Use Program
BRINM	Biomedical Research Institute of New Mexico
BSC	Biological Safety Cabinet
BSL-2	Biosafety Level 2
CBOC	Community Based Outpatient Clinic
COS	Chief of Staff
EMS	Environmental Management Service
EOC	Hospital Environment of Care (safety) Committee
IACUC	Institutional Animal Care and Use Committee
IBC	Institutional Biosafety Committee
IH	Industrial Hygienist
IO	Institutional Official = Medical Center Director
IVCS	Individually Ventilated Caging System
MCD	Medical Center Director
NMVAHCS	New Mexico VA Health Care System
OHS	Occupational Health and Safety
OWCP	Office of Workers' Compensation Program
ORO	Office of Research Oversight
PAM	Post Approval Monitoring
PI	Principal Investigator
PIN	Personal Identification Number
PPE	Personal Protection Equipment
RMW	Regulated Medical Waste
RPSS	Research Protocol Safety Survey
RSAW	Research Safety and Animal Welfare

Appendix 1: Glossary of Abbreviations and Acronyms

Abbreviation/Acronym	Definition
RSO	Radiation Safety Officer
R&DC	Research & Development Committee
SOP	Standard Operating Procedure
SPF	Specific Pathogen Free
SRSBS	Subcommittee on Research Safety, Biosafety and Security
TMS	Talent Management System
UPS	Uninterrupted Power Supply
VA	Veteran Affairs
VA ORD	Veterans Administration Office of Research and Development
VDS	New Mexico Veterinary Diagnostic Service
VISTA	Veterans Health Information Systems and Technology Architecture
VMC	Veterinary Medical Consultant
VMU	Veterinary Medical Unit

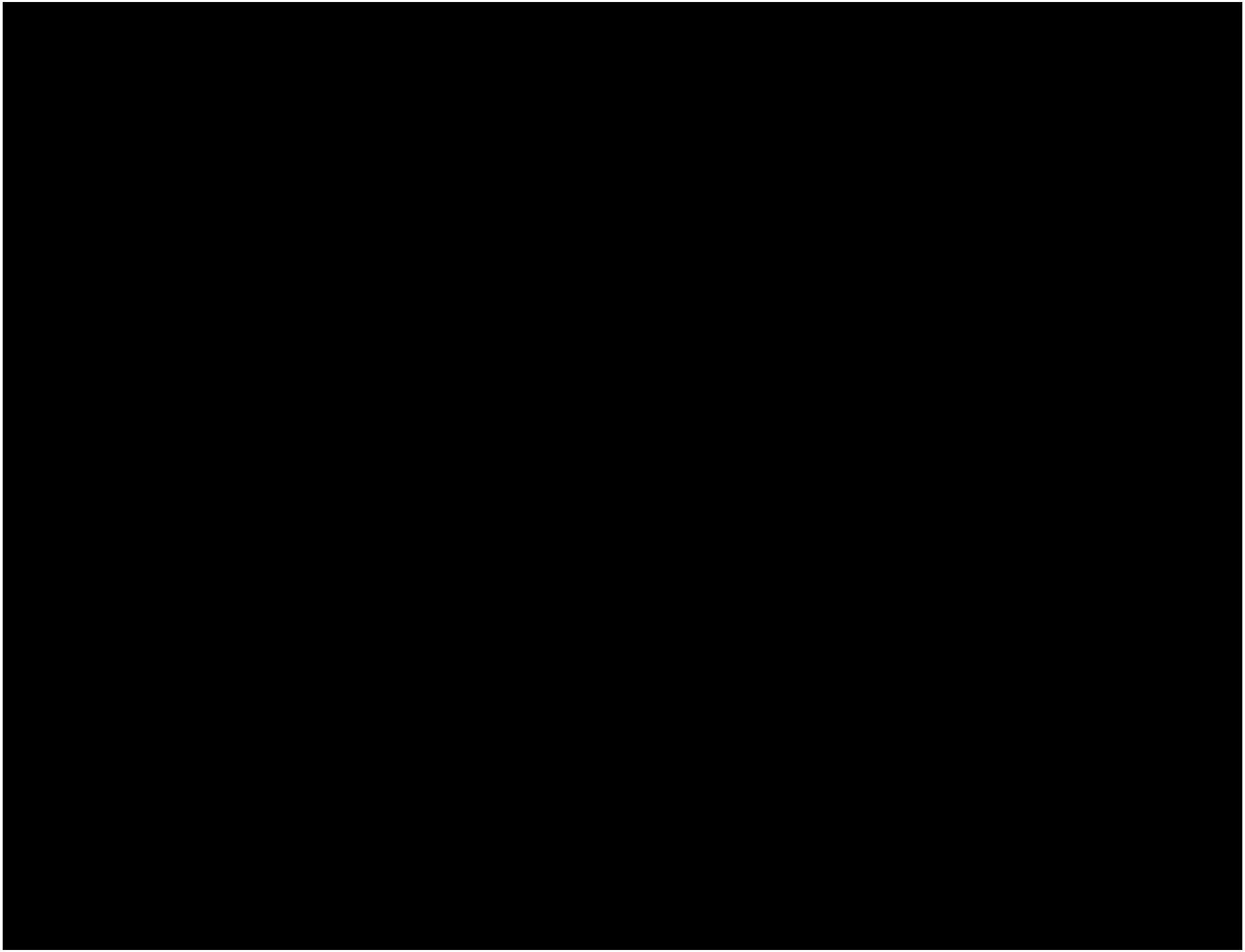
Appendix 2: Summary of Animal Housing and Support Sites

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.

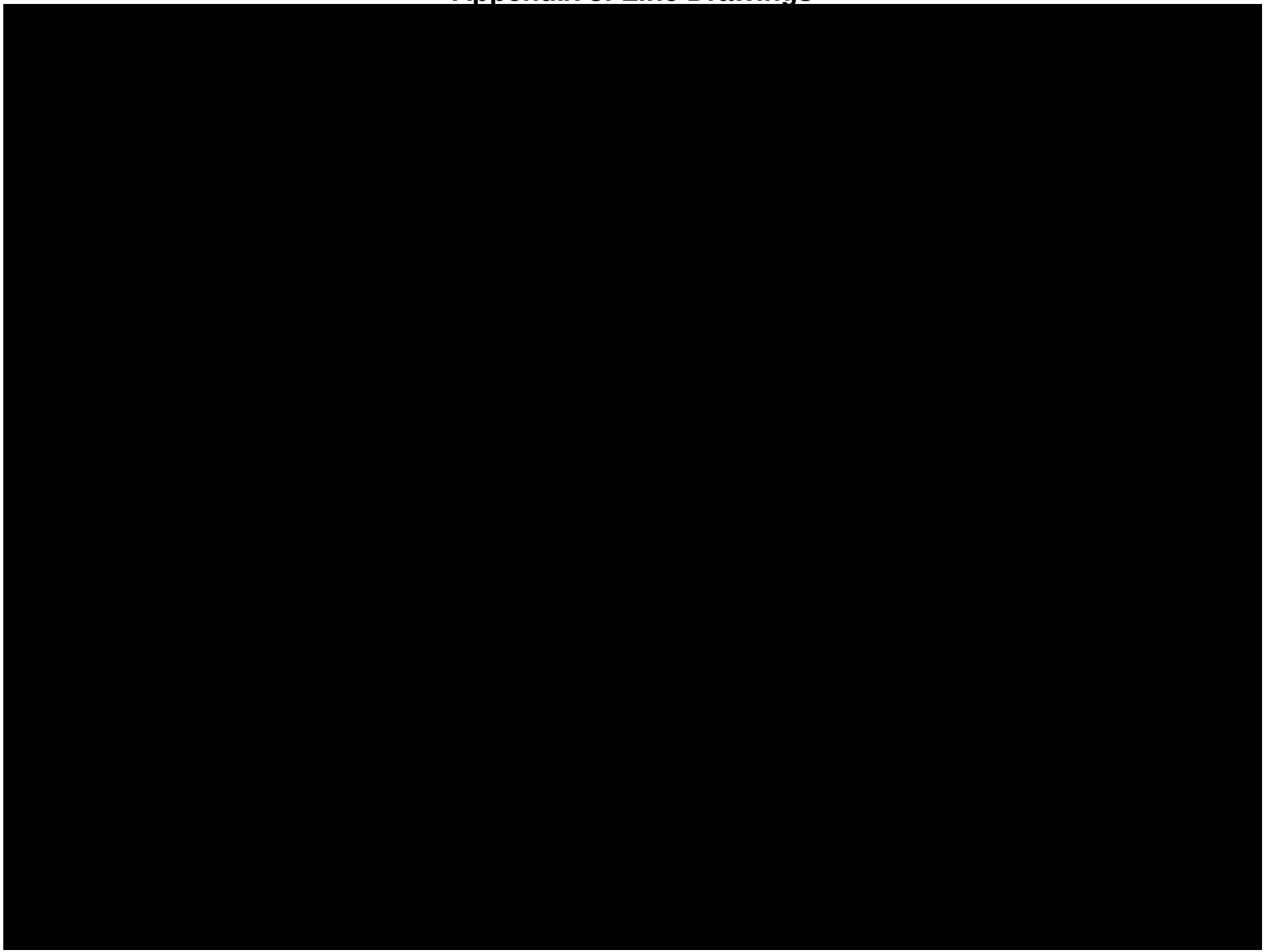
Animal Housing and Support Sites						
Location (building, site, farm name, etc.[a])	**Distance from main facility[b]**	**Approx. ft^2, m^2, or acreage for animal housing**	**Approx. ft^2, m^2, or acreage for support or procedures**	**Species housed**	**Approx. Daily Animal Census by species**	**Person in charge of site**
[redacted]	N/A	1,360	6,478	Mice Rats	390 7	[redacted]

Totals:	**1,360**	**6,478**	[redacted]
Total animal housing and support space:	**7,838 ft^2**		
	(please specify ft^2 or m^2)		

[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.

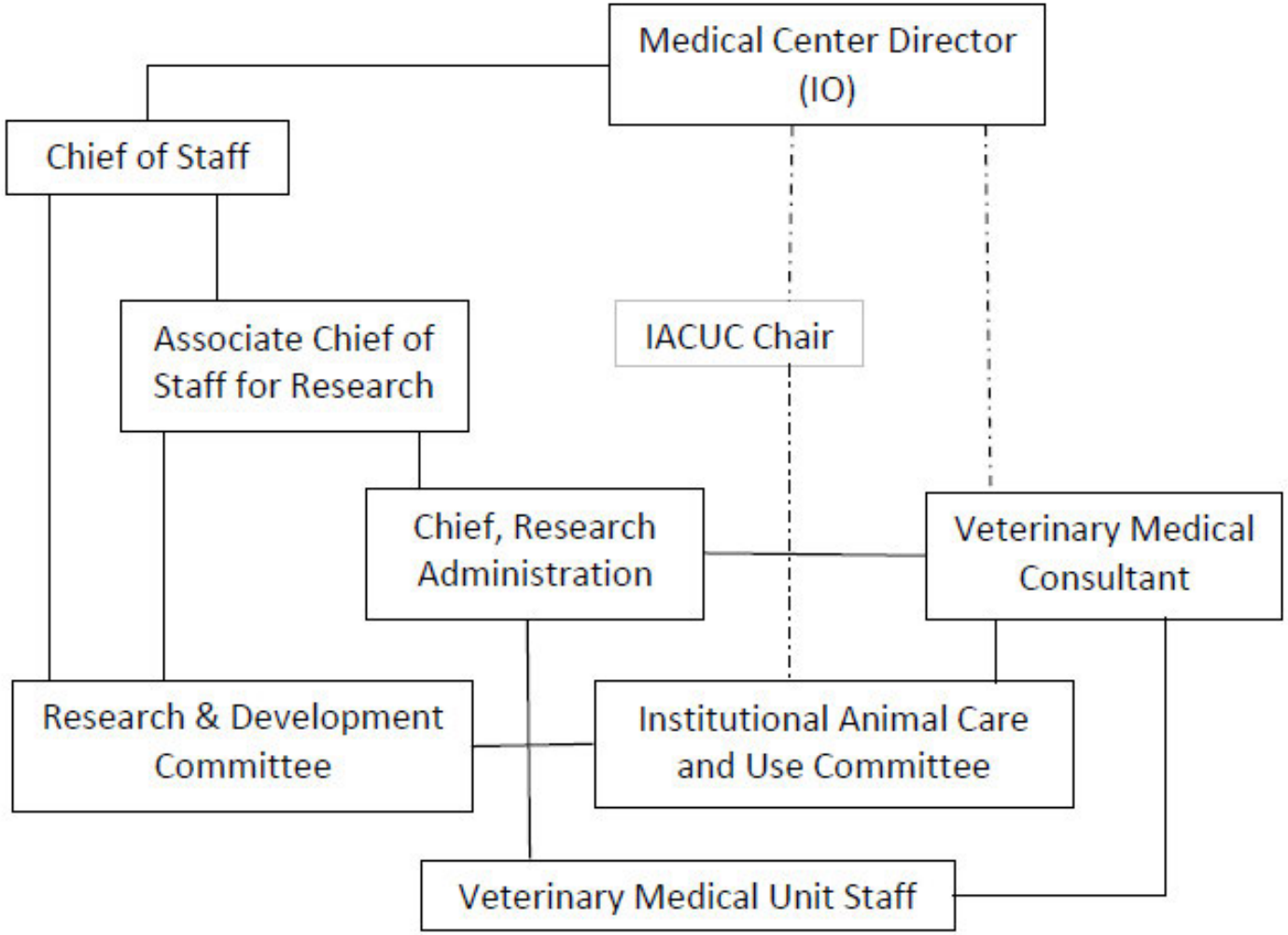


Appendix 3: Line Drawings



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)
A Novel Vaccine to prevent *Clostridium difficile* colitis	12-A187	[redacted]	mouse	2300	D, E			✓		✓	
"HMBC57BL/6 " mouse breeding and colony maintenance for enteric infection research projects	12-A189	[redacted]	mouse	690	B						
Murine Models of Post-Infectious Irritable Bowel Syndrome	16-A204	[redacted]	mouse	756	C					✓	
Sphingosine 1-Phosphate: A new target for early diabetic retinopathy	12-A185	[redacted]	mouse	300	C, D			✓		✓	

Appendix 5: Animal Usage

Project/Protocol Title	IACUC/OB Number	Principal Investigator	Species	Total Number of Animals Approved	Pain & Distress Category (1)	Special Considerations (use checkmark if applicable)					
						SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
Sphingosine 1-Phosphate: A new target for early diabetic retinopathy - Rat	12-A209	[redacted]	rat	90	C, D			✓		✓	
Animal Model of GWS, a condition of Increased H2S Exposure	11-A154	[redacted]	mouse	1894	D			✓			
Effects of Bacteria-derived Gas: A Model of GWS	13-A207	[redacted]	rat	1476	D			✓			
Regulation of Intestinal Epithelial Tight Junction Barrier	11-A70	[redacted]	mouse	658	B, D						
Transgenic Mouse Breeding and Colony Maintenance for Brain and Somatic Research Projects	15-A177	[redacted]	mouse	4600	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)
Addiction Genetics: Dose-Response Differences and CAM Gene Variation	15-A140	[redacted]	mouse	24,032	B, C						
Peripheral and Central Pain Generators of Chronic Trigeminal Neuropathic Pain	16-A214	[redacted]	[redacted]	672	E	✓	✓				

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

Pain/Distress Classification Description/Definition, if applicable:

Definition of USDA Pain/Distress Categories:

B: Animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery, but not yet used for such purposes.

Appendix 5: Animal Usage

Examples include breeding colonies of any animal species that are held in legal sized caging and handled in accordance with the Guide and other applicable regulations, breeding colony includes parents and offspring, newly acquired animals that are held in proper caging and handled in accordance with applicable regulations, animals held under proper captive conditions.

C: Live animals used in research, teaching and testing involving NO MORE THAN MOMENTARY, SLIGHT PAIN OR DISTRESS. Examples include simple injections of non-pain producing substances, blood sampling, food deprivation, less than 24 hours, tail docking of weanling mice, ear punching, or tagging, short-term electrical shock that is escapable, non-painful or non-stressful vaccine development, some cancer studies or infectious disease studies in which the animals are not expected to develop clinical signs associated with pain or distress, euthanasia with anesthetics or sedatives, percutaneous catheter placement. Animals that are euthanized BEFORE tissue collection or other manipulations are also commonly placed in this category.

D: Live animals used in research, teaching, testing, who are subjected to MORE THAN MOMENTARY PAIN OR DISTRESS for which anesthetics, analgesics, or tranquillizers will be used. Other methods of alleviating pain or distress may be employed such as: early removal prior to progression to painful condition or treatment such to prevent progression. Examples of potentially painful or distressful procedures include: minor procedures that require sedation or anesthesia (e.g. imaging), survival and non-survival surgery, alter physiology, disease, or toxicity induction, infectious disease studies if there is a potential to become sick or die, antibody production, prolonged restraint. Euthanasia by decapitation or cervical dislocation without anesthesia or sedation (Must provide justification and assurance that individuals performing these procedures are properly trained).

E: Animals used in research, teaching or testing that involve potential for MORE THAN MOMENTARY, PAIN OR DISTRESS and appropriate ANALGESICS OR ANESTHETICS ARE WITHHELD because their use would adversely impact scientific objective of the project. The following provision must be met for this category: 1) An explanation and scientific justification for withholding analgesics, 2) bibliographic references, and/or evidence from pilot studies or documented communication from other 'experts' in the field supporting the contention that analgesics interfere with the experiment.

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

Animal Type or Species	Approximate Annual Use
Mouse	2,376
Rat	44

Animal Type or Species	Approximate Annual Use
Rabbit	0 (If funded we may have a project with rabbit starting in a few months.)

Appendix 6: Personnel Medical Evaluation Form

ANNUAL MEDICAL CLEARANCE QUESTIONNAIRE
Research Services (151)

DIRECTIONS: Please complete Sections I, II, and III. Once the form is complete, visit Employee Health [redacted]) for clearance to work with animals (Section IV).

Section I: Personal Information

Name:

Email: Phone:

Primary Employer: ☐ BRINM ☐ UNM ☐ VA ☐ OTHER:

Job Status: ☐ Animal Technician ☐ Principal Investigator ☐ Postdoctoral Fellow ☐ Lab Technician

☐ Study Coordinator ☐ Volunteer ☐ Student ☐ Other:

Supervisor: Email: Phone:

☐ I decline to receive services not required by the NMVAHCS to protect the health of the animals or other personnel. *(You are still considered to be enrolled in the OHSP even though you decline optional services.)*

Section II: **Animal** Contact Information

What species of animals or unfixed animal tissue do you handle or will you be handling at the NMVAHCS?

Total amount of contact time *(including contact time with animal tissues, waste, body fluids, carcasses, or animal housing areas)*: ☐ One hour or less per week ☐ One to eight hours per week ☐ OTHER:

Does your work involve human or animal pathogens? ☐ No ☐ Yes *(Describe below)*

Do you work with species of, or biological material from, **non-human primates**? ☐ No ☐ Yes *(Describe below)*

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

☐ No ☐ Yes

How often do you wear the following as part of your assigned duties?

	Daily	Sometimes	Rarely	Never
Disposable Gloves	☐	☐	☐	☐
Gown	☐	☐	☐	☐
Mask	☐	☐	☐	☐
Hair Cap	☐	☐	☐	☐
Eye protection	☐	☐	☐	☐

How often do you do the following after handling animals during the day?

Appendix 6: Personnel Medical Evaluation Form

	Daily	Sometimes	Rarely	Never
Wash Hands	☐	☐	☐	☐
Change Clothing *(if soiled)*	☐	☐	☐	☐
Shower	☐	☐	☐	☐

Do you smoke, eat, or drink in animal holding or procedure areas? ☐ No ☐ Yes *(Describe below)*

ALLERGY HISTORY: Do you have a history of asthma, hay fever, allergic skin problems, eczema, sinusitis, chronic respiratory infections, or disease? ☐ No ☐ Yes *(Describe below)*

List any allergies to medications:

Do you have any of the following allergic symptoms?
☐ No ☐ Yes *(Describe below)*

Symptoms	Daily	Sometimes	Rarely	Never
Sneezing spells	☐	☐	☐	☐
Runny or stuffy nose	☐	☐	☐	☐
Itchy, irritated eyes	☐	☐	☐	☐
Coughing	☐	☐	☐	☐
Wheezing in chest	☐	☐	☐	☐
Shortness of breath	☐	☐	☐	☐
Skin rash or hives	☐	☐	☐	☐
Trouble swallowing	☐	☐	☐	☐

Have these symptoms occurred during, or after, contact with any of the following? ☐ No ☐ Yes *(Describe below)*
☐ Animals *(identify species)*:
☐ Latex gloves or other latex containing items:
☐ Chemicals *(identify)*:
☐ OTHER:

Do you have house pets? ☐ No ☐ Yes *(Describe below)*

Have you ever contracted a disease from animals, or experienced an animal related injury *(including bites, scratches, needle sticks, etc)*? ☐ No ☐ Yes *(Describe below)*

Section lll: Employee Health Information

Have you ever suffered from an inguinal or similar hernia, back pain or trouble, or from joint problems or arthritis? ☐ No ☐ Yes *(Describe severity and corrective measure(s), such as surgery or rehabilitative therapy below)*

Appendix 6: Personnel Medical Evaluation Form

Do you have any other significant health history that might be affected by exposure to workplace hazards?

☐ No ☐ Yes *(Describe below)*

IMMUNIZATIONS:

Date of last tetanus shot/booster:

Date of Hepatitis B Vaccination Series completion/declination:

Date of last Rabies Titer (if you've had rabies vaccine):

Date of last PPD Skin Test: Result (Check One): ☐ Positive ☐ Negative

_____

Printed Name

_____ _____

Signature Date

Section IV: To Be Filled Out By Employee Health Physician

☐ Cleared for Animal Contact

☐ Cleared for Animal Contact with the following Restrictions:

Comments:

_____ _____

Signature of Provider Date

Appendix 7: IACUC/OB Membership Roster

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

Name/Code	Degrees	Membership Role	Affiliation
[redacted]	PhD	Chairperson	Research Scientist
[redacted]	DVM, DCLAM	Veterinarian	Veterinary Medical Consultant
C13	PhD	Scientist	Research Scientist
C05		Non-Affiliated Scientific	Wildlife Rehabilitator
C16		Non-Scientific/Non-Affiliated	Retired Educator
C01	LATG	Member	Supervisor, VMU
C08	LAT	Member	Animal Health Technician
C10		IACUC Administrator	Research Administration

Appendix 8: IACUC/OB Minutes

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

Starts on next page

Institutional Animal Care and Use Committee
New Mexico VA Health Care System
New Mexico VA Health Care System • 1501 San Pedro Dr. SE • Albuquerque, NM 87108
[redacted] Conference Room

[CONFIDENTIAL]
MINUTES

Tuesday, October 4, 2016

Present

Voting

[redacted] PhD, Chairperson	Affiliated Scientific
C01	Supervisor, Vet. Med. Unit
C05	Non-affiliated Scientific EXCUSED 11:18 a.m.
[redacted] DVM	Vet. Med. Consultant
C13	Affiliated Scientific
C08	Animal Health Tech

Staff

C10, IACUC Coordinator

Excused

Voting

C16	Non-scientific/Non-affiliated
C14	Affiliated Scientific

Total Voting Members: 8 **Total Voting Attendees:** 6 **Quorum:** 5

Guests

Research Administrative Support Assistant

Time Started: 9:13am

Call to Order

1. Conflict of Interest - None

Minutes

1. Review of Minutes for the July 12, 2016 meeting
   Motion to approve with edits.
   Approved [For: 6 Against: 0 Abstained: 0 Recused: 0 Excused: 0]

Unfinished Business

1. 2014-07-22 - SOP RA-004, IACUC Amendments to Approved Protocols
Reviewed: incorporate new OLAW changes and modify attachment, Amendment Request Form [redacted] 263). Committee will review revised form.
At the 4/19/16 IACUC meeting, the committee approved the following administrative changes that can be made by amendment, that involve the veterinarian only, without FCR or DMR. Changes in:
1) anesthesia, analgesia, sedation or experimental substances
2) euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals
3) duration, frequency, type, or number of procedures performed on an animal
10/04/16 Discussion: The "Responsibility" language was extracted from the United States Department of Agriculture (USDA) and Animal Welfare Regulations (AWR) regulations to describe the Veterinary Review (VR). Added details of the different methods an amendment can be reviewed and approved – Administrative Review (AR), Full Committee Review (FCR), Designated Member Review (DMR) and VR. Incorporate changes in form Rept. FL 151-263, Amendment for Animal Component of Research Protocol.
Motion to approve

Approved [For: 6 Against: 0 Abstained: 0 Recused: 0 Excused: 0]

New Business

1. Breeding Colony Management
Discussion: PI14 has a strain of mice that has an unforeseen use. The VMU is breeding and euthanizing these mice and they feel the amount of waste is unethical. This strain is available commercially. The VMU wants PI14 to halt breeding of this strain until they are ready to use them. They have gone through 111 offspring and 19 breeders since receipt of this strain from NIDA. The IACUC recognizes that the PI might have a scientific justification to keep them. The investigator has one lab staff and it is unlikely that one person can use this many animals in addition to ongoing animal work. The investigator is relying on additional funding to hire more staff to perform more experiments. There was agreement among members that this is a waste of animals, resources, and employee time. The VMC suggested if the investigator does not get additional funding in November and is unable to initiate research with specific mouse genetic lines (strains) within the next 4-6 months, that the committee should request that the PI reduce the number of mice within breeding lines, that are not available commercially, to a level necessary to sustain the unique genetic strains and to remove any genetic breeding lines that are available commercially. The IACUC will send the PI a letter to request he provide good justification to keep the colony or remove them. The letter will discuss the IACUC's concerns and request a meeting to discuss plans to downsize the colony.
Motion to write a letter to PI14 to express concerns and request a meeting

Approved [For: 6 Against: 0 Abstained: 0 Recused: 0 Excused: 0]

2. Veterinary Medical Unit (VMU) Annual Standard Operating Procedures (SOP) Review
Discussion: The VMC and the VMU Supervisor review and amend, as needed, all of the VMU SOP annually. The dates are reflected in the attached spreadsheet. The IACUC needs an SOP regarding controlled substances such that if a controlled substance is to be used as a test substance in an ACORP, the PI will have to secure approval (this may include Pharmacy Service) prior to review of the ACORP by the IACUC. The Drug Enforcement Administration (DEA) Controlled Substance SOP for the VMU already has a lot of information on how Controlled Substance are handled. The IACUC will either modify SOP VMU-008 and enter details that will cover the controlled substance use or create a whole new SOP.
Motion to approve as written.

Approved [For: 6 Against: 0 Abstained: 0 Recused: 0 Excused: 0]

Review of Reportable Incidents

1. None

Post Approval Monitoring

1. None

Semi-Annual Program Review & Facilities Inspection

1. Date of Review: September 27, 2016
2. Program Review:
   Discussion:
   - Is the Work Order (WO) to correct the building steam completed? It was called "house utilities", not "building steam".
   - The WO to fix the motion sensor took longer because it was a big job that had to be contracted out.
3. Facility Review
   Discussion:
   1300 - Batteries for hand sanitizer just came in and will be replaced.
   1351 – The new floors in the animal rooms seem to have oxidized. New buffer pads have been ordered.
   1451 – Currently the feed coming out of that room is o.k. Until the WO is completed any new bags of food that are placed in that room that do not have an inside plastic liner will be placed in a plastic bag.
   1700 – WO placed to paint steam stub-out for safety purposes.
   2400 – There are instructions to the guillotine; they need to be put in SOP format.
4. Next Review Deadline: April 2017

Motion to approve and send the Semi-Annual Program Review & Facilities Inspection forward for the Facility Director's approval

Approved [For: 6 Against: 0 Abstained: 0 Recused: 0 Excused: 0]

Announcements

1. Office of Research Oversight (ORO) On-site Focused Review
   ORO conducted an on-site focused review of the Animal Care and Use Program (ACUP) and the Research Safety and Security Program (RSSP) at the New Mexico VA Health Care System (NMVAHCS) June 21-23, 2016. ORO Case Nos. 501-0039-A
   - The program was commended for high standards
   - There were no regulatory deficiencies
   - ORO Case Nos. 501-0039-A - CLOSED

   Discussion: ORO did recognize it is impossible for our facility to reach the humidity recommended in the Guide due to arid environmental conditions in this region. The results of the evaluation of the performance of the environmental monitoring and alarm system as well as the effectiveness of facility Engineering Service personnel to detect and respond to potential environmental emergencies will be better documented in the IACUC minutes. The VMU will use smaller (lower profile) glue traps for insect vermin that will prevent entrapment of rodents. The Associate Chief of Staff for Research (ACOS/R) will be invited to discuss the results of the IACUC semiannual program review and facility inspection with the Medical Center Director.

   No Action Taken

Initial Review

1. **PI12**

Sphingosine-1-Phosphate: A new target for early Diabetic Retinopathy - Rat

ID: **00209** Prom#: **0003** Protocol#: **12-A209** Protocol Dt: **09/28/2016**

STATUS: Pending

Sponsor: VA Merit

ITEMS REVIEWED (* = stipulations):

- ACORP - IR - Rat (09/28/2016; Category: C, D)
- ACORP App 3: Test Substances - Biosafety (09/28/2016)
- ACORP App 4: Antimortem Specimen Collection (09/28/2016)
- ACORP App 6: Special Husbandry and Procedures (09/28/2016)

Discussion: PI needs to adjust the number of animals. Remove mouse references. Need to detail experience of lab staff. Correct date of Veterinary Consultation.
Motion to request clarifications from the PI and the IACUC will review PI's response by DMR.
Deferred [For: 5 Against: 0 Abstained: 0 Recused: 0 Excused: 1] C05 EXCUSED 11:18 a.m.

Amendment

1. **PI01**

A Novel Vaccine to Prevent Clostridium difficile Colitis
ID:**00187** Prom#: **0012** Protocol#: **12-A187**
VETERINARIAN 07/19/2016
ITEMS TO BE REVIEWED:

- APPROVAL DATE - References All Items Listed Below (07/19/2016)
- Amendment - AM-A Replace C57BL/6 with HMBC57BL/6 (07/15/2016)

2. **PI01**

"HMBC57BL/6 " mouse breeding and colony maintenance for enteric infection research projects
ID: **00189** Prom#: **0012** Protocol#: **12-A189**
DESIGNATED 08/10/2016
ITEMS TO BE REVIEWED:

- APPROVAL DATE - References All Items Listed Below (08/10/2016)
- Amendment - AM-A Use Offspring as Breeders (07/28/2016)

3. **PI01**

A Novel Vaccine to Prevent Clostridium difficile Colitis
ID: **00187** Prom#: **0012** Protocol#: **12-A187**
ADMINISTRATIVE 09/22/2016
ITEMS TO BE REVIEWED:

- APPROVAL DATE - References All Items Listed Below (09/22/2016)
- Amendment - Add personnel (03/08/2016)
- Conflict of Interest - COI (08/16/2016)
- Study Personnel List (03/08/2016)

Amendment

4. **PI06**
   Animal model of GWS, a condition of increased H2S exposure
   ID: **00154** Prom#: **0002** Protocol#: **11-A154**
   VETERINARIAN 07/15/2016
   ITEMS TO BE REVIEWED:
   - APPROVAL DATE - References All Items Listed Below (07/15/2016)
   - Amendment - AM-H Single Housing (07/14/2016)
     Single housing of mice during the fecal microbiome transplants (FMT) experiment.

5. **PI06**
   Animal model of GWS, a condition of increased H2S exposure
   ID: **00154** Prom#: **0002** Protocol#: **11-A154**
   DESIGNATED 07/19/2016
   ITEMS TO BE REVIEWED:
   - APPROVAL DATE - References All Items Listed Below (07/19/2016)
   - Amendment - AM-I FMT with Treated Mice, add 24 Mice (07/14/2016; Major)

6. **PI14**
   Addiction Genetics: Dose-Response Differences and CAM Gene Variation
   ID: **00140** Prom#: **0001** Protocol#: **15-A140**
   DESIGNATED 07/13/2016
   ITEMS TO BE REVIEWED:
   - APPROVAL DATE - References All Items Listed Below (07/13/2016)
   - Amendment - AM-C Chronic Illudalic Acid (05/18/2016)

7. **PI14**
   Addiction Genetics: Dose-Response Differences and CAM Gene Variation
   ID: **00140** Prom#: **0001** Protocol#: **15-A140**
   VETERINARIAN 08/02/2016
   ITEMS TO BE REVIEWED:
   - APPROVAL DATE - References All Items Listed Below (08/02/2016)
   - Amendment - AM: D Quantify Mobility (07/29/2016)

DESIGNATED - Continuing Review

1. **PI10**
   Regulation of Intestinal Epithelial Tight Junction Barrier
   ID: **00070** Prom#: **0005** Protocol#: **11-A70**
   DESIGNATED 09/07/2016
   ITEMS TO BE REVIEWED:
   - APPROVAL DATE - References All Items Listed Below (09/07/2016)
   - Continuing Review Application - 2nd Year (08/28/2016)

DESIGNATED - IACUC 3 Year Renewal

1. **PI06**
   Effects of Bacteria-derived Gas: A Model of GWS
   ID: **00207** Prom#: **0004** Protocol#: **13-A207**
   DESIGNATED 08/25/2016
   ITEMS TO BE REVIEWED:
   - APPROVAL DATE - References All Items Listed Below (08/25/2016)
   - ACORP - Category D (08/25/2016)
   - ACORP App 3: Test Substances - Biosafety (08/25/2016)
   - ACORP App 4: Antimortem Specimen Collection (08/25/2016)
   - ACORP App 5: Surgery (08/25/2016)
   - ACORP App 6: Special Husbandry and Procedures (08/25/2016)

DESIGNATED - Initial Review

1. **PI15**
   Murine Models of Post-Infectious Irritable Bowel Syndrome
   ID: **00204** Prom#: **0001** Protocol#: **16-A204**
   DESIGNATED 08/24/2016
   ITEMS TO BE REVIEWED:
   - APPROVAL DATE - References All Items Listed Below (08/24/2016)
   - ACORP - IACUC IR (08/24/2016; Category: C)
   - ACORP App 3: Test Substances (08/24/2016)
   - ACORP App 4: Antimortem Specimen Collection (08/24/2016)
   - ACORP App 6: Special Husbandry and Procedures (08/24/2016)

DESIGNATED - Study Closure

1. **PI01**
   Effect of Zinc on Attaching/Effacing E. coli Infection
   ID: **00063** Prom#: **0008** Protocol#: **13-A63**
   STATUS: Closed
   ADMINISTRATIVE 10/03/2016
   ITEMS TO BE REVIEWED:
   - APPROVAL DATE - ACORP Closure (10/03/2016)

2. **PI06**
   Effects of Bacteria-derived Gas: A Model of GWS
   ID: **00069** Prom#: **0004** Protocol#: **13-A69**
   STATUS: Closed
   ADMINISTRATIVE 08/19/2016
   ITEMS TO BE REVIEWED:
   - APPROVAL DATE - ACORP Closure (08/19/2016)

Next Meeting: Tuesday, January 10, 2017

Time Adjourned: 11:20am

Meeting Adjourned

[redacted] 1/23/17
Date

Approval / Disapproval

[redacted] 1/26/17
Date

[redacted] 1/30/17
Date

Staff/Research

Acknowledge

Andrew M. Welch. MHA. FACHE. Medical Center Director 2-2-17
Date

Institutional Animal Care and Use Committee
New Mexico VA Health Care System
New Mexico VA Health Care System • 1501 San Pedro Dr. SE • Albuquerque, NM 87108
[redacted] Conference Room

[CONFIDENTIAL] MINUTES

Tuesday, January 10, 2017

Present

[redacted] LATG, Acting Chairperson	Supervisor, Vet. Med. Unit;
C16	Non-scientific/Non-affiliated
C05	Non-affiliated Scientific
[redacted] DVM	Vet. Med. Consultant (VMC)
C13	Affiliated Scientific Excused at 10:50am
C08	Animal Health Tech

Staff
C10, IACUC Coordinator

Excused
Voting

[redacted] PhD, Chairperson	Affiliated Scientific

Total Voting Members: 7 **Total Voting Attendees:** 6 **Quorum:** 4

Time Started: 9:06am

Call to Order

1. Affiliated Scientific Member, C14, resigned from committee 11/17/16.

2. Conflict of Interest: C13 -PI01 project: 0012, ACORP: 12-A187 AM-B

Minutes

1. Review of Minutes for the October 4, 2016 meeting
   Motion to approve with minor changes
   Approved [For: 6 Against: 0 Abstained: 0 Recused: 0 Excused: 0]

Informational

1. Office of Laboratory Animal Welfare (OLAW) Guidance from Lab Animal, Volume 45, No.10, October 2016: "How should an IACUC handle high mortality rates?"
   Discussion: The IACUC discussed the scenario and the three responses with emphasis on the third response that Post- Approval Monitoring (PAM) could have identified problems earlier. The guidance from OLAW states you don't have to reclassify the mice that died into USDA Category E, but it is required for the VA.

   No Action Needed

2. The Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) Site Visit 2017
   Discussion: We will get more details as to when they are coming and if they will be looking for anything specific as we get closer to the visit date. We have until April 1st to prepare and submit our program description to AAALAC. The program description format is patterned after the 8th Edition Guide and is used by the site visitors to assess our program during their visit. They also like to meet with the IACUC.

   No Action Needed

3. Office of Research and Development (ORD)-Office of Research Oversite (ORO) Joint Guidance on Semi-annual Reviews of the Animal Care and Use Program (ACUP)
   Discussion: The Medical Center Director, IACUC Chairperson, IACUC Veterinarian and Associate Chief of Staff – Research (ACOS-R) must be involved in the meeting to discuss the Semi-Annual review with the Medical Center Director. It is a "Must" that the ACOS-R attends the meeting. All IACUC members are invited to attend the meeting. The Director must attend the meeting and sign the Review; he cannot delegate this task. Any of the other required members can be delegated but it must be in writing and it must be reflected in the minutes. The meeting must be conducted in "real time" either in person or by video conference.

   No Action Needed

4. Veterinary Medical Unit (VMU) Annual Report Submitted to ORD Wednesday, December 7, 2016

   No Action Needed

Unfinished Business

1. Breeding Colony Management
   Discussion: The IACUC sent a letter, to the PI14, to discuss the committee's concerns and request a meeting to discuss plans to downside the colony. It was requested that a plan to minimize the colony be devised within four months. Before a meeting could be arranged PI14 wrote back to the IACUC describing how he could potentially use the animals. Since the last IACUC meeting, PI14 has not used any of the animals and there are no known plans to use any of them. PI14 has not notified the committee that he will be receiving new funding. There needs to be an immediate plan to use the animals or remove the animals that can be purchased. The IACUC will send another memo to PI14 to remind him that he has one more month left to address the issue.

   Open

Review of Reportable Incidents

1. None

Post Approval Monitoring

1. Training
   PI01 and PI14 Lab Personnel
   PI01 – The VMU Supervisor trained lab technician on the location of the Animal Component of Research Protocol (ACORP) in the VMU, how they are organized and the importance of keeping them up to date and knowing their specific lab's protocol. The VMC trained same lab technician in gavage and restraint.
   PI14 – The VMC observed lab manager with their Intraperitoneal (IP) injections.
   No Action Needed

2. Audit
   PI06 and PI14 Lab Personnel
   PI06 – The VMU Supervisor did an unscheduled observation of lab technician performing gavage and restraint during an experiment. Lab technician proved competent.
   VMU Supervisor went through lab audit form with lab manager for a three year review. There were no problems.
   PI14 – The VMC did an unscheduled observation on submandibular bleeding with lab manager.
   No Action Needed

3. Tamoxifen Use Review in PI14 Lab – After an experiment with injectable Tamoxifen about 50% of the animals died. Their death wasn't immediate; some of them died three to seven days after the experiment. Their procedures for mixing solutions should be reviewed. Tamoxifen can be toxic. Mortality is normally not expected to be greater than 25%. Tamoxifen is used to knock out or induce conditional gene mutants and in certain conditions outcomes can be lethal. Some investigators have dosed Tamoxifen orally in diet formulations. It is a smaller dose over a longer period of time. Based upon a few treatments using commercial diet delivery it appeared to result in less clinical morbidity. If they use injectable again and there is higher than expected mortality, the VMC recommends a culture of the solution to confirm sterility and a necropsy to determine cause of death. It will also be suggested that they consider switching to oral dosing as a refinement.
   No Action Needed

Semi-Annual Program Review & Facilities Inspection

1. Part 2 Open Items:
   Item 1351, VMU - Buff Floors: The floors were buffed but it did not make a difference. The floor is still oxidized. The VMU staff will get in touch with the manufacturer to find a better product.
   Item 1451, Feed Cold Room - Humidity control: It would be a big investment to purchase a dehumidifier to use in the few months where the humidity is too high. The humidity is fine during the winter. The food bags currently used have plastic liners and can be sealed to keep excess moisture out of the food.
   There is one type of autoclavable diets that are contained in bags with perforations to allow penetration of steam for sterilization. When those are stocked they will not be stored in the cold room, to mitigate this concern.
   Item 1454, Rm. [redacted] - Refrigerator/freezer defrost: Done
   Item 1700, Rm. [redacted] - Paint steam stub: Done
   Item 2000, Rm. [redacted] - What pesticide used: The product used is safe and appropriate for continued use .
   Item 2400, Rm. [redacted] - Guillotine SOP: The SOP has not been written there are no plans to use it. An SOP will be written if there is a plan to use.
   Item 1053, Note - Feedback from CVMO regarding the inability of VMU supervisor and Veterinary Medical Consultant (VMC) to order controlled substances for the animal facility: Our site has not heard anything back from the CVMO. The Pharmacy handbook may have been updated, the VMU

Supervisor will look to see if this issue has been clarified.

No Action Needed

Semi-Annual Program Review & Facilities Inspection

2. Next Review Deadline: April 2017

3. The September 27, 2016 Semi-Annual Review:
   a. Presented to the facility director 11/02/2016
   b. Sent to CVMO 11/11/16

Program Review

1. Annual ACUP Review 2017
   Discussion: The VMU Supervisor has summarized everything that has been done in the past year regarding the Animal Care and Use Program (ACUP). Since C14 has left the committee C01 will be the liaison between the IACUC and the Research and Development Committee (R&DC). C08 will be the liaison between the IACUC and the Subcommittee on Research Safety, Biosafety & Security (SRSBS). The IACUC composition has been updated. All Memorandums of Understanding (MOU) are still current.
   Animal per Diem rates were cut by 90% last year in hopes this would attract new investigators, there was more money in the general research fund last year to compensate for this expense. This year all funding is significantly less. Current VMU per Diem rates do not cover the animal's expenses. It is suggested the rates be increased to a reasonable level to compensate for the cost. Animal technicians have observed that these lower rates only encourage mismanagement of breeding colonies.
   One goal from last year were met.
   Attaining protocol and committee management software will be added as a goal for the next year.
   No Action Needed

Committee Training

1. IACUC Training Exercise 2016 #3: Non-Affiliated Member (NAM) and Non-Scientific Member (NSM) Revision Guidance
   Discussion: The flowchart is a really good tool to use when identifying new NAM and NSM.
   No Action Needed

2. IACUC Training Exercise 2016 #4: compliance with Public Health Service (PHS) Policy and VA Handbook 1200.07
   Senario for Discussion: The investigator unknowingly let his ACORP lapsed and the animals were moved to a holding protocol. Will there be a problem paying per Diems? If the funding is National Institutes of Health (NIH) they will not pay but if the funding is Veterans Administration (VA) the per Diems will be paid.
   A holding protocol is not required by the VA. However, our facility has a holding protocol.
   No Action Needed

Amendment

1. **PI14**

   Addiction Genetics: Dose-Response Differences and CAM Gene Variation

   ID: 00140 Prom#: 0001 Protocol#: 15-A140

   ITEMS TO BE REVIEWED:

   • Amendment - AM-E Cocaine CPP Illudalic Acid (01/06/2017)

   Discussion: There are questions with the design of this amendment. They want to increase the number of animals. If they determine there is no benefit from the drug then their next phase will be to vary the time of dosing to give more opportunity to fix CAM sites in the brain. They also want to use a new vehicle, Hydroxypropyl betadex. They have started experiments using DMSO as a vehicle. If the DMSO works they may not use the Hydroxypropyl betadex. They will analyze brain tissue for drug concentration. They will also assess behavior. This experiment is being conducted only in the wildtype mice. They will compare this data to data with the CAM knockout mice to show the knockout mice do not have addiction and removing the gene has a benefit.
   Motion to send amendment back to investigator for corrections; then it can be reviewed by Designated Member Review (DMR).

   Voteded [For: 6 Against: 0 Abstained: 0 Recused: 0 Excused: 0]

2. **PI01**

   A novel vaccine to prevent Clostridium difficile colitis

   ID: 00187 Prom#: 0012 Protocol#: 12-A187

   ITEMS TO BE REVIEWED:

   • Amendment - AM-B Use Older Mice (12/30/2016)

   Discussion: They plan to use older age humanized mice to ensure they show the same immunogenicity as the approved age of mice. There is a concern that the older mice fight and that the majority of males may have to be singly housed. It should also be documented that the older mice remain humanized. They need to define group ages.
   Motion to decide that it is a new aim to add the older group and should be considered a major amendment. Have investigator clarify age groups and continue review by DMR.

   Voteded [For: 4 Against: 0 Abstained: 1 Recused: 0 Excused: 1]

C13 has Conflict of Interest. Excused at 10:50am

Interim - Amendment

1. **PI12**

   Sphingosine-1-Phosphate: A new target for early Diabetic Retinopathy - Rat

   ID: 00209 Prom#: 0003 Protocol#: 12-A209

   ITEMS TO BE REVIEWED:

   • APPROVAL DATE - References All Items Listed Below (11/30/2016)

   • Amendment - AM:A Use Rats by Weight not Age (11/29/2016)

2. **PI12**

   Sphingosine-1-Phosphate: A new target for early Diabetic Retinopathy

   ID: 00185 Prom#: 0003 Protocol#: 12-A185

   ITEMS TO BE REVIEWED:

   • APPROVAL DATE - References All Items Listed Below (11/15/2016)

   • Amendment - Remove Personnel, Add Personnel (07/22/2016)

Interim - Amendment

3. **PI06**
   Animal model of GWS, a condition of increased H2S exposure
   ID: 00154 Prom#: 0002 Protocol#: 11-A154
   ITEMS TO BE REVIEWED:
   - APPROVAL DATE - References All Items Listed Below (11/30/2016)
   - Amendment - Add Personnel (09/20/2016)

4. **PI06**
   Effects of Bacteria-derived Gas: A Model of GWS
   ID: 00207 Prom#: 0004 Protocol#: 13-A207
   ITEMS TO BE REVIEWED:
   - APPROVAL DATE - References All Items Listed Below (11/30/2016)
   - Amendment - Add Personnel (09/20/2016)

Continuing Review

1. **PI12**
   Sphingosine-1-Phosphate: A new target for early Diabetic Retinopathy
   ID: 00185 Prom#: 0003 Protocol#: 12-A185
   ITEMS TO BE REVIEWED:
   - APPROVAL DATE - References All Items Listed Below (11/21/2016; 1st Yr CR)
   - Continuing Review Application - ACORP 1st Yr (10/28/2016)

2. **PI14**
   Transgenic Mouse Breeding and Colony Maintenance for Brain and Somatic Research Projects
   ID: 00177 Prom#: 0001 Protocol#: 15-A177
   ITEMS TO BE REVIEWED:
   - APPROVAL DATE - References all Items Listed Below (11/21/2016)
   - Continuing Review Application - ACORP 1st Yr (11/07/2016)

DESIGNATED - Initial Review

1. **PI12**
   Sphingosine-1-Phosphate: A new target for early Diabetic Retinopathy - Rat
   ID: 00209 Prom#: 0003 Protocol#: 12-A209
   ITEMS TO BE REVIEWED:
   - ACORP - IR - Rat (11/14/2016; Category: C, D)
   - ACORP App 3: Test Substances - Biosefety (11/14/2016)
   - ACORP App 4: Antimortem Specimen Collection (11/14/2016)
   - ACORP App 6: Special Husbandry and Procedures (11/14/2016)

Next Meeting: Tuesday, April 11, 2017 @

Time Adjourned: 11:07am

Meeting Adjourned,

[redacted] LATG, Acting Chairperson _____ Date

Approval / Disapproval

[redacted] MD, Chair, R&D Committee _____ Date

Acknowledge

[redacted] _____ Date

Acknowledge

Andrew M. Welch, MHA, FACHE, Medical Center Director _____ Date

Appendix 9: IACUC/OB Protocol Form

ANIMAL COMPONENT OF RESEARCH PROTOCOL (ACORP)
Main Body
VERSION 4

See Instructions for Completion of the Animal Component of Research Protocol (ACORP Instructions), for help in completing specific items.

A. **ACORP Status.**

1. Full Name of Principal Investigator(s)►

2. VA Station Name (City) and 3-Digit Station Number►

3. Protocol Title►

4. Animal Species covered by this ACORP►

5. Funding Source(s). Check each source that applies:

►( ) Department of Veterans Affairs.
►( ) US Public Health Service (e.g. NIH).
►( ) Private or Charitable Foundation -- Identify the Foundation:
►( ) University Intramural Funds – Identify the University and Funding Component:
►( ) Private Company – Identify the Company:
►( ) Other – Identify Other Source(s):

6. Related Documentation for IACUC reference.

   a. If this protocol applies to a project that has already been submitted to the R&D Committee for review, identify the project:

      (1) Title of project►

      (2) If approved by the R&D Committee, give the date of approval►

   b. Triennial review. If this protocol is being submitted for triennial *de novo* review, complete the following:

      (1) Identify the studies described in the previously approved ACORP that have already been completed
      ►

      (2) Indicate the numbers of animals of each breed/strain/genotype that have already been used, and adjust the numbers shown in Item I accordingly
      ►

      (3) Describe any study results that have prompted changes to the protocol, and <u>briefly summarize</u> those changes, to guide the reviewers to the details documented in other Items below.
      ►

c. List any other relevant previously approved animal use protocols (copy the lines below as needed for each protocol listed).

(1) Title of other protocol ►
(2) IACUC approval number of other protocol ►
Give the name of the VA station or other institution that approved it, if it was not approved by the IACUC that will review this ACORP ►

7. Indicate the type(s) of animal use covered by this protocol (check all that apply):

►( ) Research
►( ) Teaching or Training
►( ) Testing
►( ) Breeding and colony management only; not for any specific research project
►( ) Holding protocol (as specified by local requirements; not required by VA, PHS, or USDA)
►( ) Other. Please specify►

Proposal Overview

B. **Description of Relevance and Harm/Benefit Analysis.** Using non-technical (lay) language that a senior high school student would understand, briefly describe how this research project is intended to improve the health of people and/or other animals, or otherwise to serve the good of society, and explain how these benefits outweigh the pain or distress that may be caused in the animals that are to be used for this protocol.
►

C. **Experimental Design.**

1. **Lay Summary**. Using non-technical (lay) language that a senior high school student would understand, summarize the conceptual design of the experiment in no more than one or two paragraphs.
►

2. **Complete description of the proposed use of animals.** Use the following outline to detail the proposed use of animals.

a. **Summarize** the design of the experiment in terms of the specific groups of animals to be studied.
►

b. **Justify the group sizes and the total numbers of animals requested.** A power analysis is strongly encouraged; see ACORP instructions.
►

c. **Describe each procedure** to be performed on any animal on this protocol. (Use Appendix 9 to document any of these procedures that involve "departures" from the standards in the *Guide*. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)
►

D. **Species.** Justify the choice of species for this protocol.
►

Appendix 9: IACUC/OB Protocol Form

Personnel

E. **Current qualifications and training.** (For personnel who require further training, plans for additional training will be requested in Item F.)

1. PI

Name►

Animal research experience ►

Qualifications to perform specific procedures

Specific procedure(s) that the PI will perform personally	Experience with each procedure in the species described in this ACORP

2. Other research personnel (copy the lines below for each individual)

Name►

Animal research experience ►

Qualifications to perform specific procedures

Specific procedure(s) that this individual will perform	Experience with each procedure in the species described in this ACORP

3. VMU animal care and veterinary support staff personnel (copy the lines below for each individual)

Name►

Qualifications to perform specific support procedures in the animals on this protocol

Specific support procedure(s) assigned to this individual	Qualifications for performing each support procedure in the species described in this ACORP (e.g., AALAS certification, experience, or completion of special training)

4. For each of the research personnel listed in items 1 and 2 above, enter the most recent completion date for each course

Appendix 9: IACUC/OB Protocol Form

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)

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"

►

F. **Occupational Health and Safety.**

1. Complete one line in the table below for each of the personnel identified in Item E:

Name	Enrollment in OHSP		Declined optional services	Current on Interactions with OHSP? (yes/no)
	VA program	Equivalent Alternate Program – identify the program		
	( )	( )	( )	

2. Are there any non-routine OHSP measures that would potentially benefit, or are otherwise required for, personnel participating in or supporting this protocol?

► ( ) Yes. Describe them ►

► ( ) No.

Animals Requested

G. **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

H. **Numbers of animals requested.** See ACORP Instructions, for descriptions of the categories and how to itemize the groups of animals.

Appendix 9: IACUC/OB Protocol Form

USDA Category B

Procedures►						
Species / Experimental Group / Procedures(s)	Year 1	Year 2	Year 3	Year 4	Year 5	**Category B TOTAL**

USDA Category C

Procedures►						
Species / Experimental Group / Procedure(s)	Year 1	Year 2	Year 3	Year 4	Year 5	**Category C TOTAL**

USDA Category D

Procedures►						
Species / Experimental Group / Procedure(s)	Year 1	Year 2	Year 3	Year 4	Year 5	**Category D TOTAL**

USDA Category E

Procedures►						
Species / Experimental Group / Procedure(s)	Year 1	Year 2	Year 3	Year 4	Year 5	**Category E TOTAL**

TOTALS over all Categories

Species / Experimental Group /Procedure(s)	Year 1	Year 2	Year 3	Year 4	Year 5	**GRAND TOTAL**

I. **Management of USDA Category D procedures**. Indicate which statement below applies, and provide the information requested.

► ( ) This protocol does NOT include any Category D procedures.

► ( ) This protocol INCLUDES Category D procedures. List each Category D procedure and provide the

information requested. (For surgical procedures described in Appendix 5, only identify the procedure(s) and enter "See Appendix 5 for details.)

Procedure	Monitoring (indicate the method(s) to be used, and the frequency and duration of monitoring through post-procedure recovery)	Person(s) responsible for the monitoring	Method(s) by which pain or distress will be alleviated during or after the procedure (include the dose, route, and duration of effect of any agents to be administered)

J. **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

K. **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) ►

L. **Husbandry.** As a reference for the animal husbandry staff, summarize here the husbandry requirements of the animals on this protocol. (Use Appendix 6 to justify the use of any special husbandry and to detail its effects on the animals. Use Appendix 9 to document any aspects of the husbandry that involve "departures" from the standards in the *Guide*. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)

1. Caging needs. Complete the table below to describe the housing that will have to be accommodated by the housing sites for this protocol:

Appendix 9: IACUC/OB Protocol Form

a. Species	b. Type of housing*	c. Number of individuals per housing unit**	d. Is this housing consistent with the *Guide* and USDA regulations? (yes/no***)	e. Estimated maximum number of housing units needed at any one time

*See ACORP Instructions, for guidance on describing the type of housing needed. If animals are to be housed according to a local Standard Operating Procedure (SOP), enter "standard (see SOP)" here, and enter the SOP into the table in Item Y. If the local standard housing is not described in a SOP, enter "standard, see below" in the table and describe the standard housing here:
►

** The *Guide* states that social animals should generally be housed in stable pairs or groups. Provide a justification if any animals will be housed singly (if species is not considered "social", then so note)
►

***Use Appendix 9 to document "departures" from the standards in the *Guide*.

2. Enrichment. Complete the table below to indicate whether "standard" exercise and environmental enrichment will be provided to the animals on this protocol, or whether any special supplements or restrictions will be required (See ACORP Instructions, for more information on enrichment requirements. Use Appendix 9 to document any enrichments requirements that represent "departures" from the standards in the *Guide*.):

a. Species	b. Description of Enrichment*	c. Frequency

*If enrichment will be provided according to a local SOP, enter "standard (see SOP)" and enter the SOP into the table in Item Y. If the local standard enrichment is not described in a SOP, enter "standard, see below", and describe the standard species-specific enrichment here.

►

3. Customized routine husbandry. Check all of the statements below that apply to the animals on this protocol, and provide instructions to the animal husbandry staff with regard to any customized routine husbandry needed.

► ( ) This ACORP INCLUDES genetically modified animals.

List each group of genetically modified animals, and describe for each any expected characteristic clinical signs or abnormal behavior related to the genotype and any customized routine husbandry required to address these. For genetic modifications that will be newly generated on or for this protocol, describe any special attention needed during routine husbandry to monitor for unexpected clinical signs or abnormal behavior that may require customized routine husbandry.
►

► ( ) Devices that extend chronically through the skin WILL be implanted into some or all animals on this protocol. Describe any customized routine husbandry to be provided by animal husbandry staff to minimize the chances of chronic infection where the device(s) penetrate the skin.

►

► ( ) Some or all of the animals on this protocol WILL require other customized routine husbandry by the animal husbandry staff, beyond what has been described above. Describe the special husbandry needed.

►

► ( ) This ACORP does NOT include use of any animals that will require customized routine husbandry.

M. **Housing Sites**. Document in the tables below each location where animals on this protocol may be housed.

► ( ) Housing on VA property. Identify each location on VA property where animals on this protocol will be housed, and indicate whether or not each location is inside the VMU.

Building	Room number	Inside of VMU?	
		Yes	No
		( )	( )

► ( ) Housing in non-VA facilities. Identify each location not on VA property where animals on this protocol will be housed, and provide the information requested in the table.

Name of Non-VA Facility	Is this facility accredited by AAALAC?		Building	Room Number
	Yes -- enter status*	No**		
	( )	( )**		

*See ACORP Instructions, for a list of AAALAC accreditation status options.

**For any facility listed above that is not accredited by AAALAC, attach documentation that a waiver has been granted by the CRADO.

Special Features

N. **Antibody Production.** Will any of animals on this protocol be used for the production of antibodies?

Appendix 9: IACUC/OB Protocol Form

► ( ) 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.

O. **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.

P. **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
	( )	**( )**		**( )**	**( )**

Q. **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")
	( )	**( )**	**( )**	**( )**

R. **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.

S. **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.)
►

T. **Termination or removal from the protocol**. Complete each of the following that applies:

► ( ) Some or all animals will NOT be euthanatized on this protocol. Describe the disposition of these animals. (Use Appendix 9 to document any "departures" from the standards in the *Guide* represented by these methods of disposition. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)

►

► ( ) Some or all animals MAY be euthanatized as part of the planned studies. Complete the table below to describe the exact method(s) of euthanasia to be used. (Use Appendix 9 to document any departures from the standards in the *Guide* represented by these methods. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)

Check each method that may be used on this protocol	Method of Euthanasia	Species	AVMA Classification		
			Acceptable	Conditionally Acceptable	Unacceptable
( )	CO_2 from a compressed gas tank Duration of exposure after apparent clinical death► Method for verifying death► Secondary physical method►		( )	( )	( )
( )	Anesthetic overdose Agent► Dose► Route of administration►		( )	( )	( )
( )	Decapitation under anesthesia Agent► Dose► Route of administration►		( )	( )	( )

( )	Exsanguination under anesthesia Agent► Dose► Route of administration►		( )	( )	( )
( )	Other (Describe) ►		( )	( )	( )

1. For each of the methods above that is designated as "Conditionally Acceptable" by the AVMA, describe how the conditions for acceptability will be met:
   ►

2. For each of the methods above that is designated as "Unacceptable" by the AVMA, give the scientific reason(s) that justify this deviation from the AVMA Guidelines:
   ►

3. Identify all research personnel who will perform euthanasia on animals on this protocol and describe their training and experience with the methods of euthanasia they are to use in the species indicated.
   ►

4. Instructions for the animal care staff in case an animal is found dead.
   a. Describe the disposition of the carcass, including any special safety instructions. If disposition is to be handled according to a local SOP, enter "according to local SOP" and enter the information requested about the SOP into the table in Item Y.
      ►

   b. Describe how the PI's staff should be contacted.
      ► ( ) Please contact a member of the PI's staff immediately. (Copy the lines below for each individual who may be contacted)

      Name►

      Contact Information►

      ► ( ) There is no need to contact the PI's staff immediately. Describe the routine notification procedures that will be followed. If the routine notification procedures are described in a local SOP, enter "according to local SOP" and enter the information requested about the SOP into the table in Item Y.

      ►

U. **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.

Appendix 9: IACUC/OB Protocol Form

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:	( )**

*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.)

V. **Consideration of Alternatives and Prevention of Unnecessary Duplication.** These are important to minimizing the harm/benefit to be derived from the work.

1. Document the database searches conducted.
   List each of the potentially painful or distressing procedures included in this protocol.

   ►

   Then complete the table below to document how the database search(es) you conduct to answer Items W.2 through W.5 below address(es) each of the potentially painful or distressing procedures.

Name of the database	Date of search	Period of years	Potentially painful or	Key words and/or search strategy used	Indicate which mandate each search addressed

		covered by the search	distressing procedures addressed		Replacement of animals (item W.2)	Reduction in numbers of animals used (item W.3)	Refinement to minimize pain or distress (item W.4)	Lack of unnecessary duplication (item W.5)
					( )	( )	( )	( )

2. Replacement. Describe the replacements that have been incorporated into this work, the replacements that have been considered but cannot be used, and the reason(s) that further replacements are not acceptable.
   ▶
3. Reduction. Describe how the number of animals to be used has been minimized in this protocol and explain why further reduction would disproportionately compromise the value of the data.
   ▶
4. Refinement. Describe the refinements that have been incorporated into this work and explain why no further refinements are feasible.
   ▶
5. Describe how it was determined that the proposed work does not unnecessarily duplicate work already documented in the literature.
   ▶

W. **Other Regulatory Considerations**.

1. **Controlled drugs**.

   a. Complete the table below for each drug that is used in animals on this protocol and that is classified as a controlled substance by the DEA. See ACORP Instructions, for explanations about the information requested.

Controlled substances	Storage		Personnel Authorized to Access	Location for Use		Procurement	
	Double-locked	Not Double-locked*		VA Property	Not on VA Property	VA Phar-macy	Non-VA
	( )	( )*		( )	( )	( )	( )
	( )	( )*		( )	( )	( )	( )
	( )	( )*		( )	( )	( )	( )

*For any controlled substance that will NOT be stored under double lock, with limited access, describe how it will be stored, and explain why this is necessary.

►

b. Check each statement below that applies, to confirm that all controlled substances used on this protocol will be procured according to VA pharmacy policies:

► ( ) Some controlled substances will used on VA property, and all of these will be obtained through the local VA pharmacy.

► ( ) Some controlled substances will not be obtained through the local VA pharmacy, but none of these will be used on VA property. See the ACORP Instructions, for further information.

► ( ) Other. Explain►

2. **Human patient care equipment or procedural areas**. Does this protocol involve use of any human patient care equipment or procedural areas?

► ( ) Yes, some human patient care equipment or procedural area(s) will be used for the animal studies on this protocol. Check "Appendix 7" in Item Y, below, and complete and attach Appendix 7, "Use of Patient Procedural Areas for Animal Studies".

► ( ) No human patient care equipment or procedural areas will be used for the animal studies on this protocol.

3. **Explosive agents**. Does this protocol involve use of any explosive agent?

► ( ) Yes, some explosive agent(s) will be used on this protocol. Check "Appendix 3" and "Appendix 8" in Item Y, below, and complete and attach Appendix 8, "Use of Explosive Agent(s) within the Animal Facility or in Animals", as well as Appendix 3, "Biosafety".

► ( ) No explosive agent(s) will be used as part of this protocol.

X. **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. <u>Do not check off or attach any appendices that are not applicable to this ACORP.</u>

► ( ) 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*"

Appendix 9: IACUC/OB Protocol Form

Standard Operating Procedures (SOPs). List in the table below, each of the SOPs referred to in this protocol, providing the information requested for each one. The approved SOPs must be included when the approved ACORP and Appendices are submitted for Just-in-Time processing before release of VA funding support.

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

Y. **Certifications.** Signatures are required here for any ACORP that is to be submitted to VA Central Office in support of an application for VA funding. Include the typed names and dated signatures as shown below for the Main Body of the ACORP and for each of the Appendices that apply to this protocol. Do NOT include signatures for, or attach, any appendices that do NOT apply.

1. **Main Body of the ACORP.**

a. **Certification by Principal Investigator(s):**

I certify that, to the best of my knowledge, the information provided in this ACORP is complete and accurate, and the work will be performed as described here and approved by the IACUC. I understand that IACUC approval must be renewed at least annually, and that the IACUC must perform a complete *de novo* review of the protocol at least every three years, if work is to continue without interruption. I understand further that I am responsible for providing the information required by the IACUC for these annual and triennial reviews, allowing sufficient time for the IACUC to perform the reviews before the renewal dates, and that I may be required to complete a newer version of the ACORP that requests additional information, at the time of each triennial review.

I understand that further IACUC approval must be secured before any of the following may be implemented:

- Use of additional animal species, numbers of animals, or numbers of procedures performed on individual animals;
- Changing any procedure in any way that has the potential to increase the pain/distress category to which the animals should be assigned, or that might otherwise be considered a significant change from the approved protocol;

- Performing any additional procedures not already described in this ACORP;
- Use of any of these animals on other protocols, or by other investigators.

I further certify that:

- No personnel will perform any animal procedures on this protocol until the IACUC has confirmed that they are adequately trained and qualified, enrolled in an acceptable Occupational Health and Safety Program, and meet all other criteria required by the IACUC. When new or additional personnel are to work with the animals on this protocol, I will provide this information to the IACUC for confirmation before they begin work;
- I will provide my after-hours contact information to the animal care staff for use in case of emergency.

Name(s) of Principal Investigator(s)	Signature	Date

b. **Certification by IACUC Officials.**

We certify that:

- We, with the IACUC, have evaluated the care and use of animals described on this ACORP, in accordance with the provisions of the USDA Animal Welfare Act Regulations and Standards, PHS Policy, the *Guide for the Care and Use of Laboratory Animals*, and VA Policy;
- The IACUC has determined that the care and use of animals described in this ACORP is appropriate, and has therefore approved the protocol;
- The full text of any minority opinions is documented here as indicated below:

► ( ) No minority opinions were submitted by any IACUC participant for inclusion.

► ( ) Minority opinions submitted by IACUC participants are copied here

►

► ( ) Minority opinions submitted by IACUC participants are attached on separate pages labeled “IACUC Minority Opinion” (indicate the number of pages►)

Name of Attending Veterinarian (VMO or VMC)	Signature	Date

Name of IACUC Chair	Signature	Date

2. **Appendix 2. Antibody Production.** No signatures required.

3. **Appendix 3. Biosafety.**

   a. **Certification by PI(s) and IACUC Officials:**

   We certify that:

   - Before any animal experiments involving hazardous agents (identified in Item 10.a of Appendix 3) are performed, SOPs designed to protect all research and animal facility staff as well as non-study animals will be developed and approved by the appropriate VA or affiliated university safety committee and by the IACUC;

   - All personnel who might be exposed to the hazardous agents (identified in Item 10.a of Appendix 3) will be informed of possible risks and will be properly trained ahead of time to follow the SOPs to minimize the risks of exposure.

Name(s) of Principal Investigator(s)	Signature(s)	Date
Name of Institutional Veterinarian	Signature	Date
Name of IACUC Chair	Signature	Date

   b. **Certification by Biosafety Official.** I certify that:

   - Each agent to be administered to animals on this protocol has been properly identified in Item 1 of Appendix 3 as to whether it is “toxic”, “infectious”, “biological”, or “contains recombinant nucleic acid”;

   - The use of each of the agents thus identified as “toxic”, “infectious”, or “biological”, or “contains

recombinant nucleic acid" is further documented as required in Items 4, 5, 6, and/or 8, as applicable, and in Item 10.a of Appendix 3;

- The use of each of these agents has been approved by the appropriate committee(s) or official(s), as shown in Item 10.a of Appendix 3.

Name of the Biosafety Officer, or of the Chair of the Research Safety or Biosafety Committee	Signature	Date

c. **Certification by Radiation Safety Official.** I certify that:

- Each agent to be administered to animals on this protocol has been properly identified in Item 1 of Appendix 3 as to whether it is "radioactive";
- The use of each radioactive agent is further documented as required in Items 7 and 10.a of Appendix 3;
- The use of each radioactive agent has been approved by the appropriate committee(s), as shown in Item 10.a of Appendix 3.

Name of the Radiation Safety Officer, or of the Chair of the Radiation Safety or Isotope Committee	Signature	Date

4. **Appendix 4. Ante-mortem Specimen Collection.** No signatures required.

5. **Appendix 5. Surgery. Certification by the PI(s).** I certify that:

- To the best of my knowledge, the information provided in Appendix 5 of this ACORP is complete and accurate;
- The surgical procedures will be performed and the post-operative care (including administration of post-operative analgesics) will be provided as described;
- The spaces where any survival surgical procedures will be performed (listed in Item 4 of Appendix 5) are suitable for sterile/aseptic surgery;
- The names and contact information for research personnel to notify or consult in case of emergencies will be provided to the VMU supervisor and veterinary staff;
- Post-operative medical records will be maintained and readily available for the veterinary staff and the IACUC to refer to, and will include the following:

- Identification of each animal such that care for individual animals can be documented.
- Daily postoperative medical records for each animal, that include documentation of daily evaluation of overall health and descriptions of any complications noted, treatments provided, and removal of devices such as sutures, staples, or wound clips;
- Documentation of the administration of all medications and treatments given to the animals, including those given to reduce pain or stress.
- Daily records covering at least the period defined as "post-operative" by local policy.
- The signature or initials of the person making each entry.

. Name(s) of Principal Investigator(s)	Signature(s)	Date

6. **Appendix 6. Special Husbandry and Procedures.** No signatures required.

7. **Appendix 7. Use of Patient Care Equipment or Areas for Animal Studies.**

   a. **Certification by the Principal Investigator(s).** I certify that, to the best of my knowledge, the information provided in Appendix 7 of this ACORP is complete and accurate, and the use of patient care equipment or areas for these animal studies will be as described.

Name(s) of Principal Investigator(s)	Signature(s)	Date

   b. **Certification by the officials responsible for the use of any human patient care equipment in animal procedural areas.** Each of the following must sign to indicate that they have granted approval for the human patient care equipment to be moved to the VMU or other animal procedural area to be used on animals and then returned to the human patient care area, as described in Appendix 7. Leave this section blank, if not applicable.

Name of IACUC Chair	Signature	Date

Name of the Manager of the Human Patient Care Equipment	Signature	Date

c. **Certification by the officials responsible for the use of the equipment in human patient care areas for these animal studies.** Each of the following must sign to indicate that they have granted approval for animals to be transported into human patient care areas for study or treatment, as described in Appendix 7. Leave this section blank, if not applicable.

Name of IACUC Chair	Signature	Date
Name of Attending Veterinarian (VMO or VMC)	Signature	Date
Name of the Chair of the Clinical Executive Board, or the Service Chief responsible for the Patient Care Area and Equipment	Signature	Date
Name of ACOS for R&D	Signature	Date
Name of Chief of Staff	Signature	Date
Name of Director or CEO of the Facility (Hospital or Clinic)	Signature	Date

8. **Appendix 8. Use of Explosive Agent(s) within the Animal Facility or in Animals.**

a. **Certification by the Principal Investigator(s).**

Appendix 9: IACUC/OB Protocol Form

I certify that, to the best of my knowledge, the information provided in Appendix 8 of this Animal Component of Research Protocol (ACORP) is complete and accurate, and the use of explosive agents in these animal studies will be as described.

I further certify that:

- Procedures involving explosive agent(s) will be performed within a properly operating, ventilated safety hood;
- All electrical equipment operating when explosive agent(s) are in use will be positioned and powered outside of the hood;
- Once the seal is broken on any containers of explosive agents, they will be kept in a safety hood throughout use, stored in an explosion-proof refrigerator or other approved storage area, and discarded properly once completely emptied;
- Proper procedures will be used for safe and appropriate disposal of items (including animal carcasses) that may contain residual traces of the explosive agent(s).

Name(s) of Principal Investigator(s)	Signature(s)	Date

b. **Certification by the officials responsible for overseeing the use of explosive agent(s) in this protocol.** Each of the following must sign to verify that they or the committee they represent have granted approval.

Name of IACUC Chair	Signature	Date
Name of Attending Veterinarian (VMO or VMC)	Signature	Date
Name of Safety/Biosafety Officer for the Facility	Signature	Date
Name of ACOS for R&D	Signature	Date

Name of VISN Regional Safety Officer	Signature	Date

9. **Departures from "Must" and "Should" Standards in the *Guide*.** No signatures required.

Appendix 9: IACUC/OB Protocol Form

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.)

Appendix 9: IACUC/OB Protocol Form

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.
2.
   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:
   ►

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

3. **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.

32Describe 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)

a. 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:

►

► ( ) 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):

►

b. 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).

►

4. **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:

►

►( ) 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:
►

5. **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.
►

6. **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

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.)

Appendix 9: IACUC/OB Protocol Form

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_	( )	( )	( )	( )	( )

Appendix 9: IACUC/OB Protocol Form

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):
►

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.
►

Appendix 9: IACUC/OB Protocol Form

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 ►

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)	( )	( )	( )**

*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 ►

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).

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

    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.

Appendix 9: IACUC/OB Protocol Form

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

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		( )	( )	( )	( )*

*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 ►

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)	Role in Surgery

	(see Item 1)	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
			( )	( )*	( )*

*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 ►

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.

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

Appendix 9: IACUC/OB Protocol Form

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)
1					

*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. After-hours contact information for the personnel listed must be provided to the veterinary staff for use in case of an emergency.

(1) Immediate post-operative monitoring

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

(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 ►

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

Surgery 1 ►

Surgery 2 ►

(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.

Appendix 9: IACUC/OB Protocol Form

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

*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 ►

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

Special Procedure 1 ►

Special Procedure 2 ►

Appendix 9: IACUC/OB Protocol Form

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. **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.

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]

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					

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

Special Procedure 1 ►

Special Procedure 2 ►

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 ►

Special Procedure 2 ►

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		

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.
   ►

   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				

   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			( )	( )

   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).
   ►

   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

Last Name of PI►
Protocol No. Assigned by the IACUC►
Official Date of Approval►

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

Annual Review of Animal Use
Albuquerque, NM

Principal Investigator:

Project Title:

Project No: ACORP No: Review Period:

Funding/Administration: ☐ 1st year ☐ 2nd year ☐ Triennial

Approved Species/Strain:

Approved USDA categories: *Number of animals used (list Category E animals below):* _____
Were Category E animals used? ☐ Yes ☐ No *If **Yes**, how many were used?* _____

1. Project Status: (check one)

   ☐ Project is Active and animal subjects are being used.
   ☐ Project is active, animal subjects are currently not being used.
   ☐ Project is completed, funding is not active, animal use may be closed.

2. Approved protocol is being followed. ☐ Yes ☐ No
   *If **No**, submit an amendment memo to the IACUC with an explanation of changes to the approved protocol.*
   All research projects using animals must receive prior approval by the IACUC, and any change in animal use requires prior approval by the IACUC.
3. Are there any hazards involved with this project? ☐ Yes ☐ No

   *If **Yes**, what is the date of the last SRSBS approval?* _____

4. List current personnel working on this project: _____

I am aware that continuation of approval requires annual review, that animal use in projects not reviewed and approved is not allowed, and that a copy of all animal related matters must be retained by the Principal Investigator for three (3) years after the study has ended. This form, together with any requested additional information, is submitted in compliance with these regulations.

_____ _____
Signature Date

Approved/Disapproved:

_____ _____
[redacted] Date

Chair, Institutional Animal Care and Use Committee

SUBCOMMITTEE ANNUAL PROJECT REVIEW CHECKLIST

Appendix 9: IACUC/OB Protocol Form

PROJECT #: _____

PRINCIPAL INVESTIGATOR: _____

PROJECT TITLE: _____

Part I – For Principal Investigator to complete:

Research Data Security and Confidentiality of Records checklist:	
NA	**No changes** - there have been no changes in the checklist since the last review
NA	**Changes** - there have been changes to the checklist since the last review and an updated checklist is attached.
Study Personnel:	
☐	Attached is the current list of study personnel
☐	All personnel have been appropriately added to the study
	Conflict of Interest forms
	☐ **No** changes in COI and COI forms are all current
	☐ **Yes**, there have been changes to the COI status of the following personnel List: (insert names of personnel with updates): 1. 2. 3. ☐ updated COI forms are attached
	Scope of Practice or clinical privileges:
	☐ All study personnel are only performing study related duties under their current Scope of Practice and/or clinical privileges
	☐ Scope of Practice for the following study personnel require updating due to new study related duties not currently included in their Scope of Practice or clinical privileges. List: (insert names of personnel with updates): 1. 2. 3. ☐updated Scope of Practice forms are attached

_____ _____

PRINCIPAL INVESTIGATOR SIGNATURE **DATE**

SUBCOMMITTEE ANNUAL PROJECT REVIEW CHECKLIST

Appendix 9: IACUC/OB Protocol Form

PART II: RESEARCH OFFICE TO COMPLETE

YES	NO	N/A	Review Item	Comments:
Project Review by ACOS/R or R&DC Chair				
☐	☐	☐	ACOS/ R or R&DC Chair has reviewed the progress of the research regarding assessment of barriers to research, appropriateness to VA mission, progress of the project and appropriate use of VA resources.	
☐	☐	☐	Has the annual ePromise progress report been completed?	
☐	☐	☐	Is the project funded?	
Staff Qualifications and Training				
☐	☐	☐	Do the PI and all members of the research staff continue to maintain valid privileges, credentials and/or scopes of practice that encompass work on this project?	
☐	☐	☐	Have the PI and all members of the research staff continued to complete required research training?	
P.O. and ISO Reviews				
☐	☐	☒	Is the Privacy Officer review current?	
☐	☐	☒	Is the Information Security Officer review current?	
Conflict of Interest				
☐	☐	☐	Have any conflicts of interest been identified?	

Checked by (signature) _____ Date _____

Appendix 9: IACUC/OB Protocol Form

Part III Annual Committee Review (for committee to complete)
(Attach to committee determination communication)

Review Committee (check one)	☒ IACUC ☐IRB ☐SRSBS ☐IBC ☐ R&DC
Review Date:	

Conflict of Interest		
☐ yes	☐ No	Have any conflicts of interest been identified? If yes, are all conflict of interest concerns related to this project still appropriately managed? ☐ yes ☐ no (explain)

☐ Committee acknowledges receipt of this information for their review.

☐Attached is the committee determination.

[redacted], Committee Chair Date

Appendix 9: IACUC/OB Protocol Form

For Office Staff Only

Review Type:

☐ Adm ☐ DMR☐ FCR☐ VR

Amendment for Component of Research Protocol

Date:

Principal Investigator:

Approved NMVAHCS ACORP #:

VA Project number and Title #:

Funding Source and location of funds:

Provide a brief (1-4 sentences) summary of this amendment.

Answer the following questions and provide detailed information where applicable.

1. Is the purpose of the amendment to change the funding source associated with this ACORP? Yes□ No□

   Source of funds and any identifying number:

   Location of funds (UNM, BRINM, LRRI, VA):
2. Is the purpose of the amendment to request replacement of animals of the same strain or substitution of animals of a different strain? Yes □ No □ - If yes, briefly describe why the replacement/substitute animals are requested, and include the number of replacement/substitute animals requested.
3. Is the purpose of the amendment to add additional animals of the same or different strain? Yes □ No □ If yes, briefly describe why. State how many additional animals are requested and provide a justification for how this number was reached. State the stress/pain category to which these animals will be assigned.
4. Is the purpose of the amendment to add a new test substance(s)? Yes □ No □
   If yes, please briefly describe the reason for adding the new compound. Also, provide the dose, route, volume and frequency, and any potential pain and distress likely to be experienced by the animals for each new test substance. If the test substance is hazardous, submit a new RPSS form to include the new hazard to the SRSBS for review and give date of approval.
5. Is the purpose of the amendment to add a new procedure(s), change the method of anesthesia or euthanasia, or change the duration, frequency, type or number of procedures? Yes □ No □

   If yes, please describe the changes to procedures or new procedure(s), provide a rationale for adding the procedure(s) and comment on whether this procedure will change the pain category assigned to this protocol. If the new procedure(s) has the potential to cause pain and/or distress, please describe the nature of the pain and/or distress, the criteria that will be used to assess pain and/or distress, and what will be done to alleviate the potential pain and/or distress. Include any scoring sheets used for evaluating pain and distress.

6. If not addressed above, explain the amendment request below.

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.

Starts on next page

►Name of VA Facility: Raymond G. Murphy VA Medical Center (NMVAHCS) Version 02/28/13
►Station Number: 501
►City, State: Albuquerque, New Mexico
►Date of Semiannual Evaluation: October 4, 2016

VA SEMIANNUAL EVALUATION
of the
INSTITUTIONAL ANIMAL CARE AND USE PROGRAM AND FACILITIES
Part 1 – Checklist
Section A. Review of the Program

The Review of the Program is largely an administrative evaluation of all of the policies, plans, standard procedures, and systems under which the institution fulfills its responsibilities to ensure humane animal care and use. Some of the programmatic items may appear similar to items included in Section B (Inspection of the Facilities), but the focus here (Review of the Program) is on what is intended or expected, while Section B focuses on observed implementation.

►Date(s) of the most recent previous Review of the Program: **April 12, 2016**

►Date(s) on which this Review of the Program was conducted: **September 27, 2016**

Names of voting IACUC members who participated in the Program Review:

Name	Specific Role on IACUC (if any)	Date(s) of Participation
► [redacted]	Attending Veterinarian	09/27/16
► [redacted]	Chairperson	09/27/16
► [redacted]	Member	09/27/16

Non-IACUC members who participated in the Program Review:

Name	Title	Date(s) of Participation

Items that reflect changes in the 8th edition of the *Guide* are flagged as follows, and may require particular attention as the 8th edition is implemented.

‡ denotes a new "must" item
† denotes a new "should" item

► Name of VA Facility: Raymond G. Murphy VA Medical Center (NMVAHCS) Version 02/28/13
► Station Number: 501
► City, State: Albuquerque, New Mexico
► Date of Semiannual Evaluation: October 4, 2016

I. Institutional Policies and Responsibilities

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
A. Shared Responsibilities						
100†	A formal written MOU, contract, or agreement is in place for any arrangement in which the VA shares responsibility for animal research with any other institution. This includes the use of an external IACUC and any collaborative arrangements for support, housing, or use of animals in research. *[1200.07 (8.b(1)); Guide, p. 15]* ► Name(s) of other institution(s) and the date(s) on which current formal written understanding(s) took effect: **LRRI: 9/10/14**		X			
B. General IACUC Function						
150	The official appointment of each member of the IACUC by the CEO *[PHS (IV.A.3a): 9 CFR (2.31(a))]* is documented and specifies the duration of the appointment and any specific role to which the member is appointed. *[1200.07 (8.a)]*		X			
151	The IACUC has at least five members, including at least one member qualified for and appointed to each of the required roles. *[PHS (IV.A.3); Guide (p. 24)]*		X			
152‡	The IACUC meets as necessary to fulfill responsibilities. *[Guide (p.25)]*		X			
153	The IACUC has adequate authority, administrative support, and other resources to fulfill its responsibilities. *[Guide (p. 14-15)]*		X			
154†	The IO has authority to allocate needed resources. *[Guide (p.13)]*		X			
155	The IACUC communicates regularly with the R&D Committee, by providing the R&D Committee with a set of final, signed, IACUC minutes, and all other notifications required by the R&D Committee, and through an individual who regularly attends meetings of both the IACUC and the R&D Committee. *[1200.07 (8.h (2)); 1200.01 (11.f)]*		X			
156†	Program needs are regularly communicated to the IO by the AV and/or the IACUC. *[Guide (p. 13)]*		X			
157	The IACUC communicates effectively as needed with the SRS and/or the IBC. *[1200.07 (Appendix C-.8.a)]*		X			
158	All minority opinions that are submitted are included in the final document that results from any action of the IACUC (e.g., meeting minutes, report of semiannual evaluation, and reports to oversight entities). *[PHS (IV.B.); 9 CFR (2.31(c)(3))]*		X			
159	The research office provides packets to IACUC members no later than 3 business days before the IACUC meeting. This packet must include an agenda with all business items listed, including reviewer assignments for all new protocols. *[1200.07(8.f(2)(d))]*		X			
160	A written draft of the minutes of the latest IACUC meeting is provided to all IACUC members at least 1 week before the next meeting.		X			
161	Review and approval by the IACUC is required before any work related to the use of animal subjects in VA research begins or is changed significantly. *[1200.07(8f(2)); PHS (IV.B.6-7); 9CFR (2.31(c)(6-7)); Guide (p. 26)]*		X			
162	All protocol forms used comply with PHS Policy and USDA AWAR. *[PHS(IV.C);9 CFR (2.31(d)]*		X			

▶Name of VA Facility: Raymond G. Murphy VA Medical Center (NMVAHCS) Version 02/28/13
▶Station Number: 501
▶City, State: Albuquerque, New Mexico
▶Date of Semiannual Evaluation: October 4, 2016

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
163	The current version of the VA ACORP (or an alternate form that has been approved by the CVMO) is used for any protocol involving work to be supported with VA funding. *[1200.07 (8.f(2)(e))]*		X			
164‡	Consultation with a qualified laboratory animal veterinarian is required before a protocol may be submitted for review by the IACUC. Veterinarian provides consultation when pain and distress exceeds anticipated level in protocol.*[1200.07 (Appendix D -1.k(2)); 9 CFR (2.31(d)(1)(iv)(B);, Guide (p.5)]*		X			
165‡	No IACUC member participates in the review or approval of any protocol in which that member has a real or apparent conflict of interest (financial or otherwise). *[Guide (p. 26)]*		X			
166	The IACUC does not approve any protocol that involves use of hazardous agents until the Biosafety Official and/or the Radiation Safety Official, as applicable, has signed in Item Z to confirm that the hazardous agents are properly documented in the ACORP. *[1200.07 (Appendix C-.8.c(1)); Guide (p. 21)]*		X			
167	Use of any patient care area for VA-funded animal research is prohibited unless the IACUC and appropriate local clinical and administrative officials first grant approval and the IACUC has reviewed and approved a completed ACORP Appendix 7 that justifies no reasonable alternative to the use of human clinical areas or equipment exists. *[1200.07 (7.k(1))]*	X				
168†	A system of post-approval monitoring is in place to ensure that all work with research animals is performed according to IACUC approved protocols. *[Guide (p. 33)]*		X			
169	The IACUC conducts continuing reviews of all protocols annually. *[9 CFR (2.31(d)(5)]*		X			
170	IACUC approval of each protocol expires on ~~or before~~ the third anniversary of its initial approval. *De novo* review and approval of a complete updated protocol by the IACUC before the date of expiration is required for work on the protocol to continue beyond three years without interruption. *[PHS (IV.C.5)]*		X			
171	Humane endpoints are established for studies in which pain and/or distress is anticipated (i.e., tumors, infectious disease, vaccine challenges, trauma, etc.) *[Guide (p.27)]*		X			
172	The IACUC has established oversight procedures for pilot and field/wildlife studies; studies involving genetically modified animals, food/fluid restriction, and the use of pharmaceutical versus non-pharmaceutical grade chemicals receive special consideration by the IACUC. *[Guide (p. 27-33)]*		X			
173	Surgical procedures are determined to be major or minor, multiple surgical procedures on a single animal are justified and the outcome evaluated, and multiple survival procedures regardless of species conform to regulated species standards. *[Guide (p.30)]*		X			
174‡	Requests for exemptions from major survival procedure restrictions are made to the USDA/APHIS through the IO. *[Guide (p. 30)]*	X				
175	Toe-clipping is approved by the IACUC only when no other individual identification method is feasible; the procedure is performed aseptically and with pain relief. *[Guide (p.75)]*	X				

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
176‡	The use of restraint devices is justified in the animal use protocols. IACUC approval is given when the purpose and duration of the restraint are justified. The justification addresses: the lack of feasible alternatives to physical restraint, provisions for the removal of maladaptive animals, training of animals, and appropriate observation of restrained animals. Veterinary care is provided if lesions or illness associated with restraint occur. *[Guide (p 29-30]*		X			
C. Semiannual Evaluations of the Animal Care and Use Program						
200	Program Review -- At least every six months, the IACUC reviews the animal care and use program. For VA animals used at an affiliate institution, this is done according to the MOU in place between the VA facility and the affiliate. *[1200.07 (8.f(1)): PHS (IV.B.1): 9CFR (2.31(c)(1))]*		X			
201	Facilities Inspection -- At least every six months, the IACUC inspects all facilities in which animals in the VA animal research program are used. For VA animals used at an affiliate institution, this is done according to the MOU in place between the VA facility and the affiliate. *[1200.07 (8.f(1)): PHS (IV.B): 9CFR (2.31(c)(2))]*		X			
202	Under no circumstances is the report of any semiannual evaluation altered after it has been signed by the IACUC. *[1200.07 (8.f (1)(f))]*		X			
203	The report of each semiannual evaluation of the animal care and use program, signed by the IACUC, is discussed personally with the Director of the VA facility in a meeting with at least one representative voting member of the IACUC. *[1200.07 (8.f(1)(e)): PHS (IV.B): 9 CFR (2.31(c)(5): Guide (p. 25)]*		X			
204	Within 60 days of approval by the IACUC, the report of each semiannual evaluation, signed by the facility Director, is submitted to the CVMO (ORD), or the CVMO's office is notified of the reason for delay and the expected date of submission. *[1200.07(8.k(3))]*		X			
D. Standard Operating Procedures (SOPs)						
250	At least annually, the IACUC oversees a review of the complete set of all local SOPs by the Attending Veterinarian with the VMU supervisor and other qualified personnel. *[1200.07 (7.c)]* ►Date of latest review: **October 4, 2016**		X			
E. Addressing Concerns about Animal Welfare						
300‡	The responsibility for animal well-being is assumed by all members of the program; therefore, procedures are in place for the IACUC to receive, review, investigate, and address internal or external concerns or allegations about animal care and use. *[PHS (IV.B); 9 CFR (2.31(c)(4)); Guide (p. 1;23-24)]*		X			
301	Procedures are in place to protect "Whistle-blowers" from discrimination or reprisal for reporting potential regulatory violations within the animal care and use program. *[9CFR (2.32(c)(4)); Guide (p. 24)]*		X			
302	Any animal activity may be suspended by the IACUC (by a majority vote of a quorum), or immediately and unilaterally by the facility Director or any other official designated by the facility Director. *[1200.07 (8.)j; 9 CFR (2.31(c)(8) and 2.31(d)(6))]*		X			
303	The IACUC notifies local administrators (facility Director, RCO, ACOS/R&D) and external oversight entities (CVMO, ORO, OLAW, and AAALAC) immediately when an investigation is undertaken. *[1200.07 (8.i)]*		X			

►Name of VA Facility: Raymond G. Murphy VA Medical Center (NMVAHCS) Version 02/28/13
►Station Number: 501
►City, State: Albuquerque, New Mexico
►Date of Semiannual Evaluation: October 4, 2016

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
304	Within 5 business days of determining that a reportable deficiency has occurred, the IACUC submits an initial report to the facility Director and the IO, with copies to the ACOS/R&D and other relevant research review subcommittees. *[1058.01(8.e); PHS (IV.F.3); 9 CFR (2.31(c)(3) and 2.31(d)(7))]*		X			
305	Within 5 business days (*ORO requirement)* of receiving a report of a reportable deficiency from the IACUC, the facility Director and IO submit the report to the CVMO, ORO, OLAW, AAALAC, the Animal Care Section of USDA APHIS, and any other non-VA funding sources, as applicable, with copies to the IACUCs of any affiliate institutions with shared responsibility. *[1058.01(8.e); PHS (IV.F.3); 9 CFR (2.31(c)(3) and 2.31(d)(7))]*		X			
306	The corrective action plan, the timetable for its implementation, and interim and final reports on the correction of each reported deficiency are submitted to the facility Director and IO, and through them to the CVMO, ORO, OLAW, AAALAC, the Animal Care Section of USDA APHIS, and any other non-VA funding sources, as applicable, with copies to the IACUCs of any affiliate institutions with shared responsibility. *[1200.07 (8.i)]*		X			
	F. Reporting to Oversight Entities					
350	The USDA Annual Report of Research Facility was completed and submitted by December 1 within the past year, as required by USDA, and a copy is on file locally. *[9CFR (2.36)]* ►Date of most recent submission: **December 1, 2015**		X			
351	The VA facility is covered by a PHS Assurance, approved by OLAW, and revised as needed to reflect any significant changes in the animal care and use program. *[PHS (IV.A)]* ►Name of the Institution that holds the PHS Assurance: **New Mexico VA Health Care System (NMVAHCS)** ►Effective date of most recent approved Assurance: **August 26, 2013**		X			
352	The annual report to OLAW was submitted within the past year by the end of the month immediately following the end of the last reporting period, and a copy is on file locally. *[PHS (IV.F.1-2)]* ►Date of most recent submission: **February 3, 2016**		X			
353	The VA facility is fully accredited by AAALAC, and a copy of the triennial comprehensive AAALAC Program Description is on file locally. *[1200.07 (7.e)]* ►Name of the Institution that holds the accreditation: **NMVAHCS**		X			
354	The AAALAC Annual Report was submitted within the past year as required by AAALAC, and a copy is on file locally. *[1200.07 (8.l(2)(b))]* ►Date of most recent submission: **January 26, 2016**		X			
355	The VA Veterinary Medical Unit (VMU) annual report, which includes mice and rats, was submitted online by the specified deadline (usually January 15) within the past year. *[1200.07 (8.l(4))]*		X			
356	All other correspondence with oversight entities (USDA, OLAW, AAALAC, and ORO) relevant to the animal research program (except for routine notifications and reminders) is copied to the CVMO within 15 days of receipt or submission. *[1200.07 (9)]*		X			

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
357	All documents relevant to the animal care and use program are maintained on file for at least three years, or according to the latest VA requirements (current VA policy requires all records to be kept indefinitely), whichever is longer. This includes acquisition/disposition records, IACUC meeting minutes, semiannual reports, and all reports to, and correspondence with, oversight entities. *[1200.07 (Appendix E-2. c); 9CFR2.35(f); PHS (IV.E)]*		X			
358	All documents relevant to individual studies are maintained for at least the duration of the study and for three additional years after the completion of the study, or according to the latest VA requirements (current VA policy requires all records to be kept indefinitely), whichever is longer. *[1200.07 (8.f(1)(h));9CFR2.35(f); PHS (IV.E)]*		X			
	G. Personnel Qualifications and Training					
400‡	The IACUC does not approve any protocol until each individual listed on the protocol has documented completion of required VA training at the prescribed intervals. *[1200.07 (8.m(1)).; PHS (IV.A.1.g); 9 CFR (2.32); Guide (p. 15); US Government Principle VIII)]*		X			
401‡	The IACUC confirms that each individual is appropriately trained before approving that individual to perform the procedure without supervision. This includes non-surgical and surgical procedures, anesthesia monitoring, and euthanasia. *[PHS (IV.C.1.f); 9 CFR (2.31(d)(1)(viii); Guide (p. 15 & 115)]*		X			
402‡	All personnel are documented as being appropriately trained for their positions, and participating in formal and/or on-the-job continuing education at the prescribed intervals. *[1200.07 (8.m); PHS (IV.A.1.g); 9 CFR (2.32); Guide (p. 16-17)]*		X			
403†	IACUC members receive training in all aspects of humane animal care and use through the documented completion of VA training at the required intervals. *[PHS (IV.A.1.g); 9 CFR (2.32); 1200.07 (8.m); Guide (p.17)]*		X			
	H. Occupational Health and Safety					
	Occupational Health and Safety Program (OHSP)					
450‡	An OHSP has been established and is maintained by the VA facility to protect personnel involved in animal research (laboratory or field setting) from associated risks including but not limited to direct animal contact, exposure to unfixed tissues or fluids, hazardous agents used in the research, etc. *[PHS (IV.A.1.f); Guide (p.17; 32); 1200.07 (10)]*		X			
451	All personnel at risk of exposure have the opportunity to participate in the OHSP. This includes personnel whose duties include work with animals (e.g., VMU staff, investigators, research technicians), regardless of whether they are paid employees, without compensation (WOC) personnel, students, or trainees, as well as , personnel that do not have contact but are exposed to animals (e.g., maintenance and engineering staff assigned to the VMU, other service personnel, etc.). *[1200.07 (10.a); Guide (p. 18)]*		X			
452	**Hazard Identification and Risk Assessment –** The IACUC, the local veterinarians, the SRS, and the Safety Officer work together effectively to identify potential hazards that exist in the animal research program, to assess the consequent risks to personnel, and to determine appropriate strategies to manage the risks. *[Guide (p. 18-19)]*		X			

▶Name of VA Facility: Raymond G. Murphy VA Medical Center (NMVAHCS) Version 02/28/13
▶Station Number: 501
▶City, State: Albuquerque, New Mexico
▶Date of Semiannual Evaluation: October 4, 2016

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
453	**OHSP Training** – Training is provided to all personnel covered by the OHSP, with regard to personal hygiene practices, use of safety equipment, and SOPs appropriate to each individual's duties and risks of exposure. *[Guide (p. 20)]*		X			
The OHSP – Facilities and Procedures						
454	**Ergonomic efficiency** – Procedures and policies are in place to reduce the risks of ergonomic injuries to personnel (e.g. facility design, SOPs, and the use of equipment such as ramps, carts, and hydraulic lifts). *[Guide (p.19- 20)]*		X			
455	**Control of exposure** – Personal exposure to hazardous agents is limited through the design of the facility, establishment of SOPs (e.g. separation of animals treated with hazardous agents from untreated animals), selection/maintenance/certification of safety equipment (e.g., showers, eyewash stations, fume hoods, etc.), and careful monitoring of agents to ensure that they remain within permissible ranges. *[Guide (p. 19-20)]*		X			
456	**Policies and Procedures associated with nonhuman primates (NHPs)** – have been established and include training with regard to the risks of exposure to *Macacine herpesvirus 1* (formerly *C. herpesvirus* or Herpes B virus); tuberculosis screening for exposed personnel; training on and the handling of bites, scratches, or other injuries; medical evaluation and treatment of injuries; and provision of appropriate PPE. *[Guide (p. 23)]*	X				
The OSHP – Personal Hygiene						
457	The OHSP includes guidelines on appropriate personal hygiene practices, including hand washing and showering, use of protective clothing, and restricting consumption of food and beverages to designated break areas. *[Guide (p. 20-21)]*		X			
458	The VA facility provides uniforms, laundry service, and all other necessary personal protective equipment (e.g., gloves, ear protection, protective eyewear, steel-toed footwear, respirators, with appropriate fit testing and training, and other special equipment), as appropriate to the duties of the personnel. *[Guide (p. 20-22)]*		X			
The OHSP – Medical Evaluation and Preventive Medicine for Personnel						
459	A pre-employment medical evaluation is performed on each prospective new employee. *[1200.07(Appendix C-4(2)(a))]*		X			
460	A follow-up medical evaluation is performed at routine intervals (usually annually) on each OHSP participant. *[1200.07(Appendix C-.4(2)(b))]*		X			
461	Enrollment in OHSP is prerequisite to approval for access to the VMU and for beginning work with animals. *[1200.07(Appendix C- 4(2)(c))]*		X			
462	Personnel are not permitted to decline immunizations or tests required by the VA facility that are necessary to protect the health of the animals or personnel. *[1200.07 (10.b)]*		X			
463	All vaccines (e.g., tetanus, rabies) are provided to personnel as currently recommended by CDC, free of charge. *[1200.07 (10.f(2)); Guide (p. 23)]*		X			

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
464	Personnel are required to report and be treated for all injuries and illnesses potentially related to working in the VMU or other animal research areas, or otherwise in connection with work with animals. *[1200.07(Appendix C-4.b; Guide (p. 23)]*		X			
465‡	The program considers confidentiality and other legal factors as required by federal, state and local regulations. *[Guide (p. 22)]*		X			
466‡	If serum samples are collected, the purpose is consistent with federal and state laws. *[Guide (p. 22)]*	X				

II. Physical Plant

	A. General					
500	The physical plant infrastructure (includes HVAC, plumbing, lighting, power, control systems, etc.) is adequate to support the needs and performance standards of the animal care and use program, and is compliant with and meets all applicable building codes.*[Guide (p. 133-136)]*		X			
501	Policies and procedures are in place to ensure that facilities and equipment are properly maintained and functional. *[Guide (p. 133-136)]*		X			

III. Operations Related to Animal Environment, Housing, and Management

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
	A. Physical Environment					
Temperature, Humidity, and Ventilation						
550	The response of facilities management (FM) personnel to elevations in temperature in animal rooms is tested and reported to the IACUC at least annually, and the response by FM personnel is satisfactory. *[1200.07 (7.a(2)(c))]*. ►Date of latest test: **July 19, 2016**		X			
551	HVAC reheat units serving animal rooms are designed so as to fail in the "off" position, preventing over-heating of animals. *[1200.07 (7.a(2)(a))]*		X			
Noise						
552	Policies are in place to minimize exposure of the animals and personnel to excessive vibration, unnecessary sounds, and any sounds louder than 85dB. *[Guide (p.49-50)]*		X			
	B. Husbandry					
General						
600‡	Oversight of daily husbandry and other animal care duties has been assigned to a single individual (usually, the VMU Supervisor) when a full-time veterinarian is not available on site. *[Guide (p. 14)]*		X			

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
Population Management						
601	Methods of animal identification have been established, which provide the protocol number and other pertinent information. Where applicable, genotype information is provided using accurate, consistent, and unambiguous genotype nomenclature. *[Guide (p. 75-77)]*		X			
Behavioral Management						
602	**Activity** – Each animal must have opportunities to engage in activity (motor, cognitive, and social) appropriate to its species. *[Guide (p. 60;63)]*		X			
603	**Social Environment** – Animals must be housed in appropriate compatible social groups or when single housing of social species is required (by an approved protocol or because of veterinary concerns) have contact with compatible conspecifics and/or enrichment. *[Guide (p.51, 63-65)]*		X			
604	**Environmental Enrichment** – The program to enrich the structural environment of each animal (structural additions, exercise, manipulative activities, and cognitive challenges) to accommodate the expression of species-typical postures and behavior is reviewed regularly by the IACUC, researchers, and veterinarians. *[Guide (p. 52-54)]*		X			
C. Animal Procurement and Transportation						
650‡	Only animals that are obtained lawfully may be used in VA research. *[1200.07(7.b(1)): Guide (p.106)]*		X			
651	Animal procurement is approved and initiated only after confirmation that: (1) the source of animals is appropriate; (2) appropriate housing and care for the animals upon arrival is coordinated with animal care staff; and (3) the animals are designated for use on an IACUC approved protocol. *[Guide (p. 106-109)]*		X			
652‡	Transportation (including intra-institutional, inter-institutional, interstate, international, and from commercial or non-commercial sources) complies with federal and international regulations, as applicable, and is arranged to protect the health and safety of the animals and humans (passersby as well as personnel involved in the work with the animals), to minimize stress on the animals, and to ensure animal biosecurity. *[Guide (p. 107); 9 CFR (Part 3, Standards)]*		X			
D. Preventive Medicine						
700	The institutional animal care and use program strives to maintain research animal populations that are as free of infectious agents as possible. *[1200.07 (7.d(1))]*		X			
701	A program of veterinary care, overseen by a VMO or VMC, is in place for the surveillance, diagnosis, treatment, and control of non-protocol diseases or conditions (especially those with zoonotic potential, such as Q-fever, LCMV, parasites, etc.), and for the management of diseases or conditions induced by experimental requirements. *[Guide (p. 112-114)]*		X			
702	Quarantine and stabilization of newly received animals, as well as, separation of animals by species, source, health status, and intended use, as appropriate, are used to prevent spread of pathogens. *[Guide (p. 109-112)]*		X			

▶Name of VA Facility: Raymond G. Murphy VA Medical Center (NMVAHCS) Version 02/28/13
▶Station Number: 501
▶City, State: Albuquerque, New Mexico
▶Date of Semiannual Evaluation: October 4, 2016

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
E. Waste Disposal						
750	Procedures are in place for sanitation of waste containers, as well as procedures for safe removal and disposal of conventional, biological, and hazardous wastes (including soiled bedding). All waste disposal procedures comply with facility, municipal and federal policies and regulations. *[Guide (p. 73-74)]*		X			
F. Pest Control						
800	A regularly scheduled and documented program of monitoring for and controlling pests has been implemented, which includes measures to prevent vermin entry and harborage. *[Guide (p. 74)]*		X			
801	Animal and human health concerns encourage the use of non-toxic methods of pest control instead of chemical pesticides whenever possible. If chemical pesticides are to be used, the investigators whose animals may be exposed are consulted to ensure that scientific objectives are not unnecessarily compromised. *[Guide (p.74)]*		X			
G. Medical Supplies						
850	All controlled substances needed for animal research on VA property are ordered and received by the local VA pharmacy, and dispensed to research personnel as needed. *[1200. 07 (7.m)]*		X			
851	Use of non-pharmaceutical grade compounds, expired drugs or medical supplies (e.g., sutures, antiseptics, etc.) in animals is limited to protocols in which such use has been documented not to jeopardize animal welfare or compromise the validity of the study. *[PHS (FAQ F.4); Guide (p.31)]*		X			
H. Emergency, After Hours, Weekend, and Holiday Animal Care						
900	Qualified personnel are assigned to provide routine care for the animals on weekends and holidays. *[Guide ((p. 74);* 9 CFR (2.33(b))*]*		X			
901	Veterinary care is available as needed after regular work hours on weekends, and on holidays; procedures are in place for timely notification of a veterinarian in case emergency care is needed. *[Guide (p, 74);* 9 CFR (2.33(b))*]*		X			
902‡	A disaster plan that addresses the needs of both personnel and animals is in place including animal euthanasia if necessary; the plan is approved by the IACUC. *[Guide (p. 35;75)]*		X			
903†	The disaster plan addresses triage procedures, emergency/life support services; preservation of irreplaceable animals, essential personnel, and disaster response training. The animal facility plan is approved by institution, is a component of the overall disaster plan, and is provided to first responders. *[Guide (p. 35; 75)]*		X			
904	Key animal facility personnel (e.g., the Attending Veterinarian and the VMU supervisor) are included among the official responders to be contacted in emergencies that involve animals. *[Guide (p.75)]*		X			

IV. Veterinary Medical Care

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
A. Role of the Veterinarians						
950 ‡‡	A high quality veterinary care program consistent with ethical standards has been established. *[Guide (p. 105)]*		X			
951 ‡‡	Each VMO and VMC has training and/or experience in lab animal medicine and with the species used. *[Guide (p. 15); 9 CFR (2.33)]*		X			
952†	The VMOs and VMCs provide guidance to research personnel with regard to the humane care and use of the animals in the context of the scientific and regulatory requirements (including appropriate handling of animals, sedation, anesthesia, surgery and peri-operative care, analgesia, and euthanasia). *[Guide pg. 105-106, 113-114; 9 CFR (2.31(d)(1)(iv)(B) and 2.33(b)(4-5))]*		X			
953	When veterinary care services are provided by a part-time or consulting veterinarian, the veterinarian's visits are of sufficient frequency to meet programmatic needs. A written program of veterinary care for USDA regulated species is in place if a full-time attending veterinarian is not on-site. *[Guide (p. 14):USDA-APHIS Policy #3]*		X			
954 ‡‡	Veterinary care is available as needed and effective procedures are established for timely reporting of animal injury, illness, or disease and for veterinary assessment, treatment, or euthanasia. The veterinarian is authorized to treat, relieve pain, and/or euthanize. *[Guide ((p. 106, 113, 114, 120, and 122-123); 9 CFR (2.33(b))]*		X			
955 ‡‡	The Attending Veterinarian has the authority and resources needed, and uses them appropriately to manage all aspects of animal care and use in the animal research program. *[Guide (p. 14); 9 CFR 2.33(a)(2)]*		X			
956 ‡‡	Veterinary access to all animals is provided. *[Guide (p. 14)]*		X			
B. Surgery						
1000	Aseptic technique is required for all survival surgery; is appropriate to the species; and includes preparation of the patient, surgeon, sterile materials, and supplies, as well as appropriate operative technique to reduce the risk of infection. *[9CFR (2.31(d)(1)(ix); Guide (p.118-119)]*		X			
1001	Procedures are in place to ensure that appropriate surgical anesthesia and analgesia are provided. Postoperative monitoring and care are provided by trained personnel and documented. *[Guide (p. 119-120)*		X			
1002	Major surgical procedures in non-rodents may be performed only in dedicated surgical facilities. *[9CFR (2.31(d)(1)(ix))]*		X			
1003	A system of ongoing and thorough assessment of surgical outcomes is in place to ensure that appropriate procedures are followed and appropriate corrective changes are implemented in a timely manner. *[Guide (p. 115)]*		X			
1004	Presurgical planning includes veterinary input and addresses location, supplies, anesthetic and analgesic use, peri-operative care, recordkeeping, etc. *[Guide (p.116)]*		X			
1005	For nonsurvival surgery, the surgical site is clipped, gloves are worn, and the surgical area and instruments are clean. *[Guide (p.118)]*		X			

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
C. Pain, Analgesia, and Anesthesia						
1050	Guidelines for the assessment and management of pain, distress, and animal wellbeing have been established, and include monitoring for effectiveness of pain control, consideration of non-pharmacologic pain control methods, and guidance regarding the selection and use of anesthetics and analgesics. *[Guide (p. 121-122)]*		X			
1051 ‡‡	Procedures are in place to assure anti-nociception before surgery begins. *[Guide, p 122)]*		X			
1052	Special precautions for the use of paralytics are in place to ensure adequate anesthesia. *[Guide (p 123)]*	X				
1053 ‡‡	The drug storage and control program complies with federal regulations for human and veterinary drugs; procedures have been established to ensure that analgesics and anesthetics are used prior to their expiration date. *[Guide (p.115)]*		X			
1054 †	Anesthetics and analgesics are acquired, stored, and disposed of in a legal and safe manner; drug records and storage procedures are reviewed during facility inspections. *[Guide, p. 115 & 122)]*		X			
D. Euthanasia						
1100	The methods of euthanasia approved by the IACUC are consistent with the AVMA recommendations for the species involved. *[Guide (p. 123); PHS (IV.C.1.g); 9 CFR (2.31(d)(1)(xi))]*		X			
1101	Personnel receive training on euthanasia methods appropriate for the species and age of the animal to minimize the potential for pain and distress. *[Guide (p. 123-124)]*		X			
1102 ‡‡	Procedures and training are in place to ensure that death is confirmed. *[Guide (p. 124])*		X			

V. Animal Care and Use Program Work Orders

Instructions: Enter work order data as prompted for Tables 1 and 2. All work orders related to the animal care and use program should be entered, whether or not they resulted from a semiannual evaluation. Use Table 3 to summarize the work orders in Tables 1 and 2.

Table 1: Work Orders Completed - include all work orders completed since the previous semiannual program evaluation (►Date(s) of previous evaluation: April 19, 2016).

► Name of VA Facility: Raymond G. Murphy VA Medical Center (NMVAHCS) Version 02/28/13
► Station Number: 501
► City, State: Albuquerque, New Mexico
► Date of Semiannual Evaluation: October 4, 2016

#	Enter **M**, **S**, or **No**, for **M**inor or **S**ignificant deficiency noted in semiannual evaluation, or **Not** related to semiannual evaluation	Work order (local reference) number	Summarize work requested	Date work order was submitted	Date work order was completed	Elapsed days from submission to completion
1	S	TH150211-018	Fix Motion Sensor	2/11/2015	4/25/16	434
2	S	TH150923-014	Security door alarm system is not working	9/23/2015	4/25/16	212
3	Not	TH160126-012	Adjust humidity levels in the VMU	1/26/2016	8/18/16	82
4	M	TH160415-023	Raise height of biological safety cabinets	4/15/2016	Cancelled; done by Protech	
5	Not	TH151015-017	Install waterproof light and outlet cover	10/15/2015	10/22/2015	7
6	Not	TH160126-012	Adjust humidity levels in the VMU	1/26/2016	4/18/2016	82
7	Not	TH160504-031	Door lock does not work.	5/4/2016	5/6/2016	2
8	Not	TH160504-032	Door lock is broken. Repair or replace.	5/4/2016	5/6/2016	2
9	Not	TH160504-033	Paint out inside window.	5/10/2016	5/11/2016	1
10	Not	TH160614-009	Room pressure should be negative	6/14/2016	8/23/2016	69
11	Not	TH160720-008	Light timer is not working	7/20/2016	7/22/2016	2

Table 2: Work Orders Not Yet Completed - include all open work orders generated by previous semi-annual evaluations and other sources. Work orders placed as a result of the current semi-annual review are also entered below.

#	Enter **M**, **S**, or **No**, for **M**inor or **S**ignificant deficiency noted in semiannual evaluation, or **Not** related to semiannual evaluation	Work order (reference) number	Summarize work requested	Date work order was submitted	Elapsed days from submission until **September 28, 2016** (enter date used to calculate elapsed days)
1	Not	TH160601-005	Replace weather stripping around outside door.	6/1/2016	120
2	Not	TH160627-017	Problem with hot water and steam	6/27/2016	146

3	Not	TH160720-006	Put VMU exhaust fans onto alarm system	7/20/2016	71
4	Not	TH160817-013	Program motion sensor	8/17/2016	43

Table 3: Summary

Table #	Number of work orders entered	Average days elapsed
1	10	89
2	4	95

Comments (provide any additional information relevant to the numbers of days required for completion of the work orders submitted):

The first two work orders could not be closed out until a contractor was brought in to fix existing issues.

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VA SEMIANNUAL EVALUATION
of the
INSTITUTIONAL ANIMAL CARE AND USE PROGRAM AND FACILITIES
Part 1 – Checklist
Section B. Inspection of the Facilities

The Inspection of the Facilities focuses on a physical and visual evaluation of buildings, equipment, and the environment in which animals are maintained and utilized. Some of the items here appear similar to items included in Section A (Review of the Program), but the focus here (Inspection of the Facilities) is on what is actually observed in the animal facilities, while Section A focuses on what is intended or designed.

(Note: Federal regulations require that a new Review of the Program be completed every 6 months *[PHS (IV.B.1); 9 CFR (2.31(c)(1))]*, and a new Inspection of the Facilities be completed every 6 months *[PHS (IV.B.2); 9 CFR (2.31(c)(2))]*. The "Date of Semiannual Evaluation" is the date on which the last of the components of the semiannual evaluation was completed.)

►Date(s) of the most recent previous Inspection of the Facilities: **April 12, 2016**
►Date(s) on which this Inspection of the Facilities was conducted: **September 27, 2016**

Names of voting IACUC members who participated in the Facility Inspection:
(The Facility Inspection team must include a minimum of two voting members of the IACUC [9 CFR (2.31(c)(3))]. Any non-members who also participate, at the discretion of the IACUC, may be listed in the second table.)

Name	Specific Role on IACUC (if any)	Date(s) of Participation
► [redacted]	Attending Veterinarian	09/27/16
►	Chairperson	09/27/16
►	Member	09/27/16

Non-IACUC members who participated in the Facility Inspection:

Name	Title	Date(s) of Participation

Location (name of site, building name and room number, etc.)	**Species**	**Type of Space** (e.g., VMU, satellite, investigator laboratory) **and the Nature of the Procedures Performed** (e.g., housing, terminal surgery, behavioral training, etc.)	**Name and Role** (e.g., VMU Supervisor, PI) **of Responsible Individual**
[redacted]	Mice, Rats, Rabbits	VMU	[redacted] VMU Supervisor

Items that reflect changes in the 8th edition of the *Guide* are flagged as follows, and may require particular attention as the 8th edition is implemented.

▶Name of VA Facility: Raymond G. Murphy VA Medical Center (NMVAHCS) Version 02/28/13
▶Station Number: 501
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▶Date of Semiannual Evaluation: October 4, 2016

‡ **denotes a new "must" item**
† **denotes a new "should" item**

I. Implementation of Institutional Policies

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
A. Performance of Work According to Protocol							
1150	Current versions of IACUC approved protocols are readily available to animal care staff as well as research staff.		X				
1151	Animal research procedures (observed by the IACUC inspection team includes but is not limited to conduct of surgery, behavioral testing, training, exercise, administration of anesthetics and analgesics, etc.) are being performed according to the protocols approved by the IACUC. *[PHS (IV.C.1); Guide (p. 33-34)]*		X				
1152	Individuals observed working with animals are identified on the corresponding protocols approved by the IACUC.		X				
1153	Routine husbandry tasks observed are being performed according to documented SOPs.		X				
B. Addressing Concerns about Animal Welfare							
1200	Contact information for responsible local and VA Central Office personnel are posted prominently in the animal facility for reporting of animal welfare concerns. *[1200.07 (8.k(2)); Guide (p. 24)]*		X				
C. Occupational Health and Safety							
1250	Appropriate hazard signs and relevant safety protocols are posted in plain view, and the MSDSs are readily available, where specific hazardous agents are in use. *[1200.07 (Appendix C-8.h(1)-(2))]*		X				
1251	Wherever gas anesthetics are used, waste anesthetic gas is removed via a scavenging system or by another approved method. *[Guide (p. 21; 145)]*		X				
1252	Labels on safety equipment (e.g. eye wash, emergency shower, fume hoods, etc.) indicate that maintenance and certification are current. *[Guide (p. 20)]*		X				
1253	Good safety practices are evident as indicated by proper glass and sharps disposal, gas cylinders appropriately secured, proper separation of chemicals and wastes, etc. *[Guide (p.74)]*		X				
1254	Supplies are readily available for treatment of bites, scratches, and puncture wounds according to current CDC recommendations. *[Guide (p. 23)]*		X				
1255	Adequate supplies of appropriate attire and clean protective clothing, including disposable PPE (e.g. gloves masks, shoe covers, etc.) are readily available; soiled items are disposed of, laundered, or decontaminated according to approved facility procedures. *[1200.07(Appendix E-2.e) ;Guide (p. 20-22)]*		X				

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1256	The IACUC inspection team determined that with regard to the use of hazardous agents, appropriate procedures, containment equipment, and personal protective equipment are used to safeguard personnel and animal health and are consistent (where applicable) with APHIS, USDA, and CDC Select Agent Regulations and other federal, state, and local regulations including security measures. *[1200.07 (Appendix E-2(l)); Guide (p. 20-22; 148-149)]*		X				
	D. Other observations						
1300	Batteries need to be replaced in hand sanitizer dispensers. Hand sanitizer needs to be refilled in one dispenser.				X		

II. Physical Plant

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
	A. General						
1350	Corridors are sufficiently wide and clear of obstacles so that personnel and equipment can move easily without impediment. *[Guide (p. 136)]*		X				
1351	Floor surfaces are moisture-resistant, nonabsorbent, and impact-resistant; floors are in good condition, without cracks, evidence of delamination or deterioration, of appropriate texture, and are clean and sanitized. *[Guide (p. 137-138); 9 CFR (Part 3, Standards)]*				X		
1352	Floors slope appropriately to drains; drains are filled with liquid, and those not in use for long periods are capped/covered. *[Guide (p. 138)]*				X		
1353	Wall and ceiling surfaces are smooth, moisture-resistant, nonabsorbent, impact-resistant, washable, and free of unsealed penetrations. These surfaces were found to be clean, sanitized according schedule, free of defects and evidence of water damage. *[Guide (p. 138-139); 9 CFR (Part 3, Standards)]*		X				
1354	Doors are adequately sized, fit tightly within their frames, are sealed to prevent vermin entry, and are in good repair; preferred features include self-closing mechanism, sweeps, recessed handles, and protective hardware. *[Guide (p. 137)]* Note: With the exception of doors with viewing windows that are needed for safety and other reasons, windows in animal facilities should generally be avoided.) *[Guide (p. 137)]*		X				

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
Heating, Ventilation, and Air-Conditioning (HVAC) System							
1355	Maintenance of temperature, humidity, and air pressure differentials within recommended ranges throughout the facility is documented. *[Guide (p. 43-47)]* ►List the document(s) reviewed: **Individual Room Logs**		X				
1356	HVAC reheat units serving animal rooms fail in the "off" position, as designed, to prevent over-heating of animals. *[1200.07 (7.a(2)(a))]*		X				
1357	Effective back-up mechanisms are in place to maintain temperatures and humidity within acceptable ranges in the event of an electrical outage or failure of the HVAC system in the animal research facility. *[Guide (p. 141)]*		X				
Power & Lighting							
1358	Moisture-resistant switches and outlets, and ground-fault interrupters, have been installed in wet areas (e.g. cage processing, aquatic holding areas, etc.) *[Guide (p. 141)]*		X				
1359	Light fixtures, timers, switches, and outlets are properly sealed to prevent vermin from being harbored in them. *[Guide (p. 141)]*		X				
1360	Protective covers are in place over light bulbs and light fixtures. *[Guide (p. 141)]*		X				
1361	In the event of a power failure, alternative or emergency power supply is available to maintain critical services. *[Guide (p. 141)]*		X				
Noise Control							
1362	Noise reduction practices are utilized. *[Guide (p. 49-50; 142)]* For example: • Entry doors from corridors to animal housing areas are closed when not in use. • Carts, racks, and other equipment are equipped with casters. • Noisy animals are grouped in one section of the animal • facility. • Sound-generating equipment is selected and located to minimize disturbance to animals		X				
1363	Vibration dampening procedures are practiced where applicable. *[Guide (p. 142)]*		X				
Environmental Monitoring							
1364	Environmental conditions in animal holding spaces and other sensitive areas are monitored and verified by one or more mechanism or systems. *[Guide (p. 143)]*		X				
B. Facilities for Sanitization							
1400	A dedicated cage and equipment processing area of appropriate size and design (including safety features, traffic flow, utilities, egress,		X				

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
	HVAC capacity, clean storage, etc.) is available and meets program needs.*[Guide (p. 143)]*						
1401	Appropriate safety precautions and equipment are in place and in use; including but not limited to protective clothing and equipment, posting of standard operating procedures and warning signage, eyewash/shower stations, and functioning safety devices to prevent trapping of personnel inside of walk-in equipment (e.g., cage/rack washers, bulk sterilizers). *[Guide (p. 143)]*		X				
1402	Cage wash temperatures and sterilizer effectiveness are monitored and appropriate records are maintained. *[Guide (p. 72-73)]*		X				
	C. Storage Areas						
1450	Food and bedding, toxic or hazardous agents, and wastes are stored in separate designated areas. *[Guide (p. 141)]*		X				
1451	Food and bedding is stored in a vermin-free area and is protected from contamination. Temperature and humidity conditions are appropriate in food storage areas. *[Guide (p. 141)]*				X		
1452	Food stuffs/diets are obtained from reputable vendors and are managed to maintain quality*[Guide (p. 65- 67)]*: • Feed bag stocks are rotated and used prior to expiration date or discarded. • Open bags of feed are stored in sealed, vermin-proof containers. • The storage area is clean and orderly; feed bags are stored off the floor on pallets, racks, or by other methods with adequate clearance from the wall to ensure good sanitation.		X				
1453	Bedding bags are stored off the floor on pallets, racks, or by other methods with adequate clearance from the wall to ensure good sanitation. Autoclaved bedding has been allowed to dry before use or storage. [*Guide (p. 69)]*		X				
1454	Refrigerated storage for animal carcasses and tissue waste is at <7°C (44.6 °F). *[Guide (p. 142)]*				X		
	D. Facilities for Aseptic Surgery						
1500	Are located and designed to minimize traffic and/or contamination; the facilities include areas for surgical support, animal preparation, surgeon scrub, operating room and postoperative recovery that separate the related non-surgical activities from the operating room. Equipment and services needed to support the use of the surgery facility are available. *[Guide (p. 144-145)]*		X				
1501	Procedures are in place and have been implemented to assure effective sanitation of the operating room, surgical instruments and equipment, appropriate management and use of stored sterile supplies, scavenging of anesthetic gases, monitoring of drug inventory, and recordkeeping for anesthesia and postoperative care. *[Guide (p. 115; 122; 144-145)]*		X				
1502	Equipment needed to support aseptic surgery (e.g., autoclaves, anesthetic vaporizers, etc.) are in good repair and certifications are current. *[Guide (p. 20}*		X				

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
E. Special Facilities *(include barrier, aquatics laboratory study areas, procedure areas. imaging, core service facilities ,etc.)*							
1550	Where applicable, the facility/room has appropriate drug storage/monitoring, sharps disposal, anesthetic monitoring and scavenging, safety equipment/procedures (safety signage, eyewash stations, secured gas cylinders, etc.) and carcass disposal. *[Guide (p.19-21;73-74;115;120;122;134)]*		X				
1551	Specialized facilities have procedures and equipment in place to minimize contamination risk. *[Guide (p. 147-150)]*		X				
1552‡	Appropriate sensors and ventilation are provided for areas where cryogen gases are used or stored. *[Guide (p 147)]*	X					
1553	Aquatic housing areas feature water impervious surfaces, slip resistant floors, ground-faulted electrical receptacles or circuits, and HVAC capacity to maintain appropriate temperature and humidity control. *[Guide (p 150-151)]*	X					
F. Ancillary Areas							
1600	Showers, sinks, toilets, locker rooms, and break areas are available for personnel and are separate from animal holding or support areas. [*Guide (p. 19; 136)]*		X				
1601	Space for administrative and supervisory personnel, including space for staff training and education are available and separate from animal holding or animal support areas. [*Guide (p 136)]*		X				
G. Security							
1650	Perimeter doors are closed and locked. *[1200.07 (7.i)]*		X				
1651	Security measures are in practice and mechanisms for controlling entry into the facility function appropriately. *[1200.07 (7.i); 1200.01.9.c; Guide (p. 23;151)]*		X				
H. Other Observations							
1700	Paint steam stub-out orange so that it is visible.				X		

III. Animal Environment, Housing, and Management

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
A. Physical Environment							
Temperature, Humidity, and Ventilation							
1750	Temperature and humidity in animal rooms are within acceptable ranges. *Guide (p. 43)]*			X			
1751	Odors, ammonia levels, and drafts are all within acceptable limits; ventilation and air quality are adequate. *[Guide (p. 45)]*		X				

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1752	The supply air to animal holding is 100 % outside air treated with appropriate filtration. Note: Exhaust air recycled into HVAC systems serving multiple rooms is a cross contamination risk and generally should be avoided. Exhaust air should be treated with at least 85-95% ASHRAE efficient filters prior to recycling. *[Guide (p. 45-47; 140)]*		X				
Illumination							
1753	Lighting in animal rooms is on appropriate diurnal cycles. *[Guide (p. 47)]*		X				
1754	The intensity, quality, distribution, and rates of change of intensity of the light are appropriate to the species in each room. *[Guide (p. 47-48)]*		X				
Noise							
1755	Radios and other equipment that produce unnecessary sound audible to the animals are not in use in animal rooms, except as required by approved protocols for research or enrichment. Vibration is minimized where possible. *[Guide (p. 49-50)]*		X				
B. Husbandry							
General							
1800	Animals are appropriately separated by species and disease status. *[Guide (p.111)]*		X				
1801	Animal handling (observed by the IACUC inspection team) is appropriate to the species.		X				
1802	Room logs confirm that daily observation of each animal, as well as cage cleaning, feeding, and watering are performed at appropriate intervals. *[1200.07(7.c)]*		X				
1803	Special procedures (e.g., diet or water scheduling/restriction, prolonged restraint, etc.) are conducted as described in the IACUC approved protocols based on IACUC inspection team observations. *[1200.07 (Appendix D-1.u); PHS (IV.C.1); Guide (p. 27-33)]*		X				
Housing – Primary Enclosures							
1804†	Primary enclosures, cages, and shelters are appropriate (in terms of size, construction, floor space, height, etc.) for the species housed. *[9 CFR (Part 3, Standards); Guide (p. 51-57 and 55-63;* the *Ag Guide]* Note: • The recommended minimum rabbit cage height is16 inches; rabbit cages that are less than 16 inches in height may be used if the IACUC has determined through performance assessments that the cage is sufficient to meet the behavioral, physical, and physiological needs of the animal. *[Guide(p.58-59)]* • The recommended minimum floor space for a female mouse + litter is 51 in^2 ; trio breeding may be appropriate in a cage providing 75-82 in^2 of floor space; the IACUC should make this determination based on the outcome of performance based standards. *[Guide (p.56-58)]*			X			

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1805‡	The primary enclosure allows the animal to express natural postures, turn around, access food and water, and rest away from urine and feces. *[Guide (p.56)]*		X				
1806	The primary enclosures (cages, tanks, pens, stalls, etc.) and accessories are clean, in good condition, and are free of rust and sharp edges; the enclosure provides safe species appropriate housing. *[Guide (p. 51)]*		X				
1807‡	Outdoor housing provides protection from extreme weather, conditions, the opportunity to retreat, and is adequately ventilated. *[Guide (p. 54-55)]*	X					
1808	Procedural laboratories that house animals for more than 12 hours meet the minimum standards for housing. *[1200.07 (Appendix E-3.b)]*	X					
Population Management							
1809	Animal records (e.g., cage cards) include the following information, as appropriate *[Guide (p. 75-76); 9 CFR (2.35)]*: • Source of animals • Strain or stock (including genotype using standard nomenclature where applicable) • Name and contact information for PI • Protocol number • Pertinent dates (e.g., acquisition by facility, birth) • Number of individuals per group, when identified in groups • Age or weight • Gender • Individually identifiable features (e.g., markings, tattoos, ear • tags, neck chains, implanted microchips, etc.)		X				
1810	The IACUC inspection team determined that animal records are readily available, appropriately detailed, properly maintained, and accompany animals when transferred to another institution. *[Guide (p. 75-77)]*		X				
Behavioral Management							
1811	The IACUC inspection team determined that the environmental enrichment program is appropriate to the species, ages, and number of animals housed and is beneficial to and safe for the animals. *[Guide (p. 52-54)]*		X				
1812	Animals are housed in compatible social groups as appropriate; socially housed animals are able to escape or hide from aggressive animals, and have ready access to food and water. *[Guide (p. 51-60;63-65)]*		X				
1813	The IACUC inspection team reviewed the records of singly housed animals; *Guide* recommendations for singly housed animals are being followed. *[Guide (p. 64)]*		X				
1814	Based on the behavior observed by the IACUC inspection team, the animals are appropriately habituated to routine husbandry and experimental procedures. *[Guide (p. 64-65)]*		X				
Food							

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1815	Each animal is fed uncontaminated, palatable, high quality food using a feed schedule and methods (that considers caloric management, delivery, and sanitation) appropriate to the species. *[Guide (pg. 65-67)]*		X				
Water							
1816	Each terrestrial animal has ready access to potable drinking water (quality based on periodic assessment) and the water distribution system is clean and appropriate to the species. *[Guide (p. 67-68)]*		X				
1817	For aquatic animals, the water quality is appropriate for the species. *[Guide (p. 78-79, 85)]*	X					
1818‡	In aquatic systems, chlorine, chloramines, chemical, and reactive bioproducts are removed or neutralized prior to use. *[Guide (p. 78, 86)]*	X					
1819‡	The biofilter of the aquatic life support system is of adequate size to process the bioload. *[Guide (p 80)]*	X					
Bedding							
1820	The bedding present in primary enclosures (where appropriate) is consistent with the species, facilitates good health, and meets scientific requirements. *[Guide (p. 68-69)]*		X				
Sanitation							
1821	Cleaning implements are designated for specific rooms or for areas at similar risk of contamination and are in good repair. *[Guide (p. 72)]*		X				
1822	Primary enclosures (including substrates and cage components), animal holding rooms, support spaces, etc. are cleaned and disinfected on a regular schedule consistent with the use of the area and nature of contamination. *[Guide (p 70 -72)]*		X				
1823	The effectiveness of sanitation methods/procedures are assessed and documented. *[Guide (p. 73)]*		X				
C. Animal Procurement and Transportation							
1850	Animals being transported are appropriately restrained, secured, and covered, to protect the health and safety of the animals and humans (passersby as well as personnel involved in the work with the animals), to minimize stress on the animals, and to ensure animal biosecurity. *[1200.07(Appendix E-3.a (15)); Guide (p. 107-109); 9 CFR (Part 3, Standards)]*		X				
1851	Promptly on receipt, animals are inspected by qualified personnel and moved to housing appropriate to the protocols for which they have been ordered. *[1200.07 (7.b(3)): Guide (p. 107-109)]*		X				
1852	The condition of animals on arrival indicates that transportation was consistent with USDA regulations and humane practices. *[Guide (p.107)]*		X				
D. Preventive Medicine							
1900	Based on the observations of the facility inspection team, animals are separated by species, source, health status, intended use (as appropriate) and after receipt, the animals are allowed a stabilization period. *[Guide (p. 109-112)]*		X				

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
E. Waste Disposal							
1950	Conventional, biological, and hazardous wastes are regularly collected, stored and disposed of through the use of safe handling and processing practices. *[Guide (p. 73-74)]*		X				
1951	Waste receptacles are leak-proof, labeled, cleaned regularly, and have tight-fitting covers. *[Guide (p. 73)]*		X				
1952‡	Hazardous wastes are rendered safe before removal from facility. *[Guide (p. 73-74)]*		X				
1953	Appropriate containers for sharps disposal are readily available in locations in which sharps are used, and are no more than 2/3 to 3/4 full. *[Guide (p. 74)]*		X				
F. Pest Control							
2000	A humane, effective, and documented pest prevention and control program (that includes rodents and insects) is in place; there is no evidence of pests in the facility. *[Guide (p. 74)]*				X		
2001	When it is necessary to use pesticides in animal holding areas, investigators are consulted in advance of pesticide use. *[Guide (p. 74)]*		X				
G. Medical Supplies							
2050	Non-pharmaceutical grade compounds identified during the inspection were confirmed to be associated with an IACUC approved protocol. *[PHS (FAQ F.4); Guide (31)]*		X				
H. Emergency, After Hours, Weekend, and Holiday Care							
2100	The review of log sheets confirm that animals are cared for by qualified personnel on weekends and holidays, as well as on regular weekdays. *[Guide ((p. 74); 9 CFR (2.33(b))]*		X				
2101‡	Posted contact information for veterinary staff and veterinary care entries in logs confirm that emergency veterinary care is available and provided as needed after hours, on weekends and holidays, as well as on regular weekdays. *[Guide ((p. 74;114); 9 CFR (2.33(b))]*		X				
2102	Telephone numbers of key personnel are readily accessible to police and fire agencies at all times. *[Guide (p. 74)]*		X				
I. Other Observations							
2150							

IV. Veterinary Medical Care

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
A. General							
2200	Animals are observed at least daily for signs of illness, injury or abnormal behavior by trained personnel. *[Guide (p. 112)]*		X				
2201	Visits by part-time veterinarians are documented in a log showing the date and time of each visit. *[1200.07 (Appendix E-2.f(9))]*		X				

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
B. Surgery							
2250	The IACUC inspection team determined that the recommendations of the *Guide* are followed for non-survival surgery (the surgical site is clipped, the surgeon wears gloves, the instruments and the surrounding area are clean). *[Guide (p. 118)]*						X
2251	The IACUC inspection team determined that aseptic technique is used for all survival surgical procedures, and includes appropriate preparation of the animal (shaving and disinfection of the surgical site), preparation of the surgeon (scrubbing, use of sterile glove, gowns, etc.), and use of aseptic operative techniques; the aseptic technique procedures are appropriate for the species used. *[Guide (p. 118-119)]*						X
2252	The IACUC inspection team determined that all surgical instruments and implants used in survival surgery are sterilized by steam, gas, or approved chemicals. Note: Alcohol is not a sterilant or a high-level disinfectant. *[Guide (p. 119)]*						X
2254	The IACUC inspection team observed that for multiple consecutive rodent surgeries, personnel using hot bead sterilizers or liquid chemical sterilants for instrument sterilization take appropriate precautions to prevent thermal or chemical burns. *[Guide (p. 119)]*						X
2255	The IACUC inspection team confirmed that the operating area is cleaned and disinfected prior to major survival surgery. *[Guide (p. 117)]*						X
2256	The IACUC inspection team confirmed that appropriate intraoperative monitoring of anesthetic depth and physiological parameters is performed and documented by personnel. *[Guide (p. 119)]*						X
2257	The IACUC inspection team confirmed that postoperative monitoring and care of appropriate intensity and frequency (includes anesthesia recovery, pain management, management of physiologic needs, assessment of overall well-being, wound healing, suture removal, etc.) was provided and documented by trained personnel. *[Guide (p. 119-120)]*						X
C. Pain, Distress, Analgesia and Anesthesia							
2300‡	Drug storage and control practices comply with federal regulations for human and veterinary drugs. *[Guide (p. 115)]*		X				
2301‡	Analgesics and anesthetics (as well as other drugs) are used within their expiration date. *[Guide (p. 122)]*		X				
2302	Procedures for acquiring, using and storing anesthetics and analgesics are compliant with legal and safety standards. *[Guide (p. 115; 122)]*		X				
2303‡	Observation and/or record review indicates that before surgery begins, personnel ensured a surgical plane of anesthesia is attained. *[Guide (p. 122)]*		X				
2304	The IACUC inspection team determined that neuromuscular blocking agents are used in a humane and appropriate manner in accordance with the IACUC approved protocol. (*[Guide (p. 122-123)]*	X					

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
D. Euthanasia							
2350	Personnel are competent in performing euthanasia methods that are appropriate to the animal's age and species and are consistent with AVMA Guidelines. Alternate methods of euthanasia, if used, are approved by the IACUC. *[Guide (p. 124); 9 CFR (2.31(d)(1)(xi))]*		X				
2351‡	Personnel confirm animal death after the euthanasia procedure. *[Guide (p.124)]*		X				
E. Other Observations							
2400	Before guillotine is used, there must be an SOP for maintenance and sharpening.				X		

►Name of Medical Center: Raymond G. Murphy VA Medical Center (NMVAHCS) Version 02/28/13
►Station Number: 501
►City, State: Albuquerque, New Mexico
►Date of Semiannual Evaluation: **October 4, 2016**

VA SEMIANNUAL EVALUATION of the INSTITUTIONAL ANIMAL CARE AND USE PROGRAM AND FACILITIES

Part 2 -- Table of Deficiencies and Departures

This form is for documenting the details about the observations noted in the checklists (Part 1, Sections A and B). Each deficiency, minor or significant, must be entered according to Instructions 2 and 3, below. Each "approved departure", as defined by OLAW, must be entered according to Instruction 4, below. The IACUC may also document on this form, at its discretion, other observations that are not deficiencies, and details about "deviations" that are not "departures", as defined by OLAW – these may be useful in addressing concerns raised by accreditation or regulatory agencies, or for monitoring purposes.

Instructions:

4) Enter each "departure" from PHS Policy, including the provisions of the *Guide* that has been approved by the IACUC. *[PHS (IV.B.3)]*

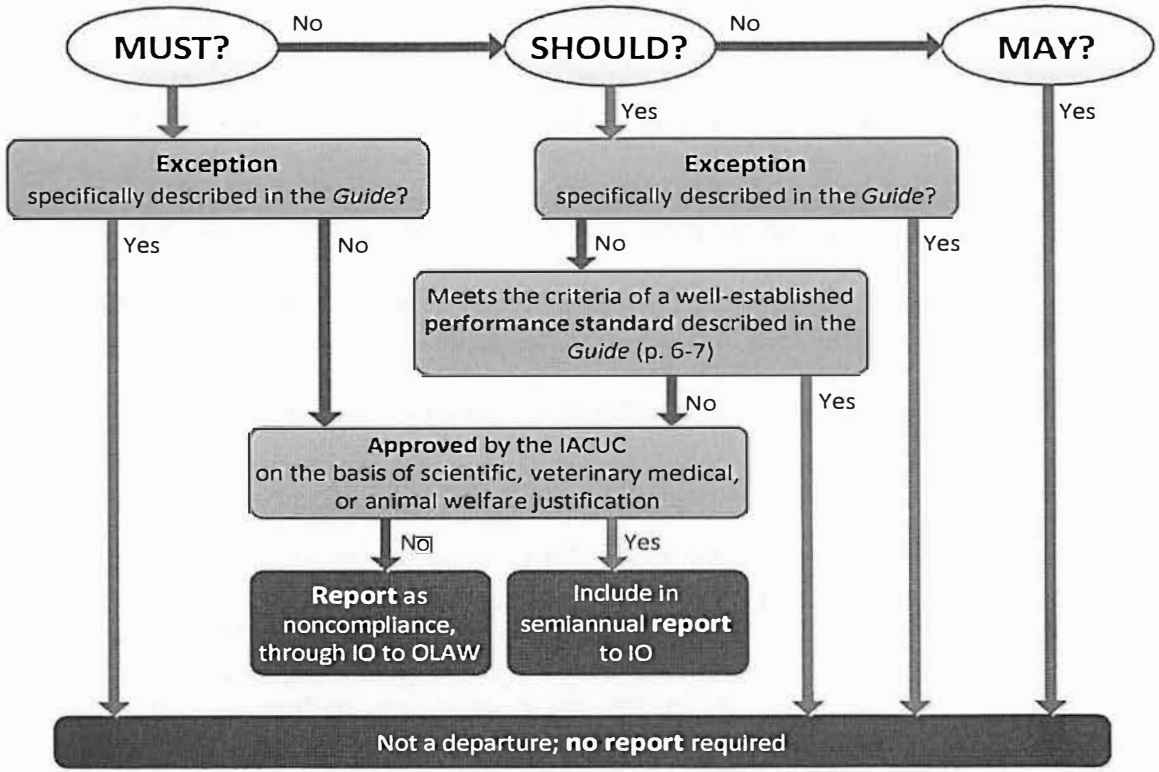
For any deviation from a general standard described in the *Guide*, the following series of test questions may be applied to determine whether the deviation is considered a "departure" by OLAW:

1. Does the Guide describe the general standard as a "May" standard? If so, this deviation from the general standard is NOT a "departure". Otherwise, for any "Should" or "Must" standard, proceed to the next question.

2. Does the Guide include an explicitly stated exception that allows for the deviation? If so, this deviation from the general standard is NOT a "departure. Otherwise, proceed to the next question.

3. Does the deviation meet a well-established performance standard for a "Should" standard, according to locally-defined and continuously monitored performance measures? If so, this deviation from the general standard is NOT a "departure". Otherwise, it IS a "departure", and may be approved by the IACUC only if justified on scientific, veterinary medical, or animal welfare grounds.

The test questions above are summarized in the following flow chart:



for approved departures that are not documented in an Appendix 9, enter the information into this form as follows:

For "Original Date Noted", enter the date of the IACUC meeting at which the departure was reviewed and approved..
[1200.07 (8.f(1)(d)2-3); PHS (IV.B.3) 9 CFR (2.31 (c)(3)); and Guide (p. 9]

If the departure relates to a specific item on Form 1, enter the Part (A or B) and Item # to which it applies.

If applicable, indicate the location to which the departure applies.

A description of the departure – include a summary of the grounds for granting approval for the departure.

Mark the "D" category, to indicate that the item details a departure.
Enter "N/A" in the columns for the "Scheduled Date of Correction" and the "Actual Date of Correction".

Original Date Noted	Form 1 Part	Form 1 Item #	Location	Descriptive Details	Category M	Category S	Category D	Scheduled Date of Correction	Actual Date Of Correction
9/27/16	B	1300	[redacted]	Batteries need to be replaced in hand sanitizer dispensers. Hand sanitizer needs to be refilled in room [redacted] Action Taken: Batteries requested from EMS. Hand sanitizer refilled. ▶Person responsible for overseeing correction: [redacted]	X			9/30/16	9/30/16
9/27/16	B	1351	VMU	Buff floors throughout the facility. Action Taken: Scheduled time to do the floors; heavier buffer pad ordered. ▶Person responsible for overseein g correction: [redacted]	X			11/30/16	
9/27/16	B	1352	[redacted]	Floor drain has dried out. Action Taken: Water poured down drain. ▶Person responsible for overseeing correction [redacted]	X			9/27/16	9/27/16
9/27/16	B	1451	Feed Cold Room	Humidity is too high. Feed bags feel damp to the touch. Action Taken: Work order placed **TH161018-013** ▶Person responsible for overseeing correctio n [redacted]	X			10/31/16	
9/27/16	B	1454	[redacted]	Refrigerator/freezer needs to be defrosted. Action Taken: Refrigerator/freezer defrosted. ▶Person responsible for overseeing correction: [redacted]	X			10/4/16	10/4/16

Original Date Noted	Form 1 Part	Form 1 Item #	Location	Descriptive Details	Category M	Category S	Category D	Scheduled Date of Correction	Actual Date Of Correction
9/27/16	B	1700	[redacted]	Paint steam stub-out orange so that it is visible. Action Taken: Work order placed **TH161018-014** ►Person responsible for overseeing correction: [redacted]	X			10/30/16	
9/27/16	B	2000	[redacted]	Find out what is in the pesticide used in this room. Action Taken: Safer Brand Ant & Crawling Insect Killer has Silicon Dioxide from Diatomaceous Earth. That is all. ►Person responsible for overseeing correction: [redacted]	X			10/4/16	10/4/16
9/27/16	B	2400	[redacted]	**NOTE:** Before guillotine is used, there must be an SOP for maintenance and sharpening. Action Taken: An SOP is being written and will be reviewed at the next IACUC meeting. ►Person responsible for overseeing correction: [redacted]	X			01/10/17	
10/13/15	B	1651	[redacted]	It was discovered that the card key system in [redacted] s not communicating with the system used by the Police; the Police are not getting any [redacted] door alarms. Engineering has been working on this, but they have reached the limit of their technical knowledge and are not able to repair the system. Until this issue is resolved, VA Police Officers will check all outside doors every two (2) hours during off hours. VMU employees will make sure that all rooms housing animals are locked during off hours. WO placed 9/23/15: **TH150923-014** Action Taken: The hospital has a contractor on station this week (4/18/16) to repair the system. Engineering expects it to be working by the end of the week. ►Person responsible for overseeing correction: [redacted]		X		April 26, 2016 ~~April 20, 2016~~	April 25, 2016

▶Name of Medical Center: Raymond G. Murphy VA Medical Center (NMVAHCS) Version 02/28/13
▶Station Number: 501
▶City, State: Albuquerque, New Mexico
▶Date of Semiannual Evaluation: **October 4, 2016**

Original Date Noted	Form 1 Part	Form 1 Item #	Location	Descriptive Details	Category M	Category S	Category D	Scheduled Date of Correction	Actual Date Of Correction
4/12/16	A	550	VMU	On 4/11/16 the temperature sensor in an unoccupied animal [redacted] was overheated starting at approximately 0810 and ending at 1240. The Energy Plant received alarms at 0813, 0834, and 1145 which the Energy Plant technician says he acknowledged and then called the HVAC technicians. The VMU was not notified. Action Taken: On 4/20/16 the VMU Supervisor and VMU Technician met with the AC Shop Supervisor and the USRO (Energy Plant) Foreman. Because the alarm system itself appears to be working correctly, we determined this deficiency was caused by human error due to the lack of: 1. written processes: The VMU Supervisor will write a draft SOP that will be reviewed by Engineering. This SOP will detail specific rooms, temperature and humidity parameters, and the actions required to be taken when the parameters are exceeded. Once the SOP is approved, a copy will be available in the VMU, Energy Plant, and HVAC Shop. Once the SOP is in place, the temperature alarm will be tested until the correct response is received and periodically thereafter. 2. available off-the-shelf web-based monitoring technology that could be bought on a government purchase card. This solution should be pursued if at all possible. ▶Person responsible for overseeing correction: [redacted]		X		April 26, 2016	June 7, 2016

Original Date Noted	Form 1 Part	Form 1 Item #	Location	Descriptive Details	Category M	Category S	Category D	Scheduled Date of Correction	Actual Date Of Correction
4/12/16	A	1053	**NOTE:**	The Controlled Substance Pharmacist says that per **Controlled Substance Handbook 1108.01** only an MD, RN, or Dentist may order controlled substances from the VA Pharmacy. Dr. Fallon was informed of this on 3/9/16 and is looking for the formal guidance from the Central Office Pharmacy Consultant that makes it clear that this is not supposed to be applied to research in animals. ►Person responsible for overseeing correction: [redacted]					Sent e-mail to [redacted] [redacted] 7/13/16
4/12/16	B	1700	Rooms [redacted]	The biosafety cabinets in these rooms were installed too low for technicians to work in comfortably. WO placed 04/15/16: **TH160415-023**; WO cancelled; Protech completed. ►Person responsible for overseeing correction: [redacted]	X			June 2, 2016	May 26, 2016
5/12/09	B	1750	VMU	The Guide requires 30-70% humidity in the animal rooms. The humidity in the VMU is usually lower than 30%. There are no rat breeding colonies that would be affected by lower humidity and the humidity levels do not fluctuate widely from day to day. The goal in the expanded/remodeled animal facility will be to achieve at least 30% humidity.			X	N/A	N/A
5/14/13	B	1804	Rooms [redacted]	Allow < 2.5 Kg NZW and Dutch Belted rabbits to be housed in 14" high cages for short-term (< 3 wks) experiments. NZW rabbits were observed during 2 experiments from 1/27/13 – 2/14/13 and 2/17/13 – 3/4/13. Animals weighed 1.6 - 2.1 Kg 7 days after arrival and 1.4 – 2.3 Kg on the last day. Every rabbit was able to sit in a natural posture with 2 -3" of space between ear tips and cage ceiling. They were also to lay stretched out without touching the cage sides.			X	N/A	N/A

►Total number of Appendix 9 pages attached: **Zero**

▶Name of Medical Center: Raymond G. Murphy VA Medical Center (NMVAHCS) Version 02/28/13
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VA SEMIANNUAL EVALUATION
of the
INSTITUTIONAL ANIMAL CARE AND USE
PROGRAM AND FACILITIES

Part 3 – Post-Review Documentation

▶Enter the date of the most recent previous Semiannual Evaluation: **April 19, 2016**

A. SUMMARY OF SEMIANNUAL EVALUATION. Summarize the results of this semiannual evaluation, including an analysis of the implications of the results for the animal research program as a whole.

The card key alarm system in [redacted] was corrected April 25, 2016 so it will not be reported to ORO, OLAW, and AAALAC.

The VMU temperature alarm was tripped on 6/7/16, 6/10/16, 7/3/16, 7/11/16, and 7/19/16. Engineering responded appropriately to all alarms. The alarms will be tested periodically.

There are still two approved departures from PHS policy, including the provisions of the *Guide*, which have been approved by the IACUC.

B. DOCUMENTATION of MINORITY OPINION(S). *Any participant in the semiannual evaluation who wishes to provide a minority opinion MUST be allowed to do so [1200.07 (8.f(1)(d)4); PHS (IV.E.1.d); 9 CFR (2.31(c)(3))].* Did any participant submit a minority opinion?

_____ Yes ___X__ No If "yes", fill out section E below.

C. Statement of AAALAC Accreditation *[PHS (IV.B.3)].* Are all VA animals housed or used only in facilities that are part of an AAALAC accredited program

_X_Yes. If yes, describe the accreditation as indicated below.

Identify the AAALAC accredited program: **NMVAHCS**

Give the date of the most recent achievement of Full Accreditation: June 13, 2014

____ No. If no, describe the components that are not Fully Accredited, as indicated below.

►Name of Medical Center: Raymond G. Murphy VA Medical Center (NMVAHCS) Version 02/28/13
►Station Number: 501
►City, State: Albuquerque, New Mexico
►Date of Semiannual Evaluation: October 4, 2016

D. DOCUMENTATION of REVIEW and APPROVAL by IACUC MEMBERS. *A majority of all voting members (not merely a majority of a quorum) must approve and sign the report [1200.07 (8.f(1)(e)); 9 CFR (2.31(c)(3))]. The report must be completed within one month of the date of the semiannual evaluation to facilitate timely progress on any corrective actions required.*

The undersigned verify that we
1) have reviewed and approved Forms 1 (Checklist, Parts A and B) and 2 (Table of Deficiencies and Departures),
2) have read any minority opinions appearing in item E of this report, and
3) hereby authorize IACUC representatives to review this report with the Medical Center Director:

TYPED NAME	ROLE ON IACUC	SIGNATURE	DATE
► [redacted]	Chairperson	► [redacted]	► 10/18/16
► [redacted]	Attending Veterinarian	► [redacted]	► 10/25/16
► [redacted]	Scientist with Animal Research Experience	► [redacted]	► 10/18/16
► [redacted]	Non-affiliated Member	►	►
► [redacted]	Non-scientific, Non-affiliated Member	► [redacted]	10/30/16
► [redacted]	Research Scientist (Retired)	[redacted]	► 10/26/16
► [redacted]	Member	► [redacted]	► 10/21/16
[redacted]	Member	[redacted]	► 10/20/16

E. MINORITY OPINION(S). If part B is checked "yes", provide the typed minority opinion(s) here:

F. COMMUNICATION WITH DIRECTOR OF THE FACILITY. After a majority of all voting IACUC members approve the report and indicate their approval (in Section D, above) by signatures next to their typed names and roles on the committee, *the report must be discussed personally with the facility Director by at least one voting member of the IACUC, representing the committee. It is recommended that the Attending Veterinarian and the IACUC Chair meet with the Director (any voting member of the IACUC who wishes to participate must be allowed to do so). It is a best practice for the ACOS for R&D and/or the AO for R&D to attend as well. After the meeting, the Director must sign the reporting indicating that he/she*

has reviewed it. [1200.7(8.f(1)(e))]. **Note: the Director's signature only indicates awareness of the contents of the report, and does not imply agreement with the report or satisfaction with the corrective measures proposed. The report may not be altered after it has been signed by a majority of the voting IACUC membership, but any disputed items may be discussed in a cover memo.**

Certification: By my signature, I acknowledge receipt of this report, and verify that I have personally discussed its contents with the representatives of the IACUC.

Typed Name of Director	Signature	Date
►Andrew M. Welch, MHA, FACHE	►	►11-9-16

G. FINAL PROCESSING

A signed copy of the complete report (including Parts 1, 2, and 3) must be sent through the ACOS/R&D and Medical Center Director to the CVMO within 60 days of the date of approval and signature by a majority of the voting IACUC members. The R&D Committee should review the approved report as an item of business, but R&D approval is not required before submission of the final document to the CVMO. Send a copy including all signatures as a hard copy to Dr [redacted] CVMO, Atlanta VA Medical Center, [redacted] 1670 Clairmont Road, Decatur, GA 30033, or as an email attachment to [redacted] The original must be retained for at least three years.

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:	[redacted]

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 HVAC system supplies 100% outside air supply and exhaust with no recirculation. Filtration pre-filters are 24x24x2 Merv 8; Final filters are 24x24x12 HEPA filters Merv 17 individually certified to be 99.97% minimum efficient. The operation of the fan system is continuous, with terminal steam reheat coils to maintain individual room temperature. Humidity is provided in the air discharge duct year-round by a steam humidifier located at the air-handling unit.

CV Boxes, digitally-controlled heating valves fail to the last position recorded on the CV Box. When digitally controlled valves fail in any position, heat is not pumped into the rooms. Uninterrupted Power Supplies (UPS) on the electronics prevent the system from losing its programing during power bumps or outages. There is a liquid mover for the heating loop heat exchanger to help alleviate intermittent high temperature alarms.

Room Temperatures/Humidity are monitored/alarmed at the ECC engineering control center boiler plant. The HVAC system to include fan controls, temperature and humidity are monitored and alarmed remotely by the energy plant 24/7. In addition, personnel in the VMU monitor and record the high/low temperatures and humidity in each animal room daily. Rooms are

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

monitored via wall-mounted differential pressure transmitters signaling wall-mounted pressure monitor display panel. Signal is extended to TCP in penthouse which ties in to the ECC engineering control center boiler plant. Room Temperatures/Humidity are monitored/alarmed at the ECC engineering control center boiler plant. A high limit static pressure switch w/manual reset shall stop the supply fan when static limits at the discharge fan are reached.

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, measurements may be left at the discretion of the institution*. Information may be provided in another format, providing all requested data is included. **[*Note: Air exchange rates have not yet been measured. We will provide an updated appendix 11 once this is completed.*]**

Room No.	**Specific Use**	**Temperature Set-Point** (define units)	**Electronic / Emergency Monitoring of Temperatures** (Y/N)	**Alert/Alarm Temperature Ranges** (if applicable; define units)	**Humidity Control** (Y/N)	**Relative Pressure**	**Air Exchange Rate** (per hour)	**Date Verified / Measured**
		(settings to be verified)					**(values to be measured)**	
[redacted]	Necropsy/BSL-2 Procedure Room	72°F	N	N/A	N	_	N/A	3/30/17
[redacted]	Anteroom	72°F	N	N/A	N	_	N/A	3/30/17
[redacted]	Animal Housing Room – Rat Conventional	74°F	Y	72-76°F 68-78°F (critical alarm)	N	_		3/30/17
[redacted]	Imaging Room	72°F	N	N/A	N	_	N/A	3/30/17
[redacted]	Anteroom	72°F	N	N/A	N	_	N/A	3/30/17
[redacted]	Animal Housing Room – Storage	72°F	Y	70-74°F 68-78°F (critical alarm)	N	_		3/30/17
[redacted]	SPF Procedure Room	72°F	N	N/A	N	+	N/A	3/30/17

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

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified / Measured
		(settings to be verified)					(values to be measured)	
[redacted]	Anteroom	72°F	N	N/A	N	_	NA	3/30/17
[redacted]	Animal Housing Room – Mouse IVCS ABSL-2	72°F	Y	70-74°F 68-78°F (critical alarm)	N	_		3/30/17
[redacted]	Animal Housing Room – Mouse IVCS	72°F	Y	70-74°F 68-78°F (critical alarm)	N	+		3/30/17
[redacted]	Animal Housing Room – Mouse IVCS	72°F	Y	70-74°F 68-78°F (critical alarm)	N	+		3/30/17
[redacted]	Animal Prep	72°F	N	N/A	N	+	N/A	3/30/17
[redacted]	Scrub and Gown	72°F	N	N/A	N	+	N/A	3/30/17
[redacted]	Operating Room	72°F	N	N/A	N	+	N/A	3/30/17
[redacted]	Recovery Room	72°F	N	N/A	N	+	N/A	3/30/17
[redacted]	Controlled Substances	72°F	N	N/A	N	_	N/A	3/30/17
[redacted]	Mouse Behavioral Core	72°F	Y	70-74°F 68-78°F (critical alarm)	N	+		3/30/17
[redacted]	Feed Storage	41°F	Y	<25°F, >50°F	N	+	N/A	3/30/17

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

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified / Measured
		(settings to be verified)					(values to be measured)	
[redacted]	Sterile Cage Storage	72°F	N	N/A	N	+	N/A	3/30/17
[redacted]	Clean Cage Wash	72°F	N			+		3/30/17
[redacted]	Bedding Storage	72°F	N	N/A	N	N/A	N/A	3/30/17
[redacted]	Clean Cage Storage	72°F	N	N/A	N	+	N/A	3/30/17
[redacted]	Housekeeping Closet	72°F	N	N/A	N	N/A	N/A	3/30/17
[redacted]	Dirty Cage Wash	72°F	N	N/A	N	_		3/30/17
[redacted]	Shipping and Receiving	72°F	N	N/A	N	N/A	N/A	3/30/17
[redacted]	Quarantine Room	72°F	N	70-74°F 68-78°F (critical alarm)	N	_		3/30/17

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

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)
N/A							

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):**
N/A									

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**
Mouse	6.25"w x 11.75"d x 5.5"h	5	Guide for the Care and Use of Laboratory Animals – 8th Edition (Guide)	Lab Products IVCS: Zyfone plastic shoebox cage with [redacted] bedding, Enviro-dri nesting material, modular diet system, micro-isolator filter top, and Lifespan rodent enrichment devices
Mouse	14.5"w x 11.75"d x 5.5"h	11 adults or 3 adults and their offspring (< 21 days old)	Guide	Lab Products IVCS: Zyfone plastic shoebox cage with [redacted] bedding, Enviro-dri nesting material, modular diet system, micro-isolator filter top
Mouse	6"w x 12.25"d x 5.5"h	4	Guide	Tecniplast IVCS: Polycarbonate plastic shoebox cage with [redacted] bedding, Enviro-dri nesting material, wire bar feeder, micro-barrier filter top and mouse house, either plastic or paper
Mouse	7.5"w x 11.5"d x 5.5"h	4	Guide	Static microisolator: Polystyrene disposable cage bottom with [redacted] bedding, Enviro-dri nesting material, wire bar feeder, micro-barrier filter top and paper mouse house
Rat	13.75"w x 17.25"d x 8"h	4 up to 400 gms; 3 up to 500 gms	Guide	Open-topped: Polypropylene plastic shoebox cage with [redacted] bedding, cloth towel and wire bar lids

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**
Rat	7.75"w x 20"d x 8"h	4 up to 300 gms, 3 up to 400 gms	Guide	Static microisolator: Polycarbonate plastic shoebox cage with [redacted] bedding and wire bar lid, microisolator filter top
Rabbit	17.5"w x 24"d x 14"h	1	Guide	Stainless steel cage with Plexiglas door and wire grid
Rabbit	24"w x 24"d x 16"h	1	Guide	Stainless steel cage with wire grid flooring
Rabbit	Flexible from 3'x 6' to 8' x 10'	2	Guide	Open-topped: Plastic cage panels set on epoxy concrete floor to provide rabbit exercise area; Dridek flooring on part of floor. Litter box filled with aspen chip bedding

*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)	Hand pre-cleaned, mechanical washer	twice a week	Sodium metasilicate (Clout)	Autoclaved
Solid-bottom cages (IVC)	Hand pre-cleaned, mechanical washer	At least every two weeks	Sodium metasilicate (Clout)	Autoclaved
Suspended wire-bottom or slotted floor cages	Hand pre-cleaned, mechanical washer	At least every two weeks	Citric acid (Urid)	
Cage lids	Mechanical washer	At least every two weeks	Sodium metasilicate (Clout)	Autoclaved
Filter tops	Mechanical washer	At least every two weeks	Sodium metasilicate (Clout)	Autoclaved
Cage racks and shelves	Hand washed or mechanical washer	Once a month	Sodium metasilicate (Clout)	
Cage pans under suspended cages	Hand pre-cleaned, mechanical washer	Once a week	Citric Acid (Urid)	
Play pens, floor pens, stalls, etc.	Mechanical washer, hand mopping	As needed	Citric Acid (Urid), Alkyl dimethyl benzyl ammonium chloride / dodecyl dimethyl ammonium chloride / ethanol (Quatricide PV-15)	
Corrals for primates or outdoor paddocks for	N/A	N/A	N/A	

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)
livestock				
Aquatic, amphibian, and reptile tanks and enclosures	N/A	N/A	N/A	
Feeders	Hand pre-cleaned, mechanical washer	At least every two weeks	Sodium metasilicate (Clout)	Autoclaved
Watering devices	Mechanical washer	Weekly	Sodium metasilicate (Clout)	Autoclaved
Exercise devices and manipulanda used in environmental enrichment programs, etc.	Hand cleaned; hand pre-cleaned, mechanical washer	At least every two weeks	Alkyl dimethyl benzyl ammonium chloride / dodecyl dimethyl ammonium chloride / ethanol (Quatricide PV-15), Sodium metasilicate (Clout)	OR when moved from one animal to another. Also cleaned if they look dirty.
Transport cages	Hand pre-cleaned, mechanical washer	After each use	Sodium metasilicate (Clout)	
Operant conditioning & recording chambers, mechanical restraint devices (chairs, slings, etc.)	Hand cleaned	After each use	Hydroxyacetic acid/sodium chlorite (Clidox)	
Euthanasia chambers	Hand cleaned	After each use	Hydroxyacetic acid/sodium chlorite (Clidox)	

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)
Macro-Environment				
Animal Housing Rooms:				
Floors	Mopping	Weekly	Alkyl dimethyl benzyl ammoniuun chloride / dodecyl dimethyl ammoniuun chloride / ethanol (Quatricide PV-15)	
Walls	Mopping or hand washing	As needed	Alkyl dimethyl benzyl ammoniuun chloride / dodecyl dimethyl ammoniuun chloride / ethanol (Quatricide PV-15)	
Ceilings	Mopping or hand washing	As needed	Alkyl dimethyl benzyl ammoniuun chloride / dodecyl dimethyl ammoniuun chloride / ethanol (Quatricide PV-15)	
Ducts/Pipes	Hand washing	As needed	Alkyl dimethyl benzyl ammoniuun chloride / dodecyl dimethyl ammoniuun chloride / ethanol (Quatricide PV-15)	
Fixtures	Hand washing	As needed	Alkyl dimethyl benzyl ammoniuun chloride /	

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)
			dodecyl dimethyl ammonium chloride / ethanol (Quatricide PV-15)	
Corridors:				
Floors	Mopping, burnishing	Weekly	Alkyl dimethyl benzyl ammonium chloride / dodecyl dimethyl ammonium chloride / ethanol (Quatricide PV-15)	
Walls	Mopping	As needed	Alkyl dimethyl benzyl ammonium chloride / dodecyl dimethyl ammonium chloride / ethanol (Quatricide PV-15)	
Ceilings	Replaced, not washed	As needed	N/A	
Ducts/Pipes	N/A	N/A	Alkyl dimethyl benzyl ammonium chloride / dodecyl dimethyl ammonium chloride / ethanol (Quatricide PV-15)	
Fixtures	N/A	N/A	Alkyl dimethyl benzyl ammonium chloride / dodecyl dimethyl ammonium chloride / ethanol (Quatricide PV-15)	

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)
Support Areas (e.g., surgery, procedure rooms, etc.); complete for each area: all support areas the same				
Floors	Mopping	As needed	Alkyl dimethyl benzyl ammonium chloride / dodecyl dimethyl ammonium chloride / ethanol (Quatricide PV-15)	
Walls	Mopping or hand washing	As needed	Alkyl dimethyl benzyl ammonium chloride / dodecyl dimethyl ammonium chloride / ethanol (Quatricide PV-15)	
Ceilings	Mopping or hand washing	As needed	Alkyl dimethyl benzyl ammonium chloride / dodecyl dimethyl ammonium chloride / ethanol (Quatricide PV-15)	
Ducts/Pipes	Hand washing	As needed	Alkyl dimethyl benzyl ammonium chloride / dodecyl dimethyl ammonium chloride / ethanol (Quatricide PV-15)	
Fixtures	Hand washing	As needed	Alkyl dimethyl benzyl ammonium chloride / dodecyl dimethyl ammonium chloride / ethanol (Quatricide PV-15)	

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):				
Mops	Hand washing	As needed	Alkyl dimethyl benzyl ammonium chloride / dodecyl dimethyl ammonium chloride / ethanol (Quatricide PV-15)	
Mop buckets	Hand washing	As needed	Alkyl dimethyl benzyl ammonium chloride / dodecyl dimethyl ammonium chloride / ethanol (Quatricide PV-15)	
Aquaria nets	N/A	N/A	N/A	
Other	N/A	N/A	N/A	
Other:				
Vehicle(s)	N/A	N/A	N/A	
Other transport equipment (list)	N/A	N/A	N/A	

*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).

[*Note*: Please remove the examples provided in the Table below.]

Building	Room No.	Equipment Type	Safety Feature(s)	Methods of Monitoring Effectiveness
10	[redacted]	Small autoclave	Gasket will not pressurize when start button is pushed if door is not completely closed.	250˚F steam indicator strip in first load of the day; Accu-Fast biological indicators at least every 40 hours of use
10	[redacted]	Bedding dump station	HEPA filter	Certified annually
10	[redacted]	None – pre-washing area	Limited to PPE	Visual assessment, then run through rack or cage/bottle washer
10	[redacted]	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 daily; RODAC plates of caging tested bi-annually.
10	[redacted]	Cage/bottle washer	Emergency "off" button	Guarantee 180-degree hot water rinse; Temperature-sensitive tape used daily; RODAC plates of caging tested bi-annually.
10	[redacted]	Pass-through autoclave	Doors will not close if anything is in their path. Doors are designed not to open until chamber pressure is approximately at atmospheric pressure.	250˚F steam indicator strip in first load of the day; Accu-Fast biological indicators at least every 40 hours of use

[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:	[redacted] **Veterinary Medical Unit**

Room Type[a]	**Light Intensity Range**	**Lighting Fixture Construction Features**[b]	**Photo-period** (hrs)[c]	**Photoperiod and Lighting Control**	**Override Mechanisms** (if applicable)
Rodent Breeding Rooms	560 lux 1 meter off floor; drops to < 120 on cage shelves	Surface mounted, red lighting	14:10	Automatic via wall-mounted timer box	Mechanical on/off switch
Rodent Housing Rooms	600 lux 1 meter off floor; drops to < 120 on cage shelves	Surface mounted, red lighting	12:12	Automatic via wall-mounted timer box	Mechanical on/off switch
Rabbit Housing Rooms	600 lux 1 meter off floor; drops to < 120 in cages	Surface mounted, red lighting	12:12	Automatic via wall-mounted timer box	Mechanical on/off switch
Surgery	725 lux	Surface mounted; arm-mounted	NA	N/A	N/A
Procedure Rooms	250-480 lux	Surface mounted	NA	N/A	N/A
Cage-Washing Rooms	Not measured	Surface mounted, water proof	NA	N/A	N/A

[a] A list of each room is not needed; group or cluster rooms by species or function
[b] Include such features as water resistance, red lighting, *etc*.
[c] Note if light cycle inverted/reversed.

Appendix 17: Satellite Housing Facilities

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

Left Blank

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
N/A							

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

Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary
Updated June 5, 2017

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:	[redacted]

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 HVAC system supplies 100% outside air supply and exhaust with no recirculation. Filtration pre-filters are 24x24x2 Merv 8; Final filters are 24x24x12 HEPA filters Merv 17 individually certified to be 99.97% minimum efficient. The operation of the fan system is continuous, with terminal steam reheat coils to maintain individual room temperature. Humidity is provided in the air discharge duct year-round by a steam humidifier located at the air-handling unit.

CV Boxes, digitally-controlled heating valves fail to the last position recorded on the CV Box. When digitally controlled valves fail in any position, heat is not pumped into the rooms. Uninterrupted Power Supplies (UPS) on the electronics prevent the system from losing its programing during power bumps or outages. There is a liquid mover for the heating loop heat exchanger to help alleviate intermittent high temperature alarms.

Room Temperatures/Humidity are monitored/alarmed at the ECC (engineering control center) boiler plant. The HVAC system to include fan controls, temperature and humidity are monitored and alarmed remotely by the energy plant 24/7. In addition, personnel in the VMU monitor and record the high/low temperatures and humidity in each animal room daily. Rooms are

Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary
Updated June 5, 2017

monitored via wall-mounted differential pressure transmitters signaling wall-mounted pressure monitor display panel. Signal is extended to TCP in penthouse which ties in to the ECC (engineering control center) boiler plant. Room Temperatures/Humidity are monitored/alarmed at the ECC (engineering control center) boiler plant. A high limit static pressure switch w/manual reset shall stop the supply fan when static limits at the discharge fan are reached.

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, 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** (define units)	**Electronic / Emergency Monitoring of Temperatures** (Y/N)	**Alert/Alarm Temperature Ranges** (if applicable; define units)	**Humidity Control** (Y/N)	**Relative Pressure**	**Air Exchange Rate** (per hour)	**Date Verified / Measured**
		(settings to be verified)					**(values to be measured)**	
[redacted]	Necropsy/BSL-2 Procedure Room	72•F	N	N/A	N	_	N/A	30Mar17
[redacted]	Anteroom	72•F	N	N/A	N	_	N/A	30Mar17
[redacted]	Animal Housing Room – Rat Conventional	74•F	Y	72-76•F 68-78•F (critical alarm)	N	_	12.5	6Apr17
[redacted]	Imaging Room	72•F	N	N/A	N	_	N/A	6Apr17
[redacted]	Anteroom	72•F	N	N/A	N	_	N/A	30Mar17
[redacted]	Animal Housing Room – Storage	72•F	Y	70-74•F 68-78•F (critical alarm)	N	_	12.5	6Apr17

Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary
Updated June 5, 2017

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified / Measured
		(settings to be verified)					(values to be measured)	
[redacted]	SPF Procedure Room	72°F	N	N/A	N	+	N/A	30Mar17
[redacted]	Anteroom	72°F	N	N/A	N	_	NA	30Mar17
[redacted]	Animal Housing Room – Mouse IVCS ABSL-2	72°F	Y	70-74°F 68-78°F (critical alarm)	N	_	9.72	6Apr17
[redacted]	Animal Housing Room – Mouse IVCS	72°F	Y	70-74°F 68-78°F (critical alarm)	N	+	19.78	6Apr17
[redacted]	Animal Housing Room – Mouse IVCS	72°F	Y	70-74°F 68-78°F (critical alarm)	N	+	12.82	6Apr17
[redacted]	Animal Prep	72°F	N	N/A	N	+	N/A	30Mar17
[redacted]	Scrub and Gown	72°F	N	N/A	N	+	N/A	30Mar17
[redacted]	Operating Room	72°F	N	N/A	N	+	N/A	30Mar17
[redacted]	Recovery Room	72°F	N	N/A	N	+	N/A	30Mar17
[redacted]	Controlled Substances	72°F	N	N/A	N	_	N/A	30Mar17
[redacted]	Mouse Behavioral Core	72°F	Y	70-74°F 68-78°F (critical alarm)	N	+	30.30	6Apr17
[redacted]	Feed Storage	41°F	Y	<25°F, >50°F	N	+	N/A	30Mar17

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

Updated June 5, 2017

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified / Measured
		(settings to be verified)					(values to be measured)	
[redacted]	Sterile Cage Storage	72°F	N	N/A	N	+	N/A	30Mar17
[redacted]	Clean Cage Wash	72°F	N			+		30Mar17
[redacted]	Bedding Storage	72°F	N	N/A	N	N/A	N/A	30Mar17
[redacted]	Clean Cage Storage	72°F	N	N/A	N	+	N/A	30Mar17
[redacted]	Housekeeping Closet	72°F	N	N/A	N	N/A	N/A	30Mar17
[redacted]	Dirty Cage Wash	72°F	N	N/A	N	_		6Apr17
[redacted]	Shipping and Receiving	72°F	N	N/A	N	N/A	N/A	30Mar17
[redacted]	Quarantine Room	72°F	N	70-74°F 68-78°F (critical alarm)	N	_	12.00	5June17

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

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