2017 Program Description
Animal Care and Use Program

Rocky Mountain Laboratories (RML)

DIR/NIAID/NIH

Redacted by agreement

Hamilton, Montana

For
AAALAC International

Date of Submission
April 2017

Table of Contents

Appendices

1. Organizational Chart(s)
2. Animal Usage Form A or B
3. Summary of Animal Housing and Support Sites
4. Line Drawings
5. Medical Evaluation Form
6. IACUC/OB Membership Roster
7. Blank IACUC/OB Protocol Form
8. IACUC/OB Minutes
9. IACUC/OB Periodic Report
10. Heating, Ventilation and Air Conditioning (HVAC) System Summary
11. Aquatic Systems Summary
12. Primary Enclosures and Animal Space Provisions
13. Cleaning and Disinfection of the Micro- and Macro-Environment

Program Description

Link to 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.

The Rocky Mountain Laboratories (RML) consists of four research laboratories; Laboratory of Bacteriology (LB), Laboratory of Persistent Viral Diseases (LPVD), Laboratory of Virology (LV), and Laboratory of Zoonotic Pathogens (LZP), a Veterinary support branch (Rocky Mountain Veterinary Branch (RMVB)), a Research Technologies Branch (RTB), Division of Occupational Health and Safety (DOHS), the Office of the Associate Director of Scientific Management and the Office of the Associate Director of Operations Management. RML is part of the Division of Intramural Research (DIR) in the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH).

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

The mission of RML is to study the etiology, pathogenesis, and treatment of infectious diseases and allergic disorders that frequently affect man. Many of these research endeavors require the use of laboratory animal models.

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

The Guide for the Care and Use of Laboratory Animals, 8th Ed, Public Health Service (PHS) Policy, and the regulations promulgated under the Animal Welfare Act (AWRs) are the standards utilized and applied for all aspects of the institutional animal care and use program.

D. Describe the organization and include an organizational chart or charts (as an Appendix/Appendices) detailing the lines of authority from the Institutional Official to the Attending Veterinarian, the Institutional Animal Care and Use Committee/Oversight Body (IACUC/OB), and the personnel providing animal care. Please include the title, name (Note: For individuals whose information is publicly available, provide the titles and names; for individuals whose information is not publicly available, you may provide titles only.), and degree (if applicable) of 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, 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.

National Institutes of Health (NIH) Office of Intramural Research (OIR)
Deputy Director for Intramural Research (DDIR): Dr. Michael M. Gottesman, Institutional Official (IO) for NIH Intramural Research Program.

Division of Intramural Research (DIR), NIAID, NIH:

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Redacted by agreement **DIR, NIAID:**

Redacted by agreement

IACUC Chair:
Olivia Steele-Mortimer, Ph.D.

Rocky Mountain Veterinary Branch (RMVB)
Chief/Attending Veterinarian:
Donald Gardner, D.V.M., DACLAM, DACVPM, DACVP

Office of the Chief:

Redacted by agreement

Reda cted **Animal Care Technicians**

Veterinary Pathology Section (VPS):

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Red acte **Histopathology Technicians**

Biocontainment Clinical Services Section (BCSS):

Redacted by agreement

Redacted by agreement

Redacted **ABSL-4 Animal Care Technicians**

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.

Dr. Michael Gottesman, Institutional Official (Deputy Director Intramural Research,
Office of Intramural Research)

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Dr. Olivia Steele-Mortimer (Chairperson, RML ACUC)

Redacted by agreement

Dr. Donald Gardner (Chief of RMVB/Attending Veterinarian)

Redacted by agreement

NIH Police/Security representative

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 one of the animal use forms included with this outline or provide the information requested in a similar format as an appendix.

Research at RML involves the study of infectious diseases of viral, bacterial, and prion origin using laboratory animals as disease models. Vaccine and therapeutic development, as well as pathogenesis studies are common objectives of the research endeavor. Teaching programs involving animals are limited to the training of research staff and animal care personnel in proper techniques for animal handling and performance of common laboratory animal procedures. There are approximately 45 Principal Investigators (PIs) at RML, utilizing laboratory animals in approximately 205 active research protocols called Animal Study Proposals (ASPs) at NIH.

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

The funding source for research involving animals at RML is the Intramural Research Program of the NIAID. The Scientific Director (SD) determines budgets. All funding is congressionally appropriated.

H. List other units (divisions, institutes, areas, departments, colleges, etc.) of your organization that house and 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.

Not Applicable

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.

Not Applicable

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

RML laboratory animal facilities include active ABSL-2, ABSL-3, and ABSL-4 vivaria.

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 p. 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.

Program needs and status are communicated to Dr. Michael Gottesman (IO) by the Attending Veterinarian (AV), Animal Care and Use Committee (ACUC), or program participants as needed. Dr. Gottesman has reinforced this open communication through a letter posted throughout the facilities detailing his contact information. At a minimum, semi-annual reports are reported to the IO regarding the status of the animal programs at RML.

The DDIR/IO has delegated authority to the Director of Office of Animal Care and Use (OACU) for ensuring compliance of the intramural Animal Care and Use (ACU) program with our PHS Animal Welfare Assurance standards, the AWRs and AAALAC accreditation standards. The Director of OACU forwards all pertinent and critical reports and documents for the DDIR/IO's review and acknowledgement/approval: i.e. semiannual reports; annual reports to OLAW, AAALAC, USDA; OLAW reportable events summaries and actions; NIH Animal Research Advisory Committee (ARAC) recommended policy changes; recommended policy manual changes, etc. The Director, OACU meets regularly with the DDIR/IO and keeps him apprised of general issues occurring within the NIH Intramural Research Program (IRP) ACU program. Additionally, senior leadership within the intramural ACU program have the ability to meet directly with the DDIR/IO to voice concerns or provide essential updates as appropriate.

Additionally, a member of the OACU senior staff serves as an Observer with the RML ACUC and provides annual site visits to ensure program liaison and communication between the RML animal care program and the IO.

b. The Attending Veterinarian [Guide, p. 14]

i. Describe the institutional arrangement for providing adequate veterinary care. For each veterinarian associated with the program (including private practitioners), provide the veterinarian's name(s), list responsibilities, and how the veterinarian is involved in monitoring the care and use of laboratory

animals. If employed full-time by the institution, note the percentage of time devoted to supporting the animal care and use program of the institution. If employed part-time or as a consultant, note the frequency and duration of visits.

The Veterinary Program at RML includes:

Redacted by agreement

Redacted by agreement is involved in all policy-level decisions regarding veterinary services/animal care for the entire DIR of the NIAID. He visits RML on-site 4 times per year and is involved in frequent conversation with the RML Animal Program via electronic or telephone conversations. RMVB consists of five full-time veterinarians, including the Attending Veterinarian (AV), two clinical veterinarians, and two veterinary pathologists.

Dr. Donald Gardner: Chief of RMVB/Attending Veterinarian- 100% of time dedicated to supporting the ACU Program. He is responsible for all aspects of veterinary services at RML, including the ABSL-2, ABSL-3 and ABSL-4 vivaria.

Redacted by agreement Clinical Veterinarian- 100% of time dedicated to supporting the ACU Program. Redacted by agreement provides veterinary clinical care and research support for the ABSL-2, ABSL-3 and ABSL-4 vivaria.

Redacted by agreement Clinical Veterinarian- 100% of time dedicated to supporting the ACU Program. Redacted by agreement provides veterinary clinical care and research support for the ABSL-2, ABSL-3 and ABSL-4 vivaria.

Redacted by agreement Veterinary Pathologist- 100% of time dedicated to supporting the ACU Program. Provides diagnostic and research support for the ABLS-2, ABSL-3 and ABSL-4 vivaria

Redacted by agreement Veterinary Pathologist- 100% of time dedicated to supporting the ACU Program. Provides diagnostic and research support at ABLS-2, ABSL-3 and ABSL-4.

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. An organizational chart depicting the reporting relationship between these individuals and the Attending Veterinarian should be included as an appendix.

All RMVB animal care technicians are in direct communication daily with the veterinary staff and the Facilities Manager. Any animal care procedures or treatments by these staff are performed only under the direction of a staff veterinarian.

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

In the case of off-site collaborations, the RML ACU program and the ARAC have a policy to create a formal written understanding that addresses the responsibilities for off-site animal care and use, animal ownership, ACUC review and oversight, and obtains copies of ASPs approved by the collaborating institution.

2. Personnel Management

a. Training and Education
Describe how the IACUC/OB provides oversight and evaluates the effectiveness of training programs. Describe how training is documented.

All animal training is documented on a training form. Once the individual is deemed proficient in the task and is authorized to perform the procedure independently, the form is signed by the trainer and given to the Training Coordinator for filing. The RML training coordinator maintains a database listing relevant training completed by animal users. All individuals listed on an ASP must provide a Training and Experience Form with each submission. Each ASP is evaluated by the ACUC and proposed animal procedures are compared with the individual's documented training. The ACUC provides oversight of the scientific staff training through the requirement of a summary of relevant training for all participants listed on an ASP, in the form of the OACU animal users online course, which is required every three years. The RMVB Clinical Veterinarians, Facilities Manager, as well as the ABSL-4 Study Coordinator and RMVB Supervisory Technicians, provide hands-on training in animal handling and technical procedures for all personnel (scientific and RMVB animal care staff) working with animals in ABSL-2, -3 and -4. This training is ongoing throughout the year.

The effectiveness of the training program is evaluated in several ways, such as direct evaluation of procedures by animal care and veterinary staff and self-reporting by research staff.

i. Veterinary and Other Professional Staff [Guide, pp. 15-16]
Provide name and credentials of veterinary and other professional staff, including the veterinary personnel listed above, and describe their qualifications, training, and continuing education. Please do not provide curriculum vitae of personnel.

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Donald Gardner, D.V.M.
Diplomate, American College of Laboratory Animal Medicine, 1994.
Diplomate, American College of Veterinary Preventive Medicine, 1991.
Diplomate, American College of Veterinary Pathology, 1999.
Over 25 years of experience in Lab Animal Medicine, Surgery and Pathology.
Receives 30 or more hours per year in CE credits.

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ii. Animal Care Personnel [Guide, p. 16]
Indicate the number of animal care personnel. Redacted by

Summarize their training, certification level and type, experience, and continuing education opportunities provided.

We have Redacted animal care personnel, including a Supervisor Technician, an ABSL-4 Study Coordinator, and Redac Biologists. All personnel are high school graduates, Redacted with post-secondary education, Redacte of which have

college degrees. AALAS technician certifications include Assistant Laboratory Animal Technicians, Laboratory Animal Technicians, Laboratory Animal Technologists, and Certified Veterinary Technicians. Primary CE may be accomplished in-house at the employer's expense via AALAS materials and webinars. Opportunities for attending regional/national AALAS meetings are provided at the expense of the employer. On-site group study/training sessions and materials are also offered to those preparing for AALAS certification.

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.

The ACUC Support Office works with the researchers to ensure they have the appropriate training and experience to work with animals. This includes initial training as listed below. In addition, animal user researchers are required to complete a "Training and Experience (T&E)" form along with the submission of their ASP, describing their previous experience with animals.

Documentation of required training is maintained by the ACUC Support Office.

ACUC Support staff will verify that animal users have the necessary training specific to each ASP submission. If the researcher is not trained for a procedure listed on the ASP, the ACUC Support Office will contact the researcher to help arrange training.

a) Briefly describe the content of any required training.

All animal users undergo the following training:

"Using Animals in Intramural Research". This is an NIH-wide required online course covering regulations, occupational health & safety, animal care and use procedures, and animal health and well-being. A refresher training is required at least every three years.

Facility orientation. This hands-on training discusses appropriate PPE, foot patterns, facility entering/exit procedures and biosecurity, while touring the respective animal facility.

Initial Hands-On training. This training is provided by the RMVB, and covers basic handling and restraint, routes of administration, anesthesia, blood collection and euthanasia (as appropriate to user's ASP).

"Working Safely with Nonhuman Primates (NHPs)". All animal users working with NHPs are required to attend the classroom-

based NIH course, which provides information on the recognition of normal and abnormal NHP behaviors, as well as appropriate behavior and conduct in the presence of NHPs. The course also includes the proper procedures for the required reporting of any concerns and/or abnormal or suspected abnormal behaviors seen in NHPs to the veterinary staff.

Animal Exposure Program (AEP): This training is provided by Occupational Medical Services (OMS). The training discusses potential allergies to small animals, methods to minimize allergen exposure, and signs of allergies. Additionally, OMS will discuss risks associated with working with laboratory animals

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

Animal users must complete the above listed training and demonstrate proficiency by veterinary staff prior to working with animals independently.

c) Describe continuing education opportunities offered.

Attendance to regional and national AALAS meetings are offered, and veterinarians may attend national meetings associated with their specialties, e.g. ACLAM forum, ACVP and APV meetings. The ACUC committee training may also include IACUC 101 and Animal Welfare Information Center (AWIC) training. In addition, the NIH offers webinars hosted by AALAS, AWIC and OLAW to all animal users.

2) Describe the process(es) to ensure surgical and related procedures are performed by qualified and trained personnel. Who determines that personnel are qualified and trained for surgical procedures? What role does the Attending Veterinarian and IACUC/OB have in this determination? [Guide, pp. 115-116]

All personnel proposing to perform surgical and/or related procedures are required to be trained and demonstrate proficiency, after consultation with, and training by experienced veterinary personnel, as well as with ACUC approval.

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

The veterinary staff is available to perform anesthesia when requested or deemed necessary. Training is provided to

investigators and technicians, as needed. Investigators and technicians may perform anesthesia based on prior training/experience and after evaluation by the veterinary staff.

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

The veterinary staff ensures all animal care personnel and members of the research team are fully trained prior to performing euthanasia independently.

b. Occupational Health and Safety of Personnel [Guide, pp. 17-23]
Describe the institutional entities that are involved in the planning, oversight, and operation of the institutional occupational health and safety program.

The Occupational Medical Service (OMS) program at RML provides for Redacted full-time nurses Redacted by agreement stationed on the RML campus. Redacted by agreement oversees the OMS program at RML, and Redacted by agreement Redacted by agreement and oversees the Biosafety and Select Agent programs at RML. The OMS program provides for a pre-employment physical examination, enrollment into the AEP, and a blood draw for serum sample storage. If working with NHPs, an annual tuberculosis (TB) test (or chest x-ray, as deemed necessary), routine vaccinations, rabies and measles titers, and specialized vaccines for specific pathogens, etc., may be required. For non-federal employee animal care staff (contractor staff), the contractor has arranged with a local health care clinic for providing the above described occupational medical services.

The Institutional Biosafety Committee (IBC) monitors research use of all infectious biohazard agents and recombinant DNA. The Radiation Safety Committee monitors research use of radioisotopes, radiography and Redacted by agreement The Safety Committee monitors the use of hazardous chemicals, fire safety, and physical safety hazards associated with equipment and physical facilities.

The Hazardous Materials Spill Response Team is responsible for responding to, and cleaning up any spills of hazardous chemicals in RML facilities. The Occupational Health and Safety Manager is responsible for monitoring and ensuring compliance with occupational health and safety policies and environmental compliance.

Federal and NIH regulations require injury reports be filed on all on-the-job injuries. The Safety Committee maintains and evaluates all reports. Individual PIs are responsible for ensuring the proper training for all individuals involved in specific research involving hazardous agents.

The RMVB management team, AV, Clinical Veterinarians, Veterinary Pathologists, Facilities Manager, and Supervisory Technician ensures personnel working in the animal facilities adhere to all personal hygiene

policies and utilize safe work practices. The entire RML staff has free access to all of the above-mentioned individuals and committees to express any concerns/questions. Injuries and other medical problems are referred to the local hospital emergency room which is a 5-minute drive away.

i. Hazard Identification and Risk Assessment [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]

1) Describe the process used to identify, evaluate and control experimental and other potential hazards (such as ionizing and non-ionizing radiation, chemical cleaning agents, animal bites, allergens, zoonoses, and venomous species) inherent or intrinsic to the use of animals by the institution. Describe how risks of these hazards are assessed and how procedures are developed to manage the risks.

Any use of hazardous agents (biological, radiation or chemical) must be approved by the appropriate RML committee: Radiation Safety Committee, IBC, or Safety Committee prior to ACUC review and approval.

The respective committee, as required for approval, sets guidelines and precautions. The PIs are responsible for ensuring all personnel associated with a particular project are fully aware of, and instructed on all appropriate safety procedures. In addition, potential hazards associated with the use of animals are identified through the cooperative efforts of the IBC, Safety Committee, AV, the Occupational Health and Safety Manager, and the Biosafety staff. Once a potential hazard is identified, appropriate control measures are implemented and appropriate training provided.

OMS provides medical risk assessment of the Intramural Research Program (IRP) populace and advises on their inclusion or exclusion from the AEP. NIH Policy Manual 3040-2 requires that all NIH personnel who have direct contact with, or are involved in the direct care of live research animals, or have contact with un-fixed, Old World NHP animal tissues or body fluids must be enrolled in the AEP or an equivalent program (i.e., contract staff). Other individuals that may have only transient exposure to research animals or their tissues/body fluids are addressed in the DOHS policy memo: Medical Surveillance of Transient Visitors into NIH Animal Facilities.

Laboratory Animal Allergy Prevention Program (LAAPP): Employees enrolled in the NIH AEP will be given a copy of the OMS primer "Allergies to Laboratory Animals, A Significant Health Risk" at their initial visit to the clinic. An OMS clinician will obtain all relevant past medical history, including existing allergies, and review the educational information with each employee. If the

employee has an existing allergy to animals, the employee will be referred to DOHS for enrollment into the NIH Respiratory Protection Program (RPP).

2) Describe procedures for reporting and evaluating exposure to hazards, work place injuries, etc.

Exposures and potential hazards are directed to the appropriate RML safety committee. Known exposures or injuries are reported to the individual's supervisor and OMS, an injury report is completed, and the individual may be sent to the local hospital. Evaluation and follow-up of the exposure/injury report is done by the respective safety committee (Radiation Safety, Biosafety, or Safety Committees). If it involves a Select Agent, the Responsible Official (RO) or Alternate Responsible Official (ARO) is notified.

In addition, employees are required to report signs and symptoms of animal allergy to OMS promptly, so that appropriate interventions can be implemented. An OMS clinician interviews employees that report possible allergic reactions to laboratory animals. If clinically indicated, the worker may be referred to a designated safety and/or health specialist for further medical management. If the worker's concerns are confirmed, workers' compensation forms are issued, and the relevant DOHS Occupational Safety and Health Specialist will be consulted to assist the immediate supervisor with the worksite evaluation and recommend improvements to minimize exposure to allergens.

ii. Facilities, Equipment and Monitoring [Guide, pp. 19-20]

1) Describe how hazardous agents are contained within the study environment and in the animal housing area.

Procedures to contain hazardous agents include: personnel training, extensive use of individually ventilated caging, negative pressure ventilated racks, Class II Biological Safety Cabinets (BSCs) or other equivalent containment devices, chemical and/or autoclave decontamination of equipment, incineration or autoclaving of waste materials, limited access, posting of animal holding areas and procedure rooms with biohazard signs, use of personal protective clothing and equipment, and disposal of sharp objects in puncture-resistant leak proof containers.

All rooms housing animals exposed to biological and/or hazardous agents are clearly marked/labeled. All contaminated caging equipment or bedding is autoclaved or chemically disinfected before cleaning or disposal. The rooms housing potential hazardous agents are maintained at a negative pressure relative to the adjacent areas and adjoining corridors. In Animal Biosafety

Level (ABSL)-2 areas, most rodents are housed in individually ventilated caging systems that are at negative pressure to the room. In ABSL-3 and ABSL-4 labs, all infected rodents are housed in individually ventilated caging systems, and studies using larger animals (e.g. NHPs, pigs, etc.) are evaluated in consultation with biosafety. These animals may be housed in open cages or open cages within ventilated enclosures depending on the scientific requirements of the study and compliance with NIH Guidelines and Select Agent regulations.

For all pathogens, a Pathogen Registration Document (PRD) must be completed, and the IBC determines the appropriate ABSL and any special containment procedures required based on the Biosafety in Microbiological and Biomedical laboratories, 5th Ed (BMBL).

The appropriate RML biosafety/safety committees are responsible for establishing necessary monitoring procedures for use of hazardous agents, as well as reviewing and approving any required standard operating procedures (SOPs). An annual safety audit for all facilities is performed by DOHS, as well as an annual biosafety audit for all facilities and areas containing Select Agents.

2) Describe facilities that use hazardous agents. Note square feet/meters, number of animal rooms, and support spaces. In addition, describe design features, construction features, and special equipment, especially as they relate to hazard containment. Note if, and how, exhaust air is treated. If special facilities are not available and animals exposed to hazardous agents are housed within conventional animal rooms, so note.

In all RML animal facilities, animal rooms housing potential human pathogens are maintained at a negative pressure relative to the adjoining corridor and all contaminated caging, equipment or bedding is autoclaved and/or chemically disinfected before cleaning or disposal.

Redacted by agreement

Redacted by agreement contains conventional animal rooms and houses rodents, rabbits and nonhuman primates (NHPs) infected with BSL-2 pathogens. It is a total of Redacted by agreement which includes 21 small animal rooms, eight procedure rooms, one necropsy room and a cage wash area with separate clean/dirty sides. Redacted by agreement also includes a primate wing that has six NHP rooms and a procedure room. All pathogen work is conducted in BSCs or equivalent containment devices. Exhaust air is hard-ducted to the outside and not recycled.

Redacted by agreement

The ABSL-3 facility houses rodents infected with BSL-3 pathogens. The facility consists of a cage wash area designed

with separate clean/dirty sides and five animal suites, which open off the main corridor. Each suite consists of an anteroom. two animal housing rooms and one procedure room Redacted by agreement Ventilated filtered caging units and BSCs are utilized for hazard containment within the facility. Directional airflow and pressure relationships between spaces is maintained and continually monitored by a central computerized building automation system (BAS). All exhaust air is HEPA filtered.

Redacted by agreement

This facility contains NHP quarantine and the Redacted by agreement Redacted by agreement which houses rodents, ferrets, bats, pigs, sheep, goats and NHPs infected with BSL-2, BSL-3 and BSL-4 pathogens. The quarantine facility includes five animal housing rooms, one procedure room and a change room opening off a main corridor on Redacted by agreement The Redacted includes nine animal holding rooms, four procedure rooms and six change rooms located on Redacted by agreement Directional airflow and pressure relationships between spaces are maintained and continually monitored by a central computerized BAS. Air supplied positive pressure protective suits are used within the facility, with chemical shower decontamination upon exiting. Ventilated filtered caging units, BSCs, downdraft/back draft procedure stations and downdraft necropsy tables are utilized for hazard containment within the facility. All supply air to the BSL-4 passes through a single HEPA filter and exhaust air passes through two HEPA filters in series.

Redacted by agreement

The facility houses rodents infected with BSL-2 pathogens. The facility consists of four animal housing rooms, three procedure rooms and two change rooms Redacted by agreement All pathogen work is conducted in BSCs. Exhaust air is hard-ducted to the outside and not recycled.

3) Describe the oversight process and husbandry practices in place to ensure personnel safety, including any personal protective equipment provided when work assignment involves hazardous agents.

The appropriate RML safety committee is responsible for establishing necessary monitoring procedures for use of hazardous agents, as well as reviewing and approving any required standard operating procedures (SOPs). The RMVB management team is responsible for ensuring any special husbandry practices are understood and adhered to. All areas containing specific hazards are clearly marked/labeled with appropriate signage. PIs are responsible for ensuring all policies

and procedures which apply to their specific research studies are properly understood and adhered to.

RML follows the standards for PPE set in the ARAC Guideline: Guidelines for Personnel Protection in Animal Facilities.

RML also complies with the NIH Policy Manual 3044-2 - Protection of NIH Personnel Who Work with Nonhuman Primates.

The Laboratory Animal Allergen Prevention Program provides safety oversight that includes work place safety and the use of PPE.

4) Describe any facilities that may also be used for 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.

Not Applicable

5) 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.

NHP cages from Redacted by agreement are transported to the cage wash facility in Redacted by agreement through a common corridor/elevator area. All caging from quarantine is chemically disinfected prior to transport, and all caging from the Redacted is autoclaved prior to transport to the cage wash facility.

Within Redacted by agreement uninfected NHPs are transported in cages from the quarantine area through a common corridor to a service elevator and through the buffer corridor surrounding the BSL-4 lab where they are taken to the appropriate animal holding room. All entrances to these corridors are posted during the brief time the NHPs are being transported to alert building occupants to stay out of the area during that time. The RMVB animal care staff transporting the NHPs wear PPE to protect against skin and eye/mucous membrane exposure when transporting NHPs. The route is thoroughly cleaned and disinfected after transportation.

All rodents are transported in secured microisolator cages and covered during transport.

6) If motorized vehicles are used for animal transport, describe how the driver is protected from exposure to hazards such as allergens or zoonoses.

All-Terrain Vehicles (ATVs) are occasionally used to transport rodents from the RML shipping and receiving building to the appropriate vivaria. The animals are held in filter-lined transport containers to prevent exposure of personnel to animals and bedding

iii. Personnel Training [Guide, p. 20]

1) Describe educational program(s) to inform personnel about zoonoses, personal hygiene, allergies, and other considerations regarding occupational health and safety.

All personnel working with laboratory animals must be enrolled in the AEP administered by OMS. Redacted by agreement Redacted by agreement conducts mandatory, annual occupational health training sessions for all RML personnel. The OMS, IBC, Radiation Safety Committee, Safety Committee, Veterinary staff, and the Facilities Manager have responsibility for providing training/information to RML personnel about zoonoses, allergies, personal hygiene and other occupational health considerations. The RML Biosafety staff conducts mandatory BSL-3/BSL-4 biosafety training for individuals working with animals in the BSL-3 and/or BSL-4 labs. Other training sessions and safety reminders are conducted as needed.

2) Describe special qualifications and training of staff involved with the use of hazardous agents in animals.

All personnel working with specific hazardous agents in animals are identified and required to undergo training concerning the specific hazardous agent involved. If applicable, the individuals are vaccinated and have appropriate monitoring of protective antibody titers. All personnel working with hazardous agents in animals receive continuing oversight by the PI, Clinical Veterinarians, Facilities Manager, Supervisory Animal Technicians, Biosafety Officers, Occupational Health Nurses, specific safety committees, and the on-site Occupational Health and Safety Manager. Individuals working in the ABSL-3 and/or ABSL-4 environment must complete a mandatory biosafety training program prior to beginning such work, including periodic training refresher courses. Select Agent training is also required for all personnel working with pathogens classified as Select Agents, including annual refreshers. A three-day training course is required of personnel to be classified as an "authorized user" of radioisotopes.

When respirator (e.g. N-95 respirator, powered air purifying respirator (PAPR), etc.) use is required, respirator training and/or respirator fit testing is provided by the DOHS, which maintains the NIH Respiratory Protection Program, in compliance with OSHA regulations.

iv. Personal Hygiene [Guide, p. 20; Ag Guide pp. 4-5]

1) List routine personal protective equipment and work clothing provided for animal care personnel, technical staff, farm employees, etc. Describe arrangements for laundering work clothing.

Coveralls, scrubs, boots, shoes, disposable gowns, lab coats, face shields, disposable gloves, leather gauntlets and gloves, surgical masks, N95 respirators, hair covers, shoe covers, eye protection, hearing protection, lead aprons/gloves/thyroid shields, insulated coats, PAPRs, and air supplied positive pressure protective suits are provided to animal care/technical staff.

Non-disposable PPE and work clothing are autoclaved followed by laundering at a local, commercial laundry. In-house laundering is available, if needed.

Safety footwear and prescription safety eyewear are issued by the DOHS as needed.

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

Hand washing sinks are available in all animal housing rooms or adjacent anterooms, and at all animal facility entrances/exits. Personnel wash their hands after removing their gloves and when exiting the laboratory or animal area. Shower facilities are provided, and daily showers are required at the end of the day for all RMVB animal care staff, or as deemed necessary by scientific staff. Lockers are provided to RMVB personnel for street clothes. Wearing of work clothes outside the immediate areas around the animal facilities is prohibited.

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

The RML campus is a smoke-free environment. Eating and drinking are not allowed in the animal facilities except in designated break rooms and administrative spaces.

v. Animal Experimentation Involving Hazards [Guide, pp. 20-22]

1) Describe briefly institutional policies governing experimentation with hazardous biological, chemical, and physical agents, including the oversight process for the use of hazardous agents. Note: Written policies and standard operating procedures (SOPs) governing experimentation with hazardous biological, chemical, and physical agents should be available during the AAALAC site visit. If such policies and procedures are not available, please explain.

RML has a Chemical Hygiene Plan and a Hazard Communication Program; both available via the DOHS webpage; Resources For Personnel Using Animals. Any work with biological hazards or recombinant DNA must be reviewed and approved by the IBC. SOPs are required for work conducted at BSL-2 with 3 practices, BSL-3, and BSL-4.

2) Describe aspects of the health and safety program specifically for personnel potentially exposed to hazardous agents.

Radiation dosimeters are provided to all radioisotope users, and vaccinations for specific pathogens are given to all personnel with potential for exposure. Annual TB skin testing for all personnel working with NHPs, as well as air purifying respirators, if working in environments which may require such protection, are provided for all personnel. Yearly physicals are required for all staff enrolled in the RML biosurety program. In addition, yearly physicals and exposure histories are provided for members of the RML HAZMAT Team. All personnel are trained on biological exposure prevention and response procedures in the New Employee Orientation training and the Annual Safety Refresher training. These procedures are outlined in detail in the RML Biological Exposure Control Plan, which is available to all personnel via the RML Share drive in the Biosafety folder. This also includes the procedures and programs available through OMS.

3) Describe safety procedures for using volatile anesthetics and how waste anesthetic gases are scavenged.

All procedure rooms in the animal facilities, as well as the surgical suite, are provided with anesthetic gas scavenging systems; either equipped with F/Air canisters, used within hard-ducted BSCs, or under hard-ducted exhaust ducts. All local exhaust ventilation devices are tested and certified by DOHS prior to use with volatile anesthetics. In the ABSL-4, the anesthesia units are used on a backdraft/downdraft table while wearing positive pressure suits.

4) 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: This information may be provided as an Appendix.

a) Biological agents, noting hazard level (CDC Biohazard Level, Directive 93/88 EEC, CDC or USDA/DHHS Select Agent, etc.).

Non-Select Agent Pathogens (biosafety level)
Viruses:
Powassan virus (3)
West Nile Virus (3)
Junín Virus (4)
Dengue Virus (2)
Langat Virus Strain TP21 and E5 (2)
LaCrosse Virus (2)
Herpes Simplex Virus-1 and -2 (2)
Lymphocytic Choriomeningitis Virus (2)
HIV Strains I and II (2)
Influenza H1N1 swine-origin related to 2009 (2)
Influenza type-A (subtypes H1-H16), except H5, H7 & 1918
Influenza type-B (2)
Bunyamwera Virus (2)
Hantavirus (Andes, Maporal, Laguna Negra, Hantaan, Sin Nombre,
Black Creek Canal, Seoul, Puumala, Tula, Prospect Hill, Choclo,
Monogahela, Dobraun, New York, Rio Mamore) (4)
Phleboviruses (Severe Fever withThrombocytopenia Syndrome
Virus, Heartland Virus, Bhanja) (3)
Coltivirus (Colorado Tick Fever Virus) (2)
VSV Strain Indiana (3)
Beta-Coronaviruses (MERS-CoV, HCoV-229E, HCoV-OC43,
HCoV-NL-63, HCoV-HKU1) (3)
Arenaviruses (IPPY, Mopeia, Mobala, Pichinde, Tacaribe) (4)
Simian Hemorrhagic Fever Virus (2)
WR Vaccinia (2)
Epstein Barr Virus (2)
Cytomegalovirus (2)
Adenovirus (2)
Sendai virus (2)
Zika virus (2)
Murine Gammaretrovirus (2)
Murine Leukemia virus (2)
Lactate dehydrogenase elevating virus (2)

Bacteria:
Francisella tularensis Strain LVS (3)

Francisella novidica Strain U112 (3)
Salmonella typhimurium (2)
Listeria monocytogenes (2)
Chlamydia trachomatis: Strains A-K, L1-3; Mouse Pneumonitis,
Chlamydia psittaci Strains MN/Cal-10, P-ORN/Cp-3, OVI/B-577,
FEL/PN-1, GPIC; Chlamydia pneumonia Strains AR-39, TW-183,
CWL, MUL, 250 (2)
Chlamydia trachomatis serovars A, B, D, G, L2, Har13, Tw2/OT,
B Jali, Hr36, D, UW3/Cx, UW524/Cx, LGV434, C. caviae GPIC,
C. muridarum MoPn, C.pneumonia AR-39, C. psittaci Mn (2)
Staphylococcus aureus (including MRSA) (2)
Borrelia burgdorferi: Strains B31, 297, N40; crocidurae, turicatae,
hermsii strains >35, parkeri strain SLO, (2)
Shigella flexneri (2)
Rickettsia spp: conorii, montana, rhipicephali, akari, austrailis, bellii,
helvetica, parkeri, slovaka, sibirica, tullamook, tsutsugumushi,
Wolbachia andersoni, W. persic, R. typhi, R. canada, and several
unclassified rickettsiae, Coxiella burnetii avirulent, Strain RSA439
(avirulent phase II) (3)
Legionella pneumophila Strains LP02, MB355 (2)
Yersinia pseudotuberculosis, enterolitica, pestis (attenuated Lcr- and
or Pgm-) (2)
Bacillus anthracis exempt lacking plasmids pX01, pX02 (2)
Leptospira spp. (2)
Coxiella burnetii (attenuated non-select agent) (3)
Proteus mirabilis (2)
Klebsiella pneumoniae (2)
Enterobacter aerogenes (2)

Transmissible Spongiform Encephalopathies:
BSE, CJD Strain Sporadic CJD, Variant CJD (2)
Other human TSE Strains including Fatal Familia Insomnia, Gerstler
Strausser Syndrome (GSS) (2)
Rodent-Adapted Scrapie (2)

Parasites:

Plasmodium berghei (2)
Plasmodium yoelii (2)
Leishmania amazonensis (2)

Toxins:
Diphtheria toxin (2)

Select Agents (biosafety level):
Viruses:
Flaviviridae: (Omsk Heamorrhagic Fever, Russian Spring Fever,
Kyasanur Forest, Far Eastern TBEV, Central European TBEV) (4)
Filoviridae: Ebola and Marburg Virus (4)
Phleboviridae: Rift Valley Fever (3)
Paramyxoviridae: Henipavirus (Hendra, Nipah) (4)
Bunyaviridae: (Crimean-Congo Haemorrhagic Fever Virus) (4)
Arenaviridae: (Guanarito, Junin, Machupo, Sabia, Lassa, Chapare,
Lujo) (4)
Highly Pathogenic Avian Influenza Virus (i.e. H5NX, H7NX), 1918 Influenza Virus (3)
SARS-CoV (3)

Bacteria:
Francisella tularensis Strain SchuS4 and FSC200 (3)
Rickettsia prowazekii (3)
Coxiella burnetti (3)
Yersinia pestis (virulent) (3)

b) Chemical agents, noting general category of hazard (toxicant, toxin, irritant, carcinogen, etc.).

Formaldehyde (carcinogen), diphtheria toxin.

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

Redacted by agreement	Radiography; cagewash equipment (noise)

5) Describe the program for housing and caring for animals exposed experimentally to the hazardous agents noted above, with emphasis on management and safety practices for containment of each class of agent. Indicate how levels of personnel exposure are assessed.

Animals are housed and maintained according to the appropriate SOPs. The biosafety level is based on current CDC/USDA recommendations and/or an onsite risk assessment as performed

and approved by the RML IBC before submission of the ASP to the ACUC. Facility or agent-specific SOPs are generated in a cooperative process between scientific program, animal program, and the biosafety office. The SOPs are finalized and approved by the IBC. All personnel are required to review facility/agent-specific SOPs before gaining entry into animal areas. Exposures are reported to direct supervisors, biosafety, and OMS. Determinations about exposure risk and follow-up health care are determined with occupational health physicians using the NIH Exposure Risk Assessment Guide.

All rooms housing animals exposed to hazardous agents are clearly marked/labeled. All rodent handling and cage changing procedures are conducted in cage changing stations, BSCs or on downdraft tables. All contaminated caging, equipment, or bedding is autoclaved or chemically disinfected before cleaning and/or disposal. The rooms housing potentially hazardous agents are maintained at a negative pressure relative to the adjoining corridor. If applicable, employees are enrolled in the Serum Storage program described in OMS Chapter 111-26.

Special facilities provided for use with hazardous agents are described as follows:

Redacted by agreement Rodents infected with BSL2 human pathogens are housed in this area which is comprised of 2 animal suites, each consisting of 2 animal housing rooms and a procedure room.
Ventilated filtered caging units and biosafety cabinets are utilized for hazard containment within the facility. All contaminated caging, equipment or bedding is autoclaved or chemically disinfected before cleaning or disposal.

Redacted by agreement is maintained under directional airflow and the pressure relationships between spaces are maintained and continually monitored by a central computerized BAS. All exhaust air is HEPA-filtered. There are 5 animal suites, each consisting of 2 animal housing rooms, an anteroom and a procedure room. All animal rooms in Redacted by agreement are maintained at a negative pressure relative to the adjacent areas and adjoining corridors. Ventilated filtered caging units and biosafety cabinets are utilized for hazard containment within the facility. All contaminated caging, equipment or bedding is autoclaved or chemically disinfected before cleaning or disposal. Redacted by agreement meets or exceeds all guidelines of the NIH/ CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL) guidelines.

Redacted by agreement is maintained under directional airflow and the pressure relationships between spaces are maintained and continually monitored by a central computerized BAS. Air supplied, positive-pressure full body suits are used within the facility, with chemical shower decontamination upon exiting. Ventilated filtered caging units, ventilated enclosures, biosafety cabinets, downdraft/back draft procedure stations and/or downdraft necropsy tables are utilized for hazard containment within the facility. Redacted by agreement meets or exceeds all guidelines of the NIH/ CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL) guidelines.

vi. Personal Protection [Guide, pp. 21-22]

1) Describe training, 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).

RML utilizes the principles of industrial hygiene to reduce potential physical injuries inherently found in an animal facility: engineering controls, administrative controls, and PPE.

The engineering controls are classified as primary barriers, (i.e., individual ventilated cages, single-use disposable cages) or containment equipment, (i.e., BSCs, chemical fume hoods, and HEPA-filtered vacuum systems).

Administrative controls are written safety programs, (i.e., Chemical Hygiene Plan, Hazard Communication Program), found on the DOHS resource web site for personnel using animals and written animal facility operating procedures used to augment the use of engineering controls to minimize the impact of potential hazards.

The Safety Committee tracks on-the-job accidents and looks for patterns that may indicate physical hazards. Equipment available to help prevent physical injuries include: forklifts and hydraulic lifts for heavy materials, carts for transport of husbandry supplies and large animals, air purifying respirators, protective gloves, face shields/safety glasses, and anesthetic gas fume scavenging. DOHS annually inspects laboratory and work spaces for safety-related issues. Refresher safety training is provided annually. In addition to the required training, "Working Safely with Nonhuman Primates", species-specific safety training for agricultural or unusual laboratory animals, for example, is provided initially and on an "as needed" basis.

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

The ORS/DOHS has a written Protocol for Certification, Maintenance, and Decontamination of Containment Equipment.

Suppliers of new equipment provide instruction for all operating personnel. BSL-4 positive pressure suits undergo integrity tests at least once per week. These suits are replaced if safety defects are noted that cannot be repaired. Certain safety equipment (lab coats, PAPRs) is replaced when in disrepair, or no longer in working condition. Anesthetic gas scavenging (charcoal canister) systems are replaced per manufacturer instructions. BSCs, backdraft and downdraft tables, and ventilated racks are certified annually. Protective lead aprons/gloves/thyroid shields are evaluated for defects at least once per year and replaced as needed.

3) Describe situations where respiratory protective equipment is available or required, such as cage washing facilities, feedmills, etc. Describe how such equipment is selected and how respirator fit testing and training in the proper use and maintenance of the respirator is provided.

RML follow the standards for PPE set in the ARAC Guideline: Guidelines for Personnel Protection in Animal Facilities. Additionally, the IBC identifies specific respiratory protective equipment required for the work described within the ASP and this is documented in the Pathogen Registration Document (PRD). Facility-specific PPE requirements are described in the Operations and Safety Procedures (OSP) manual for each facility and the agent-specific SOPs.

N-95 respirators or PAPRs are required for working in environments with potential for aerosol exposure to hazardous agents. Choice of respirator is made in consultation with DOHS (safety) specialists and as instructed in agent specific SOPs. Fit testing by DOHS personnel is conducted annually or as deemed necessary.

4) Describe program policies to ensure personnel safety when working with rack/cage washers, other sanitation/sterilization equipment, and other heavy equipment such as scrapers, tractors, and farm machinery. Describe the training program that supports these policies.

Suppliers of cage washers and autoclaves provide initial instruction for all operating personnel. Large, pass-through autoclaves are equipped with safety features, such as interlocking doors. The RMVB Facilities Manager provides training to animal care personnel for cage and rack washer safety, including autoclave safety and training for emergency exit from walk-in rack washers. RML sponsored operator training is required for certification to

operate forklifts. Forklift operator recertification is required every 3 years.

vii. Medical Evaluation and Preventive Medicine for Personnel [Guide, pp. 22-23]

1) Identify the individual(s) and/or office responsible for developing and monitoring the medical evaluation and preventive medicine program.

The OMS program at RML provides for Redac full time nurses stationed at RML in Redacted by agreement Redacted by agreement Redacted by agreement oversees the OMS program at RML.

2) Describe the categories of personnel (research staff, visiting scientists, animal care staff, students, support staff, etc.) included in the program.

All individuals working with animals, including research staff, visiting scientists, animal care staff, and facilities maintenance staff are included in the OMS program.

NIH employees
NIH PM 3040-2 makes enrollment/registration in the AEP mandatory for NIH employees who work in animal facilities and/or have contact with research animals or un-fixed, Old World NHP animal tissues or body fluids.
Students and Volunteers:
Trainees, Fellows, or Special Volunteers who conduct animal activities are eligible for enrollment in the AEP and other associated OMS programs to the extent necessary to support their involvement in the Animal Care and Use program.

NIH transient visitors
The non-affiliated community members and non-scientific members of RML's ACUC have occasional or infrequent animal contact are encouraged to enroll in the AEP. If not enrolled, the members are required to wear appropriate PPE when visiting animal care and use areas as per the NIH policy memo: Medical Surveillance for Transient Visitors into NIH Animal Facilities. This approach also applies to all transient 'visitors' that may enter the NIH animal facilities or have contact with laboratory research animals in a lab area, i.e. ORF maintenance personnel, custodial personnel, etc.

Contract employees
A standard clause is included in the contract for each personnel who performs animal support activities. The clause requires that the contractor develops and implements an occupational safety and health program for its employees that is consistent, as

appropriate, with NIH policies and procedures. The contractor must provide documentation to the government contracting officer's representative demonstrating the contractor's compliance with these specifications. However, emergency care is provided for contract personnel, and exceptions are made for injuries which may include a primate retrovirus or B-virus potential exposure. In those cases, OMS provides chemoprophylaxis if clinically indicated, and related follow-up testing and care. Additionally, contract employees may be included in the OMS Biological Surety Program (BSP) when they work in key facilities and under special circumstances.

3) Describe general features of the medical evaluation and preventive medicine programs, including pre-employment/pre-assignment health evaluation, periodic medical evaluations, immunization programs, and procedures for communicating health related issues.

The OMS medical director, in concurrence with OACU, based the design of the AEP on:
1. An understanding of relevant medical literature,
2. Workplace assessments by safety specialists, and
3. Regular analysis of occupational injuries and illnesses reported over the past 30 years.

AEP Enrollment and Routine Periodic Evaluations
NIH employees and contractors who are enrolled in the BSP, who have contact with laboratory research animals in research are eligible for enrollment in the AEP.

The enrollment evaluation provided by OMS includes: a review of the employee's personal medical history, administration of occupationally-indicated immunizations, and counseling regarding the need to report all injuries, first aid measures, accessing medical care after hours, allergies to laboratory animal proteins, and other suspected health hazards in the work environment. If the employee is expected to have contact with NHPs, the enrollment evaluation includes testing for protection to rubeola and prior infection with M. tuberculosis. If the employee will have access to human pathogens, he/she may elect to have blood drawn for purposes of serum storage.

Contract workers who are not enrolled in the BSP receive services equivalent to the AEP from a community-based healthcare provider and these services are coordinated by their employer. Contract employees identified as having access to NHPs or their living spaces are notified annually of their need to return for repeat testing for infection with M. tuberculosis. If the worker fails to return

within a month of the recall notice, a second email notice is sent to the contractor and the notice is copied to their supervisor.

AEP "For-Cause" Evaluations
Emergency medical support for work-related injuries is available to all workers at the NIH 24/7. Two OMS medical providers are on-call. Valacyclovir is included in our NHP Bite/Scratch Kits, and antiviral treatment is initiated on the advice of OMS medical staff. In addition, agent-specific guidelines are in place to help guide the clinical care provided to staff working with Select Agents and Toxins (SATs) through the BSP.

AEP Reporting
All workers enrolled in the AEP are entered into a web-based database. The database lists the animal user's name, the AEP sections they are enrolled in, and whether their enrollment is current. For participants who require annual testing for tuberculosis, key administrative individuals are given 'read only' access to the web-based AEP database to verify participation in, and compliance with the provisions of the AEP.

Annual AEP Notices
OMS sends an annual notice to all AEP participants reminding them of occupational health risks associated with working with laboratory research animals, the steps they can take to avoid injury, and what they should do if an accident occurs.

The "risk categories" that merit regular medical evaluation in the opinion of the OMS medical director are those AEP participants who have contact with NHPs and those enrolled in the BSP (because they work in or in support of ABSL-3 and -4 laboratories). These AEP participants are recalled annually for tuberculosis testing (as clinically warranted) and for a discussion of workplace hazards, respectively.

The OMS does not warrant standard rodent users to a periodic medical evaluation. The NIH health and safety standard for managing the prevention of animal-related allergies is to remove the hazard via engineering controls with 100% fresh air in all animal facilities, and by the use of ventilated caging racks and HEPA filtered or hard-ducted bedding change stations. The level of allergen exposure is further reduced by appropriately applied PPE. Employees are screened during a pre-placement medical evaluation and are counseled on, and provided information specifically regarding the potential for animal allergens and preventive measures. During the initial evaluation, employees are informed of the required procedures for contacting OMS if their health status changes during the course of their work as an NIH employee. Further medical education and reminders are provided

to employees through measures such as the OACU triennial Refresher course for PIs and Animal Users, through posting animal use areas with DOHS 'animal use' signs, and by OMS distributing periodic health and safety information. This risk-based and scientifically driven standard of medical care has proven effective for managing the animal user population and meets the needs of providing medical evaluations for personnel at risk as defined by our occupational medical team.

4) Describe special precautions or procedures for personnel exposed to potentially hazardous species (nonhuman primates, sheep, etc.) or agents (infectious agents, human origin tissues, chemicals/toxins, etc.).

All personnel working with NHPs are required to complete the NIH Course entitled "Working Safely with Nonhuman Primates" annually and to receive facility-specific training from the veterinary staff and experienced RMVB staff. Bite/wound kits are in all animal facilities housing NHPs and provision for follow-up medical care in cases of potential exposure to Herpes B-virus is provided by the OMS. Protective clothing provided for working with NHPs or infectious agents, human origin tissues, chemicals and toxins include face masks, respirators, PAPRs, eye protection, disposable solid front gowns, foot covers, heavy protective gloves and ABSL-4 positive pressure suits.

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

The DDIR/IO has a policy memo: "Communicating Animal Care and Use Concerns within the NIH Intramural Research Program" that is posted on the OACU website and has been laminated and posted prominently in all animal facilities and other routinely used animal procedure areas. This memo strongly encourages anyone with an animal welfare concern to communicate the concern to a number of individuals they can approach that includes: Veterinary Staff, PI, ACUC chair or member, or the IO. The memo also provides the OACU contact information as an avenue for anonymous reporting and the OACU voicemail phone tree will direct callers to the Director's voicemail to allow messages to be left outside normal duty hours. The procedures in this memo are discussed in all OACU sponsored mandatory training modules/lectures.

The ARAC Guidelines for Responding to Animal Care & Use Complaints from Outside NIH describe the role of the ARAC Ombudsman for assisting with animal welfare concerns that come from outside the NIH community. This guideline is posted on the OACU website and is discussed in the OACU sponsored mandatory training modules/lectures.

When an animal welfare concern is communicated, or identified internally, the ACUC chair is informed and designates a subcommittee to investigate the allegation.

All instances of noncompliance (both protocol and animal program related) are reported to the IO through the OACU Director, in a timely manner, to effect appropriate Institutional communications to determine whether the issue constitutes serious or continuing non-compliance. When issues are determined to represent serious or continuing non-compliance, the OACU Director provides a preliminary report to the DDIR/IO and to OLAW. After the ACUC investigation has occurred and corrective actions have been approved, a comprehensive final report is submitted to the DDIR/IO via the Director, OACU. The DDIR/IO submits a final report to OLAW. After OLAW acknowledges that the actions taken are sufficient, the incident is discussed by the ARAC members for their information/education.

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 an appendix.

i. Describe Committee membership appointment procedures.

Redacted by agreement is responsible for membership appointment per delegated authority from the IO. Redacted Redacted by has delegated that responsibility to Redacted by agreement for RML ACUC membership appointments.

The composition, responsibilities and function of the ACUCs are stated in NIH PM 3040-2. Additionally, the ARAC Ombudsman serves as an ex officio member of the ACUC, and that individual's responsibilities are described in PM 3040-2 and the ARAC Guidelines for Responding to Animal Care & Use Complaints from Outside NIH.

ii. Describe frequency of Committee meetings.

The RML ACUC meets monthly. If necessary, additional emergency meetings are an option.

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

The initial new ACUC member orientation involves a one-on-one orientation with the ACUC Chair and/or the ACUC Coordinator, and an ACUC member training course is provided by the NIH main campus. The NIH ACUC member orientation course: "Defining the Challenge of

ACUC Membership" Course is mandatory and involves sections dealing with ACUC processes and regulatory responsibilities of all animal users and ACUC members. Ongoing training opportunities are available. These include offers for attending OACU training, IACUC 101 meetings, participation in webinars, and Animal Welfare Information Center presentations on searches for alternatives.

b. Protocol Review [Guide, pp. 25-26]

A blank copy of your institution's protocol review form should be provided as an appendix. Also include forms used for annual renewal, modifications, amendments, etc., as applicable.

i. Describe the process for reviewing and approving animal study protocols, including research and teaching proposals. Include a description of how animal study protocols that do not involve a formal grant proposal are reviewed and approved (i.e., pilot studies or internally funded studies). Include a description of how the IACUC/OB weighs the potential adverse effects of the study against the potential benefits that may result from the research. Describe how protocols that have the potential to cause pain or distress to animals are reviewed, alternative methodologies reviewed, veterinary input solicited, and studies controlled or overseen. Specify how animals and experimental group sizes are justified.

ASPs are reviewed by the ACUC to ensure adherence to the humane and ethical principles for use of animals as outlined in the Guide, PHS Policy, the AWR, and PM 3040-2. Protocol deliberations and dispositions adhere to the standards referred to in the ARAC Guideline for Review, Approval, & Post Approval Monitoring of Animal Study Proposals Including Designated Member Review.

Many key ASP procedural details that may be technically difficult or have the potential to cause pain and distress, such as humane endpoints, survival surgery, dietary restrictions and euthanasia techniques, etc., are defined in the ARAC Guidelines which establish the standards expected by the NIH ACU programs.

The expectation is the ASP must present a clear description of the animal procedures. This standard is met through language in the protocol, simple flow charts or diagrams and through deliberations by the ACUC during review. The ACUC composition, which meets PHS Policy standards, ensures a well-rounded, knowledgeable committee, and they collectively ensure the procedures are understood and animal welfare concerns are discussed and addressed.

As the impact of the proposed procedures on the animal's well-being increases, the ACUC weighs the procedures of the study against potential animal welfare concerns in accordance with the study description of alternatives that have been considered, justification of the number of animals required, and experimental refinement. Protocols with procedures that have the potential for more painful or

distressful adverse effects, such as column E procedures, typically garner more discussion by the Committees.

Regardless of funding sources, the PI drafts an initial ASP and submits it to the ACUC coordinator, which is followed by an initial veterinary, biosafety, and facility review prior to distribution to ACUC members for formal review. The default method of ASP review is Full Committee Review.

ii. Describe process for reviewing and approving amendments, modifications, and revised protocols. If applicable, include a description of "major" vs. "minor" amendments.

Review and approval of amendments adhere to the standards referred to in the ARAC Guideline for Review, Approval, & Post Approval Monitoring of Animal Study Proposals Including Designated Member Review. Guidance on reviewing significant changes to ASPs is provided for the ACUC through the ARAC Guideline Regarding Significant Changes to Animal Study Proposals and through the RML ACUC Policy for Changes (Modifications) to Animal Study Proposals

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

i. Experimental and Humane Endpoints [Guide, pp. 27-28]
Describe how criteria for determining alternatives to experimental (humane) endpoints are developed, approved, and applied. Include a description of monitoring systems in place for studies for which information on alternative endpoints are not available.

The PI must address experimental endpoint criteria in section F, no. 10 of the ASP form. These endpoint criteria vary from study to study and are species-dependent for infectious disease studies. The ACUC has agreed upon objective criteria for some studies (e.g., clinical scoring for NHPs in the ABSL-4). Typical criteria for rodent studies include, but are not limited to, the following: activity, food and water intake, body weight, ruffled fur, hunched posture and dyspnea (see NIH ARAC Guidelines for Endpoints in Animal Studies). PIs are required to assure animal health checks of study animals on a daily basis or as specified in the approved ASP.

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

Unexpected outcomes that affect animal well-being are reported by the veterinary staff or self-reported by the research staff to the ACUC for consideration/review.

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.

Not Applicable

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.

Not Applicable

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 institutional policy(ies) regarding multiple survival surgery (major or minor) on a single animal.

NIH policy states that multiple survival surgeries on a single animal are strongly discouraged, but may be permitted if scientifically justified with ACUC deliberation, or if deemed necessary in instances of appropriate veterinary care or veterinary emergency.

2) Describe the procedure for approving multiple survival surgery (major or minor) and the criteria used to determine the potential impact on the animals' well-being.

The procedure for approving multiple survival surgical manipulations is the same as the review process used for all ASPs.

3) Summarize the protocols currently approved that involve multiple major survival surgical procedures and the time allowed between procedures on the same animal. Describe the method of institutional monitoring.

ASP Redacted by agreement (Antisense Oligonucleotides to Delay or Prevent Onset of Prion Disease in Mice): Approval for multiple intracranial administration of oligonucleotides as a potential treatment for TSE disease. Potential repeat treatments are

administered every 60 days. Health checks are performed daily and animals are monitored postoperatively for any adverse effects.

v. Food and Fluid Regulation [Guide, pp. 30-31]

1) Describe experimental situations that require food and/or fluid regulation. Note: This does not include pre-surgical fast. List title of the experiment(s), justification, species involved, and length and type of food/fluid regulation.

Food and fluid restriction are conducted in accordance with the standards outlined in the ARAC Guidelines for Diet Control in Laboratory Animals.

2) Describe animal health monitoring procedures and frequency (e.g., body weight, blood urea nitrogen, urine/fecal output, food/fluid consumed).

Not Applicable

3) Describe methods of ensuring adequate nutrition and hydration during the regulated period.

Not Applicable

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

Describe the rationale and consideration given by the IACUC/OB for use of non-pharmaceutical grade drugs or other substances, if applicable.

The ARAC Guidelines for the Use of Non-Pharmaceutical Grade Compounds in Laboratory Animals is followed. In addition, the ASP form includes a section/question regarding the use of non-pharmaceutical grade drugs and substances. Investigators list the considerations given to lack of availability, sterility, osmolarity, pH, and possible toxicity. Scientific justification must be provided for the use of any non-pharmaceutical grade drug or substance.

vii. Field Investigations [Guide, p. 32]

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

All animal manipulations that occur during field investigations are reviewed and approved by the ACUC in an approved ASP. Special considerations frequently discussed include trap-checking frequency and animal release criteria.

viii. Agricultural Animals [Guide, pp. 32-33]

Describe considerations given and guiding documents used by the IACUC/OB when reviewing "biomedical" and "agricultural" research projects involving agricultural species as study animals, if applicable.

RML conducts only "biomedical" research. When and if agricultural species are used, these species are used as appropriate animal models for biomedical research studies.

ix. Animal Reuse [Guide, p. 5]
Describe institutional policies and/or oversight of animal reuse (i.e., on multiple teaching or research protocols). Summarize the protocols currently approved that involve the reuse of individual animals.

The appropriateness of animal reuse is determined by the ACUC by full committee review on a case-by-case basis in accordance with the RML ACUC Policy on the Reuse of Laboratory Animals.

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

a. Describe mechanisms for IACUC/OB review of ongoing studies and periodic reviews (e.g., annual review, 3-year renewals if PHS funded, etc.).

Approved ASPs are reviewed annually. Laboratory spaces in which animal procedures are conducted are inspected every 6 months during the semiannual ACUC facilities inspection. Veterinary observation of selected procedures and observation of animals by animal care or veterinary staff occurs on a regular and ongoing basis. All approved ASPs must be renewed every 3 years by resubmitting as a new ASP.

b. Describe the process and frequency with which the Committee reviews the animal care and use program and conducts facility and laboratory inspections. Detail any criteria used for exempting or varying the frequency of reviewing satellite holding facilities and 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 an appendix.

In accordance with NIH PM 3040-2 , program reviews and facility inspections for all primary animal facilities, satellite facilities and survival surgery procedure areas occur semiannually. The ACUC reviews the animal care and use program and facilities every six months and submits a written report through the OACU to the IO. The most recent report is attached as Appendix 9. There are no exemptions for varying the frequency of reviewing satellite holding facilities and animal use areas. The semiannual program and facility reviews follow standards set in the ARAC Guidelines on Classifying Deficiencies Identified During Semiannual Reviews.

c. Describe institutional responses to deficiencies noted on regulatory inspection reports (e.g., government, regulatory agencies). Note: Copies of all such inspection reports for the past three years (if available) should be available for review by the site visitors.

The NIH is a federal agency, and as such, is not subject to routine USDA inspections. However, it is bound by the Animal Welfare Regulations and submits a consolidated annual report to the Raleigh, NC, USDA Animal Care Office. Individual reports are generated by each IC and forwarded to OACU for final compilation, IO signature and submission to USDA.

Copies of the last three years of Annual Reports can be made available by OACU.

d. Describe other monitoring mechanisms or procedures used to facilitate ongoing protocol assessment and regulatory compliance.

Programmatic oversight and monitoring occurs via the following measures:

Veterinary and technical/care staff: daily oversight, health checks and investigator interface.

ACUC subcommittee: when specified in the ASP for new or challenging procedures, to document investigator proficiency or provide training.

Semiannual inspection of all primary animal facilities, satellite facilities and survival surgery procedure areas in accordance with the ARAC Guidelines for ACUC Oversight of Animal Activities in Satellite Facilities, Study Areas, Laboratories and Special Procedure Areas.

At least annual inspection of all lab spaces where animal procedures are conducted, which are performed in accordance with the ARAC Guidelines for ACUC Oversight of Animal Activities in Satellite Facilities, Study Areas, Laboratories and Special Procedure Areas.

Annual Protocol Reviews

OACU Observers providing program liaison with all ACUCs to include participation with semiannual facility and program review.

II. Animal Environment, Housing and Management

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

A. Animal Environment

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

a. Describe briefly the heating and air conditioning system performance. Provide method and frequency for assessing, monitoring, and documenting animal room or housing area temperature and humidity that is appropriate for each species. Note current (measured within the last 12 months), detailed (by room) performance data

are to be provided as indicated on the enclosed Heating, Ventilation, and Air Conditioning (HVAC) System Summary appendix. If outdoor housing areas are used, so note.

The temperature and humidity set points established for all animal rooms are dependent upon the species inhabiting the room and are based on current literature/guidelines. Each animal room has an adjustable set point to maintain desired humidity and temperatures. The entire HVAC system of each vivarium is controlled by a centralized computer system with all parameters having set points that will trigger an alarm if not maintained. Computer terminals are located in multiple locations around campus with a server in the Redacted by agreement All alarms appear on the computer screens in the security control center, and give an audible signal until the alarm has been acknowledged. Any alarm generated results in the appropriate maintenance staff being notified immediately. In addition, each animal room is equipped with an independent thermometer/hygrometer, and values are recorded in the room logs daily. These room level devices function as a backup validation system of the automated monitoring systems incorporated into each vivarium.

b. If temperature set points and/or environmental conditions are outside the thermoneutral zone for the species, describe the process for ensuring behavioral thermoregulation (e.g., nesting material, shelter, etc.) and/or IACUC/OB approved exception.

Not applicable, due to no current exceptions to established thermoneutral conditions.

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

a. Briefly describe the performance aspects of the ventilation system. Provide method and frequency for assessing, monitoring, and documenting the animal room ventilation rates and pressure gradients (with adjacent areas). Note: current (measured within the last 12 months) detailed (by room) information is to be provided as indicated on the enclosed Heating, Ventilation, and Air Conditioning (HVAC) System Summary appendix.

Redacted by agreement

The HVAC system for the Redacted by agreement building employs full redundancy with two identical systems, each a single duct system with 8 zones. These units provide greater than 15 air changes per hour and utilize a single pass airflow design. 30% and 95% filter units are located in the supply air system. Supply air is maintained at 55°F by a natural gas fired furnace or a direct expansion refrigeration condenser. A steam humidifier controlled by a humidistat is located in the supply air duct. Duct hydronic (hot water) heating coils achieve the desired temperature for each room. The supply air into the surgical suite flows through diffusers designed specifically for use in surgical suites to provide low velocity vertical "laminar" airflow. Two

separate exhaust units provide 100% redundancy. All air handlers, room temperatures and humidity levels are Redacted by agreement

Redacted by agreement

Redacted by agreement

The air handler system is a single pass airflow design, with 2 filters, a 30% and a final 95% filter. Two supply fans run together to maintain supply air static pressure, temperature, and humidity. If one fan fails, the other ramps up in speed to maintain the required airflow. Steam pre-heat coils and chilled water-cooling coils maintain a constant 55° F supplied air temperature. Each room has an adjustable set point to maintain the desired temperature with its own volume controller and reheat hot water coil to maintain airflow and temperature. The air handler contains the primary humidifier which maintains the supply air at 25% RH at 70° F. The secondary humidifiers are downstream in the supply air duct to boost humidity based on two zones (north and south). All steam for humidification is pure steam with no added chemicals. The building exhaust is controlled through two exhaust fans that operate together; if one fan fails the other fan maintains exhaust. The entire HVAC system is controlled by a centralized computer system with all parameters having set points that will trigger an alarm if not maintained. The main computer terminal is located Redacted by agreement

Redacted by agreement

Redacted by agreement

air handler system is a single-pass airflow design, with two supply side filters, a 30% and a final 95% filter. Two supply fans run together to maintain supply air static pressure, temperature and humidity. If one fan fails, the other fan ramps up in speed to maintain the required airflow. Steam preheated coils and chilled water-cooling coils maintain a constant 55° F supplied air temperature. Each room has an adjustable set point to maintain desired temperature and contains its own volume controller and reheated hot water coil to maintain airflow and temperature. The air handler contains the primary humidifier which maintains the supply air at 25% RH at 70° F. The secondary humidifier is downstream in the supply air duct to boost humidity at the room level. All steam humidification is pure steam with no added chemicals. The building exhaust is controlled through two exhaust fans that operate together. If one fan fails, the other fan ramps up to maintain the required exhaust. All exhaust air is HEPA-filtered. Airflow in the building is directional, with the building negative in relation to the outside and with increased negativity the deeper you go into the building. The pressure relationships between spaces is maintained, monitored, and controlled by a centralized computer system with all HVAC

parameters having set points that will trigger an alarm if not maintained. The main computer terminal is located in Redacted by agreement Redacted by agreement Redacted by agreement

The animal rooms in the Redacted by agreement Redacted are served by a single duct CAV air system supplying 100% outdoor air. Five supply units, each running at 80% of design capacity, feed a common supply duct to provide stable operation; with a quick response to four units at 100% should one unit fail. A 10% safety factor is used for the air quantity of the fan selection. The supply air is set to maintain a constant temperature of 55° F with a set point of 30% RH. Each space has a reheat coil to maintain space temperature, and each room has a secondary humidity grid with adjustable set points. All animal rooms are trended for temperature, humidity, and air change rates. The air handlers have 30% pre-filters and 95% final filters, and each zone is supplied through a HEPA-filter unit. Each area in the high containment animal facility is divided into separate zones. All animal room, BSC, and necropsy table exhausts are connected to an exhaust system manifold. Five exhaust fans, each running at 80% of design capacity, feed a common exhaust duct to provide stable operation; with quick response to four units at 100% capacity should one fan fail. The air from each zone is exhausted through two HEPA-filter units operating in series.

The quarantine animal holding rooms located Redacted by agreement Redacted are served by a single duct CAV air system supplying 100% outside air. Four units, each running at 75% of design capacity, feed a common supply duct to provide stable operation; with a quick response to three units at 100% should one fan fail. A 20% safety factor is used for the air quantity of the fan selection. The supply air is set to maintain a constant temperature of 55° F, with a set point of 30% RH with each space having a reheat coil to maintain space temperature, and a secondary humidity grid with adjustable set points. All animal rooms are trended for temperature, humidity, and air change rates. The air handlers have 30% pre-filters and 95% final filters. Two centrifugal exhaust fans, each operating at 50% capacity with controlled bypass, serve the quarantine animal holding rooms. Failure of one fan results in the immediate ramp up to 100% for the other fan, maintaining negative pressure in the exhaust system at all times.

All HVAC parameters having set points that will trigger an alarm if not maintained. The main computer terminal is located in the Redacted by agreement Redacted by agreement

Redacted by agreement

Redacted by agreement

The air handler system is a single-pass airflow design, with 2 sets of filters, a 30% and a final 95% filter. Redundant air handlers run individually to maintain supply air static pressure, temperature and humidity. If one air handler fails, the other air handler starts and ramps up in speed to maintain the required. Hot water pre-heat coils and chilled water-cooling coils maintain a constant 55°F supplied air temperature. Each room has an adjustable set point to maintain desired temperature and its own volume controller and reheat hot water coil to maintain airflow and temperature. The air handler contains the primary humidifier which maintains the supply air humidity controlled to an exhaust humidity set point with a saturation limit at 55° F discharge air temperature. All steam for humidification is done with softened water with no added chemicals. The building exhaust is controlled through two exhaust fans that operate individually; if one fan fails the other fan starts and maintains exhaust volume. The entire HVAC system is controlled by a centralized computer system with all parameters having set points that will trigger an alarm if not maintained. There are multiple computer terminals located around campus with a server in the

Redacted by agreement

All animal housing rooms are trended for temperature, humidity, and air change rates on an ongoing basis.

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

Most rodents are housed in IVCs with stand-alone blowers and exhaust units. In the ABSL-4 animal facility, ferrets and guinea pigs are housed in ventilated biocontainment cage racks with stand-alone HVAC units.

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.

All animal care and use facilities at NIH use 100% outdoor air in a one-pass configuration with individual room temperature control.

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

Provide a general description of institutional requirements for enclosures using water as the primary environmental medium for a species (e.g., aquatics). Describe overall system design, housing densities, and water treatment, maintenance, and quality

assurance that are used to ensure species appropriateness. Please note that facility-specific tank design and parameter monitoring frequencies should be summarized in the Aquatic Systems Summary appendix.

RML currently does not house aquatic species

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.

All animals are housed in closed rooms away and separated from human-use areas. Nonhuman primates are housed in areas separate from other species. Buildings are constructed of concrete or brick, which minimizes noise transmission. Inherently noisy activities or equipment, such as back–up generators, are located away from animal facilities. Cagewash noise levels are monitored by the DOHS.

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

1. Primary Enclosures
Provide a description of primary enclosures used (e.g., cages (conventional, individually-ventilated cage systems (IVCS), etc.), pens, stalls, pastures, aviaries, tanks) in appendix.

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.

RML meets all requirements of the NRC Guide and the AWRs. The USDA APHIS Animal Care Policy may be used as a reference in certain circumstances not addressed in detail in the Guide or AWRs.

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]

RML has four species of dwarf hamsters, including Djhungarian (*Phodopus campbelli*), Siberian (*Phodopus sungorus*), Chinese (*Cricetulus griseus*) and Armenian (*Cricetulus migratorius*) hamster. These four species are approximated the size of a laboratory mouse. Because of their relatively small size, these hamsters have difficulty reaching the water lixit valve and food hopper in a standard (6" high) hamster cage, however, they are able to reach food and water comfortably in a standard (5" high) mouse cage. The RML ACUC has approved the stated performance standard for the

routine housing of these hamsters in standard mouse height cages for these dwarf species.

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

a. 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, etc.).

The following species are provided with structural elements within the primary enclosures:
Mice, hamsters and rats – lofts.
Nonhuman primates – resting boards and perches.
Bats – roost boxes.

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: nesting material, tubes, huts, manipulanda, wood blocks
Rats: nesting material, tubes, manipulanda
Hamsters: nesting material, tubes, manipulanda
Guinea pigs: tubes, huts, manipulanda, foraging
Ferrets/mink: tubes, huts, manipulanda, foraging
Rabbits: manipulanda, foraging
Swine/sheep/goats: manipulanda, foraging
NHPs: mirrors, manipulanda, foraging
Bats: manipulanda, foraging

b. Social Environment [Guide, p. 64]

i. Describe institutional policy or strategy for social housing of social species.

The standards for enrichment adhere to the ARAC Guidelines for General Species Environmental Enrichment, and accompanying appendices for Rodents and Nonhuman Primates.

The policy at RML is to pair/group house all social species whenever possible, unless scientifically justified in an approved ASP or by veterinary exception. In addition, RML has an ACUC approved "Environmental Enhancement Program to Promote the Psychological Well-being of Nonhuman Primates (The Plan)" as a specific policy for social housing of NHP species.

ii. If social animals are not socially housed, provide justification, as approved by the IACUC/OB.

Animals on approved infectious disease ASPs may be singly-housed for the duration of the studies. The avoidance of direct contact between infected animals, and therefore the potential for cross-contamination, may require single housing. In addition, animals displaying aggressive behavior, for medical and/or clinical treatment, or quarantine purposes, may be singly-housed temporarily or long term, based on assessment by the veterinary staff.

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

Individually-housed animals have visual, olfactory and auditory contact with conspecifics whenever possible. Individually housed or isolated animals receive species-appropriate environmental enrichment, including nesting materials, foraging, and manipulanda. In addition, isolated animals have increased positive human interaction, behavioral monitoring and communications amongst the veterinary and research staff.

c. 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.

All efforts are made to dedicate animal care staff to particular animal rooms, and to perform standardized husbandry practices on consistent schedules. When housing conditions are changed (such as moving into the ABSL-4), animals are allowed to acclimate to their new surroundings while maintaining routines with which they are familiar. Whenever possible, positive reinforcement training is utilized to help acclimate animals to new or repeated procedures.

d. 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.

Enrichment programs are reviewed at least annually by the ACUC and continually by the veterinary staff. Changes to the programs are made as needed.
Single housing is limited to the minimum period necessary to achieve research or veterinary objectives. NHPs may be exempted from social

housing due to its health, condition or in consideration of its well-being. If the exemption is not permanent, it is reviewed by the veterinary staff at least every 30 days.

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

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

Not Applicable

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

Not Applicable

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

Not Applicable

f. Naturalistic Environments [Guide, p. 55]

i. Describe types of naturalistic environments (forests, islands) and how animals are monitored for animal well-being.

Not Applicable

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

Not Applicable

iii. Describe how animals are captured.

Not Applicable

C. Animal Facility Management

1. Husbandry

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

i. List type and source of food stuffs.

Mice/rats/hamsters: Teklad Rodent Diet 2016/2018/2916

Guinea pigs: Teklad Guinea Pig Diet 2041
Ferrets: Teklad Ferret Diet 2072
Rabbits: Teklad Rabbit Feed 2031
Swine: Teklad Swine Diet 7200 or from vendor where animals were purchased.
Sheep/goats: Teklad Ruminant Diet 7060 or from vendor where animals were purchased.
NHPs: Harlan Primate Diet 2055
Bats: fresh fruit

Swine, sheep, and goat feed is purchased as described above, or from the vendor of which the animals were purchased. Fresh fruit, vegetables, and other items fed to the animals are purchased from local grocery vendors.

ii. Describe storage facilities of vendors, noting temperature and vermin control measures. If more than one source, describe each.

RML personnel do not inspect distributors' storage facilities. Feed is directly shipped from our feed distributers every two weeks, or as needed.

iii. Describe bulk food storage facilities, if applicable, noting temperature and vermin control measures. Note food storage areas within the specific animal facilities are described below in Section IV.B.4.a. Physical Plant.

Redacted by agreement
Food is stored on pallets in a gasketed, vermin-proof walk-in cooler maintained at 38°F.

Redacted by agreement
Food is stored on racks in a gasketed, vermin-proof walk-in cooler maintained at 38°F.

iv. Describe food storage in animal rooms.

Feed is transferred as needed, from the above-mentioned storage rooms to the animal holding rooms. Within individual animal rooms, feed is placed in plastic sanitizable bins with locking lids. Storage bins are sanitized a minimum of every 2 weeks.

v. Describe food preparation areas.

Food preparation occurs in the NHP procedure room Redacted by agreement or in the food preparation room Redacted by agreement

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

Mice/rats/hamsters: fed ad libitum via stainless steel wire cage insert.
Guinea pigs: fed ad libitum via J feeders.
Ferrets: fed ad libitum via J feeders.
Rabbits: fed ad libitum via cage mounted feeder.
Swine/sheep/goats: fed ad libitum via cage mounted feeder.
NHPs: fed twice daily via cage mounted feeder, ration based on the individual animal's body condition
Bats: fed ad libitum via cage mounted bowls and skewers.

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

There is no sampling/testing of laboratory animal feeds conducted at RML. All feed bags are inspected upon receipt of each new shipment, and defective bags are rejected. The feed contract with the national distributor requires all laboratory animal feeds to meet specific NIH laboratory feed standards. Milling dates are checked at the time of delivery and all feed is rotated by milling dates and used within 180 days of milling (or per manufacturer's recommendations). Older food is rotated such that it is used first.

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, etc.).

Redacted by agreement
A reverse osmosis (RO) water system is used to supply the automatic watering systems. In addition, RO water is used with the Hydropac™ watering system, which further filters and chlorinates the water prior to filling of the water pouches. The chlorinated water is also used to fill water bottles, if needed.

Redacted by agreement
RO water is used to supply the Hydropac™ watering system, as described above. The chlorinated water is also used to fill water bottles, if needed.

Redacted by agreement
City water is used to supply the automatic watering systems and to fill water bottles.

Redacted by agreement

Filled Hydropac™ pouches are utilized from Redacted by agreement

Provision of water to animals:
Mice/rats/hamsters: Hydropac™ water pouches, water bottles.
Guinea pigs: water bottles.
Ferrets: water bottles.
Rabbits: water bottles, automatic watering system.
Swine/sheep/goats: automatic watering system, buckets.
NHPs: water bottles, automatic watering system.
Bats: bowls.

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

The city of Hamilton monitors the water quality, which is tested monthly. The RO water systems in Redacted by agreement are equipped with an alarm to prevent disruption or loss of capacity of the system. All RO water is tested quarterly via colony plate counts by a quality control microbiologist at RML. In addition, every batch of Hydropac™ pouches are tested for sterility by our quality control microbiologist before being put into circulation.

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

The automatic watering systems in Redacted by agreement are decontaminated with sodium hypochlorite and flushed on a monthly basis. Automatic watering systems in the Redacted by agreement are connected to potable city water, which is chlorinated. The RO water from Redacted by agreement is monitored on at least a quarterly basis (or if deemed necessary). If contaminants are detected in the RO water above established thresholds, the entire RO watering system is sanitized and flushed.

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

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

Heat-treated and screened laboratory animal bedding consisting of aspen wood chips from a commercial laboratory animal bedding producer, is used as both direct and indirect bedding for all rodent species, ferrets and rabbits. Sterile paper-based or autoclaved aspen chip bedding is used for the mouse foundation stocks and immunocompromised animals.
Nesting materials are provided to rodents and may include nestlets, crinkle paper and paper sheets.

ii. Describe bulk bedding storage facilities, if applicable, including vermin control measures. Note bedding storage areas within the specific animal facilities are described below in Section IV.B.4.a.

Bulk laboratory animal bedding is stored bagged on pallets in a separate vermin proof building. To provide for daily needs, a single pallet of bedding is stored in a small separate room adjoining the clean side of the cage wash area in the main animal facility [Redacted by agreement] A contractor provides vermin surveillance and control for all storage and animal facilities.

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

The bags of bedding are inspected upon receipt of our facility. All defective bags are rejected. Older bedding is rotated such that it is used first. Autoclaved bedding is monitored with the use of sterilization indicators. Other monitoring of bedding is conducted by the manufacturer.

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.

The very short distances between facilities on the RML campus allows for most transport to be done manually in filtered transport cages/boxes. Two motorized utility vehicles (ATVs) and a small pickup, each with heated cabs, are occasionally used to transport animals short distances when deemed necessary.

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

Steam guns are available for occasional cleaning and sanitation purposes, as well as low and high pressure sprayers and wet/dry HEPA-filtered vacuum cleaners.

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.

Mice/rats/hamsters: conventional cages with contact or non-contact
bedding is changed at least once per week; individually ventilated

cages with contact bedding are changed at least once every two weeks.
Guinea pigs: contact and non-contact bedding is changed at least twice
per week.
Ferrets: contact and non-contact bedding is changed at least once every
five days.
Rabbits: non-contact bedding is changed at least twice per week.
Swine/sheep/goats: no bedding used.
NHPs: no bedding used.
Bats: no bedding used.

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

Not Applicable

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

Redacted by agreement

Most soiled bedding is disposed of in a portable laminar flow dump station in the dirty side of cage wash.
Any cages with soiled bedding potentially contaminated with BSL-2 human pathogens are autoclaved before going to cage wash for disposal.
Clean bedding is placed into clean cages on the clean side of cage wash.

Redacted by agreement

All soiled bedding is disinfected and disposed of in BSC dump stations within the animal rooms. Cages and bedding are then autoclaved before disposal or going to cage wash.
Clean bedding is placed into clean cages on the clean side of cage wash.

Redacted by agreement

Disposable caging: soiled cages/bedding are double bagged, autoclaved
and disposed of by incineration.
Reusable caging: soiled bedding is disposed of in portable laminar flow
dump stations within the animal rooms, autoclaved, and disposed of by
incineration.

Clean bedding is placed into clean cages in a staging area on the first floor. Some caging is purchased as sterile setups, and come prefilled with sterile bedding.

Redacted by agreement

Disposable caging is used exclusively and the soiled cages/bedding is double bagged within the animal rooms, stored in bins and transferred directly to the incinerator.
Clean bedding is placed into clean cages in a staging area within each facility. Some caging is purchased as sterile setups, and come prefilled with sterile bedding.

ii. Cleaning and Disinfection of the Micro- and Macro-Environments
Describe the washing/sanitizing frequency, and methods used in the Appendix, "Cleaning and Disinfection of the Micro- and Macro-Environment."

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

Not Applicable

2) Assessing the Effectiveness of Sanitation and Mechanical Washer Function

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

Cage and bottle washers are monitored with temperatures recorded during cycling as well as temperature indicators. The washers will not operate if the rinse cycle does not reach and maintain a minimum temperature of 180° F. Temperature indicators are also used on all caging. A log book is kept containing the daily temperature verification. All rodent cages are autoclaved following washing and sanitization in Redacted by agreement
Redacted
Sanitization of caging is monitored by ATP surface test weekly. Each wash load is visually inspected for debris and reprocessed if necessary.

b) Describe preventive maintenance programs for mechanical washers.

RMVB works with Sanitation Strategies for routine/quarterly preventive maintenance (PM) of all mechanical washers, as well as call backs if mechanical troubles/failures occur. In addition, two full-time biomedical equipment technicians are on the RML campus and perform autoclave and mechanical washer maintenance for RMVB equipment.

f. Waste Disposal [Guide, p. 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

Redacted by agreement

Uninfected waste is double bagged, stored in bins and transferred to the incinerator several times per week.
Any cages with soiled bedding potentially contaminated with BSL-2 human pathogens are autoclaved prior to going to cage wash for disposal. The autoclaved bedding is then double bagged, stored in bins and transferred to the incinerator several times per week.

Redacted by agreement

All waste is double bagged, autoclaved, stored in bins and transferred to the incinerator several times per week.

Redacted by agreement

All waste from quarantine is double bagged, stored in bins and transferred to the incinerator several times per week.
All waste from the Redacted is double bagged, autoclaved and transferred to the incinerator several times per week.

Redacted by agreement

All waste is double bagged, stored in bins and transferred to the incinerator several times per week. Some waste is autoclaved prior to being stored in the bins and transferred to the incinerator.

ii. Animal carcasses

Redacted by agreement

Carcasses of naive, excess rodents from breeding colonies are bagged and stored in a designated freezer until collected by local wildlife rehabilitators for use as a food source for injured raptors and/or carnivores (frequency dependent upon need).

All other carcasses are double bagged, tagged with identifying information and stored in a designated freezer until transferred to the incinerator (frequency dependent upon need).

Redacted by agreement

All carcasses are double bagged, tagged with identifying information, logged into the freezer log, and placed in the designated access-restricted freezer until transferred to the incinerator (frequency dependent upon need).

Redacted by agreement

Carcasses from quarantine are double bagged, tagged with identifying information, transferred to the designated freezer in [Redacted by agreement] and stored until transferred to the incinerator.

Carcasses from the [Redacted] are double bagged, tagged with identifying information, logged into the freezer log, and stored in a freezer within the ABSL-4 laboratory until autoclaved. Once the autoclaved load has been validated, the carcasses are then transferred to the incinerator (frequency dependent upon need).

[Redacted by agreement]
Carcasses are double bagged, tagged with identifying information and stored in a designated freezer until transferred to the incinerator (frequency dependent upon need).

iii. Hazardous wastes - infectious, toxic, radioactive, sharps and glass

Infectious waste is double-bagged, labeled, outer bag chemically disinfected and/or autoclaved, and then transported to the incinerator for burning. See above description for the disposal of infected animal carcasses. Hazardous chemicals that are to be disposed of, are placed in proper storage containers, labeled, inventoried and stored in a holding building until a private contractor picks them up for shipment and final disposal. All sharps and glass are placed in approved sharps containers, autoclaved, then incinerated. Frequency of disposal for all items is based on need.

g. Pest Control [Guide, p. 74]

i. Describe the program for controlling pests (insects, rodents, predators, etc.) noting the control agent(s) used, where applied, and who oversees the program and applies the agent(s). Include a description of natural predators (e.g., barn cats) or guard animals (e.g., dogs, donkeys) used for pest and predator control, if applicable.

A contractor is used for pest control procedures at RML and is overseen by the Occupational Health and Safety Manager. No volatile insecticides are used in animal rooms to control insects.

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

The methods used do not include volatile insecticides. In the event, such chemicals must be used, investigators and personnel will be notified.

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

i. Describe procedures for providing weekend and holiday care. Indicate who (e.g., regular animal care staff, students, part-time staff, etc.) provides and oversees care and what procedures are performed. Indicate qualifications of weekend/holiday staff if not regular staff.

RMVB animal care technician staff rotate through a weekend and holiday work schedule. A minimum of four technicians are scheduled to perform needed tasks, including daily health checks and needed cage cleaning on weekends and holidays. If any issues arise, the Facility Manager is immediately contacted.

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

Emergency call-down lists are posted within all animal facilities, providing telephone numbers of the veterinary staff, Facilities Manager and Supervisory Technicians. The lists indicate the order in which individuals should be called. A schedule detailing the on-call veterinarian and weekend/holiday husbandry staff is distributed and posted throughout the campus.

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, etc.).

Mice/rats/hamsters: cage card, sharpie, tattoo, ear punch, ear tag, microchip.
Guinea pigs: cage card, sharpie, tattoo, ear tag, microchip.
Ferrets: cage card, tattoo, ear tag, microchip.
Rabbit. cage card, sharpie, tattoo, ear tag, microchip.
Swine/sheep/goats: ear tag, sharpie, tattoo, microchip.
NHPs: cage card, sharpie, food coloring, tattoo, neck ID band, microchip.
Bats: cage card, sharpie, hair clipping, leg/thumb band, tattoo, microchip.

b. **Record Keeping**

Describe procedure(s) for maintaining individual records on animals. Identify the species for which individual records are maintained, individuals (titles, not necessarily names) responsible for maintaining the records, and where they are maintained and how veterinary and IACUC/OB access is assured.

Individual records are kept for rabbits, ferrets, swine, sheep, goats, NHPs and bats as described in the SOP titled "Animal Medical Records". Records are maintained by the clinical veterinarians, biologists and High Containment Study Coordinator. Records are kept in Redacted by agreement depending upon the animal's location. Records are available to the ACUC at all times.

c. Breeding, Genetics and Nomenclature

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

Investigators state the stock or strain requirements in the ASP. The veterinary staff and the Facilities Manager routinely provide advice on animal selection and make recommendations as to resources available for such information.

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 applies to commercially obtained animals. The genetic profiles of all mice (including transgenic and knockout strains) used at RML are available to investigators for publication and scientific uses.

iii. For newly generated genotypes, describe how new phenotypes that negatively impact well-being will be monitored, managed and reported to the IACUC/OB in a manner to ensure the animals' health and well-being.

Unusual and unexpected clinical phenotypes are reported by the animal care staff to the veterinary and scientific staff. More formal phenotypic characterization (gross pathology, histology, behavioral, etc.) can be performed by the veterinary and technical staff and some investigators may request formal phenotypic characterization of newly generated or novel genetically altered mouse lines. Phenotypes which may cause painful or distressful effects to the mice would be described in section F, (10) of the ASP. The PI would be required to describe humane endpoints and intervention strategies to alleviate pain or distress caused by such phenotypes.

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; 51-57]

1. Animal Procurement

Describe the method for evaluating the quality of animals supplied to the institution (e.g., from commercial vendors, other institutions, etc.).

Mice/rats/hamsters

Most rodents are purchased from commercial vendors and are certified specific pathogen free (SPF). Rodents from other sources must show proof of SPF status and are placed in quarantine until approved for movement into housing facilities.

Guinea pigs
All purchased guinea pigs are from a commercial SPF vendor.

Ferrets
All ferrets are purchased from a commercial SPF vendor.

Rabbits
All rabbits are purchased from a commercial SPF vendor.

Swine/sheep/goats
All swine, sheep and goats are purchased from vendors who supply records of vaccinations and herd health status.

NHPs
All NHPs are purchased from USDA licensed dealers or NIH-owned domestic colonies.

Bats
All bats are purchased from vendors who supply confirmation of herd health status.

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).

All NIH transportation is provided in accordance with the following ARAC Guidelines:
Guidelines for NIH Rodent Transportation
Guidelines for NIH Non-Rodent Transportation

Commercial couriers (USDA licensed courier for all covered species) are used for all shipments of laboratory animals to and from RML. All transport of animals between facilities at RML is done via transport cages and accomplished in a manner which protects the animals and the handlers.

B. Preventive Medicine

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

a. Describe methods used to monitor for known or unknown infectious agents.

Prior to any incoming shipment, the health status of the animals is obtained from the vendor whenever possible.

RML adheres to the ARAC Guidelines for the Prevention and Control of Tuberculosis in Nonhuman Primates to monitor and assess this aspect of NHP health.

All rodents and rodent products are imported based on the procedures in the Policy Manual 3043-1: Introduction of Rodents and Rodent Products.

Sentinel animals are established for all strains of rodents. On a quarterly basis, sentinel serum samples are sent to a commercial laboratory to test for specific pathogen titers. Selected sentinels and/or colony animals are evaluated by the RMVB Pathology Section by complete necropsy and quality control testing. The AV initiates non-routine serology and necropsy as required.

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

In the event that undesirable infectious agents are detected in animal colonies, management plans are put in place on a case-by-case basis and may include treatment, depopulation, isolation, or rederivation.

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

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

All animals receive an initial health check upon removal from their shipping containers/crates.
Ferrets, rabbits, swine, sheep, goats and bats also receive an intake physical exam within one week of arrival.
NHPs receive an intake physical exam, initiation of TB testing and viral serology testing (as needed) within one week of arrival.

b. Describe quarantine procedures for each species that are purpose bred.

Rodents
All rodents received from approved commercial SPF vendors are permitted direct entry into RML facilities. Rodents from other sources must undergo quarantine and testing prior to entry into the main facilities. Rodents undergo a minimum of six-month quarantine, with two sequential satisfactory serologic and parasite test results prior to moving into the experimental or breeding animal facilities.

In certain instances, rodents from non-approved sources may arrive and be placed directly into the MCL without undergoing a specific quarantine period.

Ferrets

Ferrets from an approved commercial SPF source are given an acclimatization period, but not a formal quarantine, prior to use on approved studies.

Rabbits
Rabbits come from one commercial SPF source and are given an acclimatization period, but not a formal quarantine, prior to use on approved studies.

Swine/sheep/goats
Swine, sheep and goats from an approved SPF source are given an acclimatization period, but not a formal quarantine, prior to use on approved studies.

NHPs
Newly arrived NHPs are quarantined for a minimum of 30 days until satisfactory physical examinations, 2 negative TB tests and serologic tests are conducted.

Bats
Bats and are given an acclimatization period, but not a formal quarantine, prior to use on approved studies.

c. Describe the quarantine facilities. In your description explain any special measures used for quarantine/conditioning of each random source (not bred and raised specifically for research) species used.

The rodent quarantine facility is located in Redacted by agreement This building consists of 4 animal holding rooms.

The NHP quarantine area is on the Redacted by agreement consisting of 5 animal rooms, a procedure room and locker room. This ABSL-2 quarantine area is dedicated for animals intended for use in approved ABSL-4 studies.

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

Mice/rats/hamsters: minimum of three days prior to use on study.
Guinea pigs: minimum of five days prior to use on study.
Ferrets: minimum of five days prior to use on study.
Rabbits: minimum of five days prior to use on study.
Swine/sheep/goats: minimum of seven days prior to use on study.
NHPs: minimum of 30 days post-arrival, and 5-7 days after transfer to study room
prior to use on study.
Bats: minimum of seven days prior to use on study.

e. 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.

Species separation is maintained in most RML animal facilities, with any exceptions listed below in 3.b. Animals from different vendors are maintained separately until cleared from quarantine and approved by the veterinary staff.

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

a. Describe isolation procedures and related facilities for animals.

No specific isolation facilities are utilized, other than the quarantine facilities. If needed, isolation of particular animals is handled on a case by case basis.

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

In some rodent housing areas, multiple species may be housed in the same room. All animals are housed in IVCs and different species are maintained on different racks whenever possible.

Redacted by agreement

Mus musculus and *Peromyscus maniculatus* and/or *P. leucopus* may be co-housed in the same room.

Redacted by agreement

Mus musculus and *Mastomys natalensis* may be housed in the same room.

Redacted by agreement

Multiple species of rodents (*Mus musculus, Mastomys natalensis, Peromyscus sp.*, hamsters) may be housed in the same room depending upon study requirements.

Redacted by agreement

Syrian golden hamsters and *Rattus rattus* may be housed in the same room.

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

a. Describe 1) the procedure(s) for daily observation of animals for illness or abnormal behavior, 2) the observer's training for this responsibility, and 3) method for reporting observations (written or verbal). Include a description of the method for ensuring that reported cases are appropriately managed in a timely manner.

ABSL-2 and ABSL-3 facilities
The animal technicians are required to perform daily health checks and observation of all animals housed in their assigned areas. Rodents are checked at least once per day. Non-rodent species are checked at least twice per day. These technicians receive training when first hired and continue to receive on-the-job training. If any sick, injured, dead (or other abnormalities) animals are detected, the animal technician flags the cage with a pink Vet Check card, completes a Morbidity and Mortality Report (Form 101) and delivers the report to the veterinary staff. In addition to the form, direct communication (i.e. phone, text, email) with the veterinary staff, Supervisory Technician, Facilities Manager and/or research team (if the animal is on study) may also occur, especially for urgent cases. The veterinary staff checks all reports and examines the animals as necessary in a timely manner. Cases are monitored by the veterinary staff until the condition resolves or the animal is euthanized. Once the case is closed, the pink Vet Check card is removed.

ABSL-4 facility Redacted by agreement
The animal technicians are required to perform daily health checks and observation of all animals housed in their assigned areas. Rodents are checked at least once per day. Non-rodent species are checked at least twice per day. If any sick, injured, dead (or other abnormalities) animals are detected, the animal technician flags the cage with a pink Vet Check card (for sick, injured or other abnormalities), completes a Morbidity and Mortality Report (Form 101) and scans the report to a file on the server. The technician then alerts the veterinary staff of the situation and report. In addition to the form, direct communication (i.e. phone, text, email) with the veterinary staff, Supervisory Technician, Facilities Manager and/or research team (if the animal is on study) may also occur, especially for urgent cases. Redacted by agreement
Redacted by agreement
Redacted by agreement The veterinary staff and/or research team responds to all reports in a timely manner.

All facilities
RML policy also places responsibility for daily (or as detailed in the approved ASP) health check and observation of experimental animals on the research team.

b. Describe the methods of communication between the animal care staff/veterinarians and the researcher(s).

Methods of communication include, but are not limited to: in-person, written, telephone, text, or email, depending on the time sensitivity of the information to be relayed.

c. Describe the procedure for providing veterinary medical care to ill animals and note who is contacted and the method of communicating (written or verbal) information to the veterinarian regarding sick animals.

During regular hours, sick animal reports (as described in section III.4.a.) may be left in a drop box outside the veterinarian's office or the technician may hand deliver the report to the veterinary staff, supervisor and/or facility manager depending upon the severity of the issue. The veterinarian responds as quickly as possible to provide veterinary assessment/care/treatment as needed.
On weekend/holidays or other non-regular hours, the form is typically left in the drop box outside the veterinarian's office in addition to direct contact with the veterinarian on-call via phone or text for urgent cases. The veterinarian then comes to the facility as necessary to provide medical care.

d. 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, etc.) for each species.

Rodents: Sentinel testing is conducted quarterly.

Ferrets: Ferrets have their nails trimmed as needed.

Rabbits: Rabbits are weighed and have their nails trimmed as needed, typically once per month.

Swine/sheep/goats: hoof trimming is performed as needed

NHPs: NHPs receive annual physical exams, hematology and clinical chemistries, TB testing, +/- serological viral testing. Dental cleanings and nail trimming are performed as needed.

Bats: bats have their nails trimmed as needed.

C. Clinical Care and Management [Guide, pp. 113-115]

1. Emergency Care [Guide, p. 114]

a. Describe the procedures to ensure that emergency care is continuously available for animals during and outside of regular work hours.

Schedules detailing weekend/holiday animal care and on-call veterinary staff coverage are distributed and posted in the animal facilities. Additionally, emergency call-down lists are posted within all animal facilities, giving the telephone numbers of the Clinical Veterinarians,

Facilities Manager and Supervisory Technicians. The roster indicates the order in which individuals should be called.

Redacted by agreement

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

The NIH Policy Memo: Timely Assessment and Resolution of Animal Issues Involving Potential Pain and Distress expresses the DDIR/IO's expectations for daily monitoring, communication, response and care of the research animals.

Policy Manual 3040-2 states: "the Facility Veterinarian has the responsibility and authority to ensure timely adequate veterinary care to all animals housed in the facility."

A completed RML Instructions for Emergency Animal Treatment and Care form must be attached at the end of the ASP form. This is a pre-arranged agreement between veterinary staff and the study PI on procedures to be followed if emergency treatment of study animals is required.

2. Clinical Record Keeping [Guide, p. 115]

Describe the procedure for maintaining medical records and documenting treatment of ill animals including: clinical laboratory findings, diagnoses, treatments, medical progress records, etc. Identify individual(s) (titles, not necessarily names) responsible for maintaining such records and identify where the records are maintained and who has access to the records. Describe the role of the Attending Veterinarian in record keeping.

Rodent Species
Treatment of rodents (such as nail trims and iodine application for dermatitis) is documented on individual cage cards by the person performing the treatment. Significant study procedures (injections, blood withdrawals, etc.) are recorded on individual cage cards. The PI is responsible for recording the data.

Non-rodent Species
Individual records are kept for rabbits, ferrets, swine, sheep, goats, NHPs and bats as described in the SOP titled "Animal Medical Records". All health and study-related animal observations/procedures/treatments/etc. are recorded and maintained within individual animal health records.

Animal health records are the responsibility of the Clinical and Attending Veterinarians, and are maintained in Redacted by agreement by the veterinarians,

biologists and High Containment Study Coordinator. Records are available to these personnel, the ACUC, the research team and selected animal care staff/supervisors.

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

   a. In-house diagnostic laboratory capabilities.

   Clinical pathology (hematology, clinical chemistries, urinalysis, blood gases), gross pathology and histopathology are available.

   b. Commercially provided diagnostic laboratory services.

   Commercial laboratories routinely provide diagnostic services. Services include serologic screening for common rodent and NHP pathogens, as well as full clinical laboratory services.

   c. Necropsy facilities and histopathology capabilities.

   Necropsy facilities and complete histopathology capabilities are available within the RMVB Pathology Section. In addition, the RMVB Veterinary Pathology Section provides full-service histology services to RML investigators. Necropsy rooms are located in Redacted by agreement and in the Redacted by animal housing area of Redacted by agreement

   d. Radiology and other imaging capabilities.

   Imaging capabilities include: digital radiography, ultrasonography, IVIS Lumina XR imaging unit, and flexible endoscopy.

4. **Drug Storage and Control**

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

   Redacted by agreement

   b. Describe record keeping procedures for controlled substances.

   Upon receipt, a controlled substance record is generated and added to the controlled substances log. The AV, who is the drug control custodian at

RML, maintains records for the use of controlled drugs, located in Redacted by agreement Redacted by agreement

Drug administration/sedation logs (Form 305) are completed when controlled substances are administered by RMVB staff. Completed logs are filed in individual animal health records and/or study records.

RMVB adheres to the NIH Policy Manual 1345 – Handling and Safeguarding of Controlled Substances for Nonhuman Use

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

1. Pre-Surgical Planning [Guide, p. 124]

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 postoperative care.

Investigators with proposed surgical procedures meet with the veterinary staff to discuss all aspects of the proposed activity, including proposed personnel and their level of training, availability of equipment, supplies and facilities, anesthesia/analgesia requirements, and pre- and post-operative care, prior to submission of the ASP to the ACUC for review.

2. Surgical Facilities [Guide, p. 116]

a. List building name(s) and room number(s) or other locations (coded, if confidential) where surgical procedures are performed. Include areas where surgical procedures are conducted in agricultural species. Indicate the type of species, nature of procedure (major/minor/emergency; survival and non-survival, etc.). Indicate for each surgical area if the use is heavy (daily), moderate (weekly), or light.

Redacted by agreement

Minor, major and/or emergency surgical procedures on non-rodent species is conducted in the surgical suite in the Redacted by agreement building, light use.

Redacted by agreement

Minor and/or emergency surgical procedures in nonhuman primates, light use, is conducted in room Redacted

Major, non-survival surgical procedures in nonhuman primates, light use, is conducted in room Redacted

Redacted by agreement

Minor and/or emergency surgical procedures in nonhuman primates, light use, is conducted in room Redacted by agreement

Redacted by agreement

Major survival rodent surgery, moderate use, is conducted in room Redacted by agreement

b. List the major surgical support equipment available at each location where survival or nonsurvival surgery is performed (e.g., gas anesthesia machines, respirators, etc.).

Redacted by agreement
Gas anesthesia machines, ventilator, HR/SpO_2/BP/temperature monitor, electrocautery, heat support.

Redacted by agreement
Gas anesthesia machines, ventilator, HR/SpO_2/BP/temperature monitor, electrocautery, heat support.

Redacted by agreement
Gas anesthesia machines, ventilator, HR/SpO_2/BP/temperature monitor, heat support.

Redacted by agreement
Gas anesthesia machines, heat support.

c. Describe any specialized considerations for designation of surgical areas (e.g., rodents, aquatics, farm animals, etc.).

Not applicable.

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, etc.).

NIH Policy, the Guide, and USDA guidelines are used to differentiate major from minor, and survival from non-survival procedures. A survival surgery that penetrates and exposes a body cavity or potentially produces an impairment of physical or physiologic function in an animal is considered a major procedure. Other procedures are considered minor procedures.

b. How is non-survival surgery defined?

Non-survival surgery would be defined, as in the Guide, as any surgery wherein the animal is euthanized before recovery 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.

Aseptic surgery is performed using standard aseptic techniques.
Patient: hair removal, surgical site preparation with iodine or chlorhexidine based solutions.
Surgeon and staff: surgeons cap, mask, hand scrub, sterile gown and gloves, sterile drapes and instruments.

b. Describe methods used to sterilize instruments and protective clothing. Indicate how effectiveness of sterilization is monitored and, if applicable, any approved alternate methods for instrument re-sterilization between serial surgeries. If used, include a description of approved liquid sterilants and instrument exposure time(s) required for each.

Rodents
Surgical instruments, drapes, etc. are routinely autoclaved with temperature/steam indicators for sterilization within all prepared packages. For rodent surgery in [Redacted by agreement] instruments are cold sterilized (2% chlorohexidine solution diluted to .05% working concentration in cold trays) with an exposure time of 20-30 minutes of immersion before the start of surgeries. Instruments are re-immersed intermittently between animals. Clothing for these procedures include a protective gown, surgical cap, masks and gloves.

Nonhuman Primates
Instruments: sterile instruments are utilized for each surgery. Instruments are steam sterilized in wrapped packs and/or peel pouches with temperature/steam indicators placed within each pack/pouch.
Clothing: sterile gloves are utilized for each surgery. Disposable, pre-packaged sterile gowns may be utilized depending upon the procedure.

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

Surgical support is provided by the veterinary staff to the investigators either in the form of direct surgical service and/or surgical training.

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.

Rodent Species
Visual monitor of respiratory rate/pattern and mucous membrane color.

Non-rodent species
Monitoring during general anesthesia is conducted and recorded at least every 15 minutes for both survival and non-survival procedures. Anesthesia records include body temperature, respiratory rate, heart rate, oxygen saturation, and vaporizer/oxygen flow settings. Records are filed in the animal's health record.

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

Rodent Species
Following surgery, an animal is allowed to recover in a heated, clean cage. Animals are monitored continuously until recovered from anesthesia, and are sternal and ambulatory. The veterinary staff, research team, Facilities Manager, or designee, provides post-surgical care and monitoring. Surgical procedures are documented on the individual animal's cage card. Additionally, the research team maintains a surgery record for survival surgery.

Non-rodent Species
Following surgery, the animal is allowed to recover in a clean cage with heat support, and is continuously monitored until recovered from anesthesia (able to maintain an upright position and/or is ambulatory). The Clinical Veterinarian or designee performs post-surgical monitoring until the surgical site has healed and the animal has fully recovered from the procedure. Post-surgical monitoring and provision of any prescribed peri-operative treatment(s) is documented and the records maintained in the animal's medical record.

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

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

The RML ACUC, using NIH Policy and USDA Guidelines, and with guidance from the veterinary staff, determines the USDA pain/distress category assigned to any laboratory animal procedure as described in a submitted ASP. Assessment of pain and distress is an ongoing process during any approved animal study. The research team, animal care technicians and the Clinical Veterinarians are all responsible for monitoring experimental animals for signs of pain and/or distress.

2. Describe how the IACUC/OB ensures that unnecessary pain and distress are avoided (e.g., pilot studies, monitoring by veterinary staff, animal use protocols, humane endpoints, other refinements, etc.).

The ARAC Guideline "Guidelines for Pain and Distress in Laboratory Animals: Responsibilities, Recognition and Alleviation", and "Guidelines for Endpoints in Animal Study Proposals" are resources for use by veterinary staff members, investigative staff, and ACUC members.

Guidelines for avoiding unnecessary pain or distress are set by the RML ACUC at the time of initial review of submitted ASPs, depending on the specific procedures outlined. Examples include: requiring euthanasia at the earliest identifiable signs of experimentally induced disease and requiring scientific justification for the use of certain adjuvants, such as complete Freund's.

A clinical scoring matrix has been developed for NHPs in ABSL-4 studies to assist in determining the criteria for euthanasia.

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

1. List the agents used for each species. Dosages, routes of administration and drug combination should be included in guidelines and available at the time of the site visit. Describe also any non-pharmacologic means used to diminish pain and distress.

Rodents
Anesthesia: isoflurane, ketamine/xylazine, ketamine/xylazine/acepromazine, pentobarbital.
Analgesia: bupivacaine, buprenorphine, buprenorphine SR, carprofen, flunixin meglumine, lidocaine, meloxicam, proparacaine, tetracaine.

Ferrets
Anesthesia: isoflurane, ketamine/acepromazine, ketamine/dexmedetomidine, ketamine/xylazine, telazol/ketamine/xylazine, telazol/xylazine.
Analgesia: bupivacaine, buprenorphine, carprofen, lidocaine, meloxicam.

Rabbits
Anesthesia: acepromazine, isoflurane, ketamine/xylazine, ketamine/xylazine/acepromazine.
Analgesia: bupivacaine, buprenorphine, flunixin meglumine, lidocaine, meloxicam.

Swine
Anesthesia: isoflurane, ketamine/acepromazine, ketamine/xylazine, midazolam, telazol, telazol/ketamine/xylazine.
Analgesia: bupivacaine, buprenorphine, carprofen, flunixin meglumine, lidocaine, meloxicam.

Sheep/goats
Anesthesia: isoflurane, ketamine/xylazine, ketamine/xylazine/diazepam, telazol, telazol/xylazine.
Analgesia: bupivacaine, buprenorphine, flunixin meglumine, lidocaine.

NHPs
Anesthesia: isoflurane, ketamine, ketamine/diazepam, ketamine/midazolam, ketamine/xylazine, midazolam, propofol, telazol.
Anesthesia: bupivacaine, buprenorphine, buprenorphine SR, carprofen, flunixin meglumine, ibuprofen, lidocaine, meloxicam.

Bats
Anesthesia: isoflurane, ketamine/xylazine.
Analgesia: bupivacaine, buprenorphine, ibuprofen, lidocaine, meloxicam.

Non-pharmacological methods to decrease pain and distress:
Potential options include the provision of heat, ice, massage, softer/deeper substrate, additional enrichment, companion, environmental thermal regulation, alternative feeding strategies and supportive care (fluids, wound care, etc.).

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

The veterinary staff reviews all proposed ASPs and has direct input to investigators concerning the choice and use of drugs, as well as potentially non-pharmacologic methods to decrease pain and distress. The Clinical Veterinarians provide ongoing consultation on use and choice of drugs for anesthesia and analgesia for all experimental animal work conducted at RML.

3. Describe the monitoring of the effectiveness of anesthetics and analgesics, including who does the monitoring.

The veterinary staff monitors the use of anesthetics and analgesics in laboratory animals at RML via pre-approval and input into ASPs as submitted to the ACUC, and by monitoring ongoing research.

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.

There are no studies involving the use of neuromuscular blocking agents approved at RML.

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

Isoflurane vaporizer calibrations are checked annually in-house using a Riken Keiki FI-21 gas indicator calibration monitor and are sent to an outside facility for servicing/calibration every 3 years, or immediately if they are +/- 10% outside normal parameters.

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

1. Describe approved methods of euthanasia, including humane slaughter. Include consideration of species, age, condition (e.g., gestational period, or neonatal) and location(s) for the conduct of the procedure.

The RML ACUC has approved Guidelines for Euthanasia. NIH policy requires research scientists and animal care staff to follow the guidelines presented in the current recommendations of the AVMA Guidelines on Euthanasia, unless a specific exemption is granted by the IC-ACUC during ASP review. In addition, the ARAC Guidelines: Guidelines for Euthanasia of Rodents Using Carbon Dioxide, Guidelines for the Euthanasia of Rodent Fetuses and Neonates, are

resources for use by veterinary staff members, investigative staff, and ACUC members.

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

The Euthanex chamber system is routinely used for rodent euthanasia in Redacted by agreement which contains programmed cycles for the different rodent species which are in compliance for approved euthanasia practices in rodents. In addition to the Euthanex system, CO2 chambers are utilized in Redacted by agreement The RMVB foreman routinely checks tanks and ensures proper operation of flow meters.

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

Methods used to confirm death include, but are not limited to: lack of heartbeat, lack of respiration, lack of corneal reflexes, cyanotic mucous membranes and fixed/dilated pupils.

IV. Physical Plant [Guide, pp. 133-151]

Repeat this section for each animal housing area, including agricultural settings, temporary holding areas for field studies, aquatic environments, and each IACUC/OB approved satellite housing facility. Include as an appendix the floor plans of each (if applicable) on 8.5" x 11" or A4 paper.

A. Location and Construction Guidelines

1. Note the location (building, floor, wing, etc.) of the animal facility(ies). Describe the management structure and program oversight for each of the areas listed in this section.

Location (Building/site name)	**Distance from main facility**	**Approx. sq. ft. animal care & use space**	**Approx. sq. ft. support space**	**Species housed**	**Person in charge of site**
Redacted by agreement		6785 sq. ft.	16219 sq. ft.	Mice (Mus musculus), *Peromyscus sp.*, Hamsters, Rabbits, Rats, Guinea pigs, NHPs	Dr. Gardner
	100 yards	600 sq. ft.	1135 sq. ft.	Mice, *Mastomys natalensis*	Dr. Gardner

Redacted by agreement	30 yards	3,900 sq. ft.	4,400 sq. ft.	Mice, *Mastomys natalensis*, *Peromyscus sp.*, Guinea pigs	Dr. Gardner
	60 yards	3088 sq. ft.	3259 sq. ft.	Mice, Hamsters, Guinea pigs, *Peromyscus sp.*, *Mastomys*, Swine, Sheep, Goats, Ferrets, Bats, NHPs	Dr. Gardner
	150 yards	1616 sq. ft.	2404 sq. ft.	Mice, Hamsters, Rats	Dr. Gardner

RMVB organizationally and functionally oversees all the above facilities.

2. Describe the physical relationship of the animal facilities to the research laboratories where animals may be used.

Animal facilities exist as separate structures from research laboratories; whether animal facilities are in separate buildings Redacted by agreement Redacted by agreement or situated separately within the building structure Redacted by agreement Redacted by agreement

Rodents from Redacted by agreement may be transported to research laboratories in the Quad, approximately 50 feet away. Other animal use is performed within the same facility in which the animals are housed.

3. Describe the general arrangement of the animal facilities (e.g., conventional, clean/dirty corridor, etc.). For animals that are maintained in a laboratory in order to satisfy the scientific aims of a protocol, describe the housing and care provided and the maximum period of stay required.

All animal facilities are conventional in design.

4. Describe finishes throughout the animal facility(ies) for floors, walls, ceilings, doors, alleyways, and gates. Note any areas that are not easily sanitized and describe how these areas are maintained.

Floors are either seamless, trowel-on epoxy or seamless, spray-on polyurea. Walls and ceilings are spray-on polyurea and/or epoxy-coated. In Redacted by agreement

animal holding areas, the walls are coated with solid Arcoplast™ panels, and in Redacted by agreement the walls are coated with solid Protec™ panels. Doors are aluminum framed FRP units. Doors in the maximum containment lab are inflatable gasket sealed, stainless steel, Air Pressure Resistant (APR) type.

5. If exterior windows are present within the animal housing or procedure areas, describe IACUC/OB consideration regarding temperature and photoperiod control, as well as potential security risks.

Not Applicable

B. Functional Areas and Operations

1. Heating, Ventilation, and Air-Conditioning (HVAC) [Guide, pp. 139-140, 143]

a. Describe the mechanical systems used to provide temperature, humidity and air pressure control. Include details such as the use of variable air volume (VAV) systems, and additional key features of HVAC systems affecting performance.

All animal housing rooms are trended for temperature, humidity, and air change rates on an ongoing basis.

Redacted by agreement

The HVAC system for the Redacted by agreement building employs full redundancy with two identical systems, each a single duct system with 8 zones. The units provide greater than 15 air changes per hour and utilize single-pass airflow design. 30% filters and 95% filter units are located in the supply air system. Supply air is maintained at 55° F by a natural gas fired furnace or a direct expansion refrigeration condenser. A steam humidifier controlled by a humidistat is located in the supply air duct. Duct hydronic (hot water) heating coils achieve the desired temperature for each room. The supply air into the surgical suite flows through diffusers designed specifically for use in surgical suites to provide low velocity vertical "laminar" airflow. Two separate exhaust units provide 100% redundancy. All air handlers, room temperatures and humidity levels are alarmed to the centralized computer system. Any alarm appears on a computer screen in the security control center, and gives and audible signal until the alarm has been acknowledged. Any alarm generated results in the appropriate maintenance staff being notified immediately.

Redacted by agreement

The air handler system is a single-pass airflow design, with 2 sets of filters, a 30% and a final 95% filter. Two supply fans run together to maintain supply air static, temperature and humidity. If one fan fails, the other fan ramps up in speed to maintain the minimum airflow, and rooms adjust to a partial volume. Steam preheated coils and chilled water-cooling coils maintain a constant 55°F supplied air temperature. Each room has an adjustable set point to maintain desired temperature and its own volume

controller and reheat hot water coil to maintain airflow and temperature. The primate wing has adjustable air flow control with a fixed exhaust set point and an adjustable offset on supply air to maintain directional air flow. The primate rooms incorporate a re-heat coil to maintain temperature with an adjustable set point. The air handler contains the primary humidifier which maintains the supply air humidity controlled to an exhaust humidity set point with a saturation limit at 55° F discharge air temperature. The secondary humidifiers are downstream in the supply air duct to boost humidity based on two zones (north and south). All steam for humidification is pure steam with no chemicals added. The building exhaust is controlled through two exhaust fans that operate together; if one fan fails the other fan maintains minimum exhaust and the rooms go into partial volume. The entire HVAC system is controlled by a centralized computer system with all parameters having set points that will trigger an alarm if not maintained. The main computer terminal is located at multiple locations around campus with a server in the Redacted by agreement Any alarms appear on a computer screen in the security control center, and give an audible signal until the alarm has been acknowledged. Any alarm generated results in the appropriate maintenance staff being notified immediately.

Redacted by agreement

The air handler system is a single-pass airflow design, with 2 sets of supply-side filters, a 30% and a final 95% filter. Two supply fans run together to maintain supply air static pressure, temperature and humidity. If one fan fails, the other fan ramps up in speed to maintain the required airflow. Steam preheated coils and chilled water-cooling coils maintain a constant 55ºF supply air temperature. Each room has an adjustable set point to maintain desired temperature and its own volume controller and reheat hot water coil to maintain airflow and temperature. The animal holding rooms, procedure rooms, and ante-rooms have variable volume controllers with a fixed exhaust and a variable supply air controlling to offset to maintain directional air flow. The air handler contains the primary humidifier which maintains the supply air humidity controlled to an exhaust humidity set point with a saturation limit of 52°F discharge air temperature. The secondary humidifier is downstream in the supply air duct to boost humidity for animal holding rooms. All steam humidification is pure steam with no chemicals added. The building exhaust is controlled through two sets of exhaust fans that operate together, if one fan fails in any set, the other fan ramps up to maintain the required exhaust. All exhaust air is HEPA-filtered. Airflow in the building is directional, with the building negative in relation to the outside and with increased negativity the deeper you go into the building. The pressure relationships between spaces are maintained, monitored, and controlled by a centralized computer system with all HVAC parameters having set points that will trigger an alarm if not maintained. The main computer terminal is located in the Redacted by agreement

Redacted by agreement Air pressure alarms appear on sensor panels located at each doorway as well as on the main computer screen. Both a visual flashing and audible alarm is triggered until it has been acknowledged. Any alarm

generated is received at the security control center, and any alarm generated results in the appropriate maintenance staff being notified immediately.

Redacted by agreement

The quarantine animal holding rooms, Redacted by agreement are served by a single duct CAV air system supplying 100% outside air. Four units, each running at 75% of design capacity, feed a common supply duct to provide stable operation; with a quick response to three units at 100% should one fan fail. A 20% safety factor is used for the air quantity of the fan selection. The supply air is set to maintain a constant 55° F temperature with a set point of 30% relative humidity with each space having a reheat coil to maintain space temperature, and a secondary humidity grid with adjustable set points. All animal rooms are trended for temperature, humidity, and air change rates. The air handlers have 30% pre-filters and 95% final filters. Two centrifugal exhaust fans, each operating at 50% capacity with controlled bypass make-up air to stabilize the fan operation serve the quarantine animal holding rooms. Failure of one fan results in the immediate ramp up to 100% for the other fan, maintaining negative pressure in the exhaust system at all times.

The Redacte d animal rooms on the Redacted by are served by a single duct CAV air system supplying 100% outdoor air. Five supply units, each running at 80% of design capacity, feed a common supply duct to provide stable operation; with a quick response to four units at 100% should one unit fail. A 10% safety factor is used for the air quantity of the fan selection. The supply air is set to maintain a constant 55°F temperature with a set point of 30% relative humidity with each space having a reheat coil to maintain space temperature, and each room having a secondary humidity grid with adjustable set points. All animal rooms are trended for temperature, humidity, and air change rates. The air handlers have 30% pre-filters and 95% final filters and each zone is supplied through a HEPA filter unit. Each area in the high containment animal areas is divided into separate zones. All animal room exhaust, BSC exhaust and necropsy table exhaust are connected to an exhaust system manifold. Five exhaust fans, each running at 80% of design capacity, feed a common exhaust duct to provide stable operation; with quick response to four units at 100% should one fan fail. A 10% safety factor is used for the quantity of fan selection. The air from each zone is exhausted through HEPA filter units operating in series.

For both animal holding areas in Redacted by agreement the pressure relationships between spaces are maintained, monitored, and controlled by a centralized computer system with all HVAC parameters having set points that will trigger an alarm if not maintained. The main computer terminal is located in the Redacted by agreement Both a visual flashing and audible alarm is triggered until it has been acknowledged. Any alarm generated is received at the security control center, and any alarm generated results in the appropriate maintenance staff being notified immediately.

Redacted by agreement

The air handler system is a single-pass airflow design with 2 sets of filters, a 30% and a final 95% filter. Redundant air handlers run individually to maintain supply air static pressure, temperature and humidity. If one air handler fails, the other air handler starts and ramps up in speed to maintain the required airflow. Hot water pre-heat coils and chilled water cooling coils maintain a constant 55°F supplied air temperature. Each room has an adjustable set point to maintain desired temperature and its own volume controller and reheat hot water coil to maintain airflow and temperature. The air handler contains the primary humidifier which maintains the supply air humidity controlled to an exhaust humidity set point with a saturation limit at 55° F discharge air temperature. All steam for humidification is done with no chemicals added with softened water. The building exhaust is controlled through two exhaust fans that operate individually; if one fan fails the other fan starts and maintains exhaust volume. The entire HVAC system is controlled by a centralized computer system with all parameters having set points that will trigger an alarm if not maintained. There are multiple computer terminals located around campus with a server in the Redacted by agreement Any alarms appear on a computer screen in the security control center and give an audible signal until the alarm has been acknowledged. Any alarm generated results in the appropriate maintenance staff being notified immediately.

b. Describe construction 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.

All animal rooms have both high limit alarms for humidity and temperature in the supply air. All re-heat coils and humidity valves fail closed and alarm. All of the building automation systems are backed up with UPS power, and are designed to remain operational during a power outage until generator power or permanent power is restored.

c. Describe how critical air pressures, ventilation, and temperature are monitored and maintained in the event of a system or component failure.

Animal housing rooms in RML animal facilities have temperature and humidity sensors connected to the centralized computer systems located at multiple locations around campus with a server in the Redacted by agreement Redacted Temperature and humidity set points are established for each room and deviations from those set points result in an alarm (visual and auditory) at the computer terminals at the security control center. Additionally, in Redacted by agreement an independent alarm system for animal room temperatures has been installed with an alarm visible just outside the building entrance. Redacted Redacted by agreement

d. Describe procedures for monitoring animal facility mechanical systems and notifying appropriate personnel in the event of a significant failure that occurs outside regular work hours.

> Alarms for facility mechanical systems are established for each room and deviations from those set points result in an alarm (visual and auditory) at the computer terminals in the security control center, which is manned 24/7.

2. Power and Lighting [Guide, p. 141]

a. Note if emergency power is provided for the animal facility and if so, what electrical services and equipment are maintained in the event the primary power source fails.

> The RML campus has a complete emergency power system, consisting of diesel-powered generators, which maintain all electrical services to all animal facilities in the event of a power outage.

b. Give history of power failures for the animal facility. Note frequency and duration. If emergency power was not available during a power failure, describe steps taken to ensure the comfort and well-being of the animals and the temperature extremes reached in the animal rooms during the failure.

> Power failures typically occur up to 5 times a year and last from a few minutes to a couple of hours, however, backup power prevents loss of power for more than a few seconds. During a power outage, all mechanical systems run on UPS back-up until the generator power is up and running (within 10 seconds). If power is lost, all animal rooms would be monitored through the BAS system (UPS power). Stand-by portable generators are also available in the event of failure of the main generators.

c. Describe lighting system(s) for the animal housing facility(ies). For each species or holding room type, list light intensity, photoperiod (Light:Dark), construction features (e.g., water resistance), and control (e.g., automatic versus manual, phasing). For systems automatically controlling photoperiod, describe override mechanisms.

Species	Light Intensity	Photoperiod (L:D)	Water-resistant light fixtures (yes/no)	Automatic control (yes/no)	Windows (yes/no)

Mice	250 – 300 Lux Normal 400 - 500 Lux For Human Activity	12/12	Yes	Yes, also dual level capability with timer for higher intensity for human activities in the animal rooms.	No
Rats	250 – 300 Lux Normal 400 - 500 Lux For Human Activity	12/12	Yes	Yes, also dual level capability with timer for higher intensity for human activities in the animal rooms.	No
Hamsters	250 – 300 Lux Normal 400 - 500 Lux For Human Activity	14/10	Yes	Yes, also dual level capability with timer for higher intensity for human activities in the animal rooms.	No
Rabbits	250 – 300 Lux Normal 400 - 500 Lux For Human Activity	12/12	Yes	Yes, also dual level capability with timer for higher intensity for human activities in the animal rooms.	No
Guinea Pig	250 – 300 Lux Normal 400 - 500 Lux For Human Activity	12/12	Yes	Yes, also dual level capability with timer for higher intensity for human activities in the animal rooms.	No
Ferrets	250 – 300 Lux Normal 400 - 500 Lux For Human Activity	12/12	Yes	Yes, also dual level capability with timer for higher intensity for human activities in the animal rooms.	No
Bats	250 – 300 Lux Normal 400 - 500 Lux For Human Activity	12/12	Yes	Yes, also dual level capability with timer for higher intensity for human activities in the animal rooms.	No

Nonhuman Primates	250 – 300 Lux Normal 400 - 500 Lux For Human Activity	12/12	Yes	Yes, also dual level capability with timer for higher intensity for human activities in the animal rooms.	No
Swine	250 – 300 Lux Normal 400 - 500 Lux For Human Activity	12/12	Yes	Yes, also dual level capability with timer for higher intensity for human activities in the animal rooms.	No
Sheep/Goats	250 – 300 Lux Normal 400 - 500 Lux For Human Activity	12/12	Yes	Yes, also dual level capability with timer for higher intensity for human activities in the animal rooms.	No

All rooms with automatic lighting controls also have lighting override switches.

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

There have been no adverse effects on animals due to power failures that have occurred at RML.

4. **Storage Areas** [Guide, pp. 141-142]

   a. Describe storage areas for feed and bedding, including temperature and vermin control.

Redacted by agreement

Food is stored on pallets in a gasketed, vermin-proof walk-in cooler maintained at 38°F.
A single pallet of bedding is stored in a temperature controlled room adjoining the clean side of the cage wash area.

Redacted by agreement

Food is stored on racks in a gasketed, vermin-proof walk-in cooler maintained at 38°F.

Redacted by agreement

For short time storage, food and bedding is stored on pallets in a temperature controlled room within the facility.

Bulk laboratory animal bedding is stored bagged on pallets in a separate vermin proof building.

A contractor provides vermin surveillance and control for all storage and animal facilities.

b. Describe storage areas for cages, equipment, supplies, etc.

Redacted by agreement
Cages and supplies are stored in a dedicated storage room.

Redacted by agreement
Cages and supplies are stored on the clean side of cage wash and in an adjacent storage room.
Additional storage for supplies is located throughout the building

Redacted by agreement
Cages and supplies are stored on the clean side of cage wash. Additional storage for supplies is located in each anteroom, as well as in one dedicated storage room.

Redacted by agreement
Cages are stored in the staging area on the first floor.
Supplies and equipment are stored in dedicated storage rooms throughout the building.

Redacted by agreement
Cages and supplies are stored in dedicated storage rooms.

c. Describe storage areas for flammable or hazardous agents and materials (e.g., disinfectants, pesticides, fuel).

With the exception of ETOH (70% ETOH is used as a disinfectant), which is stored in a labeled flammable storage cabinet, there are no other flammable agents used or stored in animal facilities. Inhalation anesthetics are stored in a cabinet in Redacted by agreement

5. Facilities for Sanitizing Materials [Guide, pp. 153]

Describe for each cage sanitation area its location, the traffic flow pattern (soiled to clean, or in and out) within the facility, and kinds of equipment (tunnel washer, bottle washer, rack washer, etc. and other related equipment such as bedding dispensing units).

The cage sanitation areas in Redacted by agreement are located in the center of the buildings with separate dirty and clean sides. Equipment includes tunnel washers, bottle washers, rack washers, and large pass-through autoclaves.

C. Special Facilities [Guide, pp. 144-146, 150]

1. Specialized Types of Animal Housing

Note specialized types of available animal housing spaces such as barrier, hazard containment (infectious, radioactive, chemical), "animal cubicles" (also known as "Illinois Cubicles", "Horsfal Cubicles," and "animal modules"), or facilities designed specifically for housing certain species such as aquatic or agricultural animals (e.g., barns, feedlots). [Guide, pp. 160-161]

Current CDC policy mandates the use of "primary containment" housing for animals infected with Select Agents. All open cages for species on such Select Agent studies in BSL-4 are placed in primary containment structures. For NHPs infected with certain Select Agents, current CDC policy considers the ABSL4 animal holding rooms to be the primary containment, thus allowing open caging in these cases.

2. Surgery [Guide, pp. 144-145]

a. Describe facilities for aseptic surgery, surgical support, animal preparation, surgeon's scrub, operating room, and postoperative recovery.

Rodent

The rodent surgery area in Redacted by agreement is a clean procedure room, with sink, organized for anesthesia, surgery and postoperative recovery. Traffic in the room is limited to the few individuals involved in the study and it is separated from animal housing areas.

Nonhuman Primates

Minor surgical procedures may occur in Redacted by agreement The surgical support functions are located within the Redacted by agreement with patient prep and recovery in Redacted by agreement surgeons scrub/instrument storage in Redacted by agreement central supply in Redacted by agreement autoclave in Redacted by agreement and change/shower in Redacted by agreement

b. Describe construction features of the operating room(s), including interior surfaces, ventilation, lighting, and fixed equipment used to support surgical procedures and enhance contamination control.

Rodent

The floors in Redacted by agreement are seamless, trowel-on epoxy. Ceilings and walls are epoxy-coated. Ventilation and lighting are building controlled as previously described.

Nonhuman Primates
The surgical facilities are located in Redacted by agreement and minor surgical procedures may occur in Redacted by agreement as previously mentioned under separate sections describing surgery. The interior surfaces of the Redacted by agreement surgery suite are spray on polyurea and/or epoxy-coated. The air pressure of the surgery suite is positive to adjoining rooms. There are surgical light fixtures in the surgery suite.

Autoclaves are available in all surgery areas.

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

Redacted by agreement is located in the Redacted by agreement All equipment that is in contact with the animals is decontaminated with an appropriate disinfectant following irradiation.

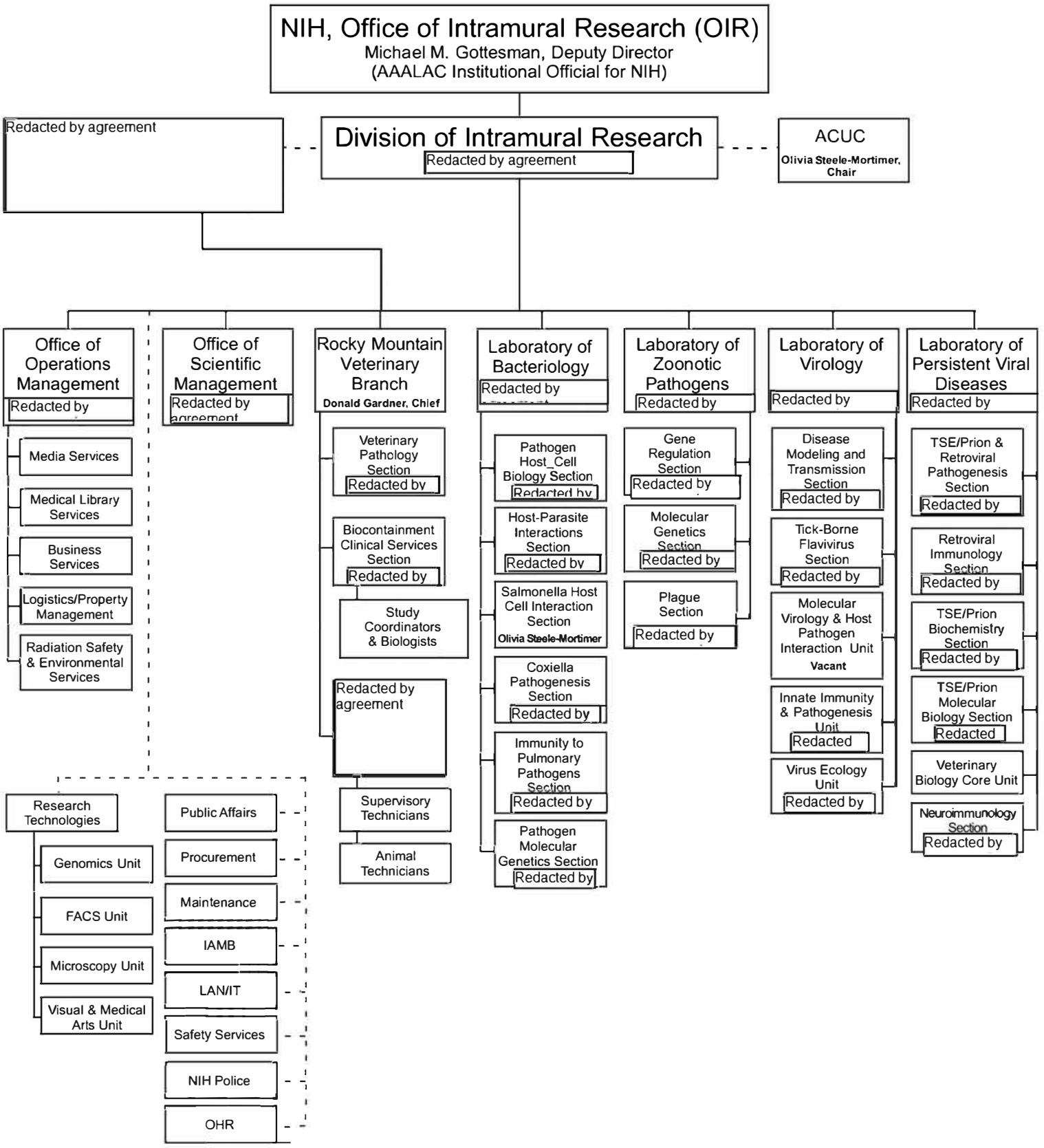
4. Other Animal Support Facilities
Describe other facilities providing animal care and use support, such as food preparation areas, feedmills, abattoirs, etc.

Not Applicable

D. Security and Access Control [Guide, p. 151]
Describe such features as control of entry, perimeter fences, gates, entryways, cameras, guards.

Redacted by agreement

Rocky Mountain Laboratories Organizational Chart



Animal Usage (Form B)

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.

Protocol Title	IACUC/OB No.	Principal Investigator	Species	# Animals Approved	Pain & Distress Category (1)	Special Considerations (use checkmark if applicable)					
						SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
La Crosse Virus (LACV) Infection of Cynomolgus Macaques	Redacted by agreement		NHP	15	C/E					X	
Identification of Requirements for Protective Immunity Against Tularemia in Mice			Mouse	303	C					X	
Competence of B. burgdorferi Variants in the Mouse/Tick Infectious Cycle			Mouse	894	C					X	
Temporal Analysis of Lassa Virus Infection and Transmission in Mastomys natalensis			Mastomys	448	C					X	
Establishment of Latent HIV Infection in TKO BLT Mice Using ART			Mouse	214	D	X				X	
Nebulized IFN-beta as a Therapeutic Intervention for MERS-CoV in Non-human Primates			NHP	24	E					X	
The Role of Aterivirus Co-Infection in the Pathogenesis of Reston Ebola Virus in Swine			Pig	64	C/E					X	
Defining the Effect of Unique Host Genetic Backgrounds on Mouse Adapted and Wild-Type Zaire Ebolavirus			Mouse	339	C/E					X	

Study of Pyroptosis in Acute CD4+ T cell Depletion in TKO BLT Mice	Redacted by agreement	Mouse	738	D	X				X	
Evaluation of Macrophages Subpopulations During Lactate Dehydrogenase Elevating Virus (LDV) Infection in Mice		Mouse	120	C					X	
Evaluation of Superantigen Requirement for Friend Virus-Induced Treg Responses in Mice		Mouse	204	C					X	
Regulatory and Effector T cell Responses to a Murine Retrovirus in APOBEC3 Knockout Mice		Mouse	656	C					X	
Determining the Role of Gamma Delta T17 Cells in Control of Y. pestis Infection in Mice		Mouse	480	C/D					X	X
Laboratory Animal Care and Use Training Program 2014 (Small Lab Animal)		Mouse Rat Hamster Guinea Pig Ferret Poultry Bats	1475 60 300 120 60 60 60	C						
Laboratory Animal Care and Use Training Program 2014 (Rabbit)		Rabbit	45	C						
Laboratory Animal Holding 2014		Mouse Rat Hamster Guinea Pig Ferret Pig NHP Rabbit	7500 150 300 180 90 90 600 60	C						
Sentinel Animal Surveillance Program 2014		Mouse Rat Hamster	3600 36 180	C						
Laboratory Animal Breeding/Production 2014		Mouse Hamster Rat Wild Mice	16500 1500 300 600	C						
Laboratory Animal Care and Use Training Program 2014 (Non-human primates)		NHP	450	C						
Sample Collection to Acquire Pathogen Isolates, Nucleic Acids		Horse Donkey	3000 3000	C					X	X

and Host Anti-Pathogen Antibodies from Domestic Animals for Global Surveillance			Mule Bovine Bison Goat Sheep Swine Camel Llama Alpaca Deer Rabbit Chicken Duck Goose Turkey Poultry Dog Cat	3000 15000 3000 6000 6000 15000 15000 3000 3000 3000 3000 30000 3000 3000 15000 9000 15000 15000							
A New Model for Middle East Respiratory Syndrome Coronavirus in Swine	Redacted by agreement		Pigs	12	C/E					X	
Laboratory Animal Care and Use Training Program (Ferret)			Ferrets	90	D						
Laboratory Animal Care and Use Training Program (Sheep and Goats)			Sheep Goat	36 36	D						
Competitive Indices of mCherry-expressing Salmonella Typhimurium in Mice			Mouse	18	C					X	
Efficacy of Monoclonal Antibody Treatment Against Marburg Hemorrhagic Fever in Syrian Golden Hamster Model			Hamster	200	E					X	
Regulation of Innate Immune Responses in Mouse Model of LACV Infection			Mouse	315	C/E					X	
Generation of Polyclonal Antibodies against La Crosse Virus in Mice and Rabbits			Mouse Rabbits	36 5	C					X	
Assessing the Extent and Duration of Spirochetemia of Borrelia Crocidurae Following Experimental Inoculation of Mastomys natalensis			Mastomys	64	C					X	

The Role of B Cells in Regulatory T Cell Responses during Persistent Viral Infection in Mice	Redacted by agreement	Mouse	200	C					
The Role of Regulatory T Cells in Modulating Antibody Responses During Persistent Viral Infection in Mice		Mouse	164	C				X	
Antibody Production to Antigens of Borrelia burgdorferi and Leptospira Species		Rabbit	30	C					
Collection of Normal Tissues from Mice		Mouse	725	C					
The Role of IL-6 in Modulating Regulatory and Effector T Cell Responses to a Murine Retrovirus in APOBEC 3 Knockout Mice		Mouse	384	C					
Timing and Examination of Blood-Brain Barrier Breakdown Following Salmonella Typhimurium in Mice		Mouse	496	C				X	
Initial Testing of a Recombinant Attenuated Salmonella Vaccine in Mice		Mouse	168	C				X	
Evaluation of Alisporivir as a Potential Therapy for Tick-Borne Flavivirus (TBFV) Infection in Mice		Mouse	240	C/E				X	
Virulence Determinants of rOmpA Mutants of Spotted Fever Group Rickettsia in Guinea Pigs		Guinea Pig	63	C				X	
Regulation of Innate Immune Responses in Mouse Model of HSV1 Infection		Mouse	640	C/E				X	
Treatment of Mice and Hamsters with a Combination of Ribavirin and Alisporivir Ebola		Mouse Hamster	55 55	C/E				X	
Systems Biology Approaches to Examine the Host Response to Ebola Virus Injection; The Role of sGP/ssGP and the GP Mucin-like Doman in Viral Pathogenicity in Mice		Mouse	270	C/E				X	
The Mechanism of Treg Suppression During Persistent Viral Infection in Mice		Mouse	256	C					

Efficacy of rVSV or rVSV-expressed miRNAs as Treatment of Ebola Virus Infection in a Mouse Model	Redacted by agreement	Mouse	234	C/E					X	
Evaluation of STAT2 KO Hamsters as Disease Models for Multiple Agents of Viral Hemorrhagic Fever		Hamster	140	E					X	
The Role of Transcription Factors Foxo1 and Foxo3 on Infection Levels and Effector and Regulatory T cell Responses to a Murine Retrovirus in Mice		Mouse	384	C						
Immunotherapeutic Blockade of PD-1, TIM-3 and SIRP to Treat Murine Retrovirus Infection in Mice		Mouse	480	C						
Efficacy of rVSV Pre and Post-exposure Treatment of Filovirus Hemorrhagic Fever in a Syrian Golden Hamster Model		Hamster	376	C/E					X	
Transmissibility of Human Prion Diseases PrP226 and F131V to Transgenic Mice		Mouse	216	D/E	X				X	
Antibody Production in Rabbits to antigens of Borrelia species		Rabbit	30	C					X	
Injection of Human Creutzfeldt Jakob Disease (CJD) Isolates of the Genotype Met/Val Into Transgenic Mice Expressing the Human Prion Protein		Mouse	440	E					X	
The Role of Mitochondria in Neuronal Degeneration of Scrapie-infected Mice		Mouse Hamster	732 60	C/D/E					X	
Immunization of Mice with Live Attenuated Y. Pestis and Intravital Microscopy of Immunized Mice		Mouse	200	C					X	X
Surveillance of Natural Foci of African Hemorrhagic Fever Viruses (HFVs)		Various	6000	C					X	X
Global Surveillance of Known and Potential Zoonotic Foci for Pathogens to Assess Human Risk		Various	6000	C					X	X

Understanding the role of MAVS in Production from TBEV Infection in the Mouse Model	Redacted by agreement	Mouse	92	C/E				X	
Efficacy of Computationally Predicted Ebola Antiviral Compound in Mice		Mouse	174	C/E				X	
Assessing the Therapeutic Potential of Human Anti-Sin Nombre Virus Polyclonal IgG Antibodies Against the Development of Hantavirus Pulmonary Syndrome in Non-human Primates		NHP	22	C/E				X	
Evaluation of FX06 for the Treatment and Prevention of Hantavirus Pulmonary Syndrome in Syrian Hamsters		Hamsters	40	C/E				X	
Production of Prion-Infected Tissues in Mice		Mouse	176	C/D/E				X	
Defining Post-vaccination Immune Response of VSV Vector Vaccines in Hamsters		Hamster	64	C				X	
Production of TKO-BLT Mice		Mouse	3432	C/D	X			X	
Monocyte Recruitment to the CNS Following Virus Infection in Mice		Mouse	270	E				X	
Friend Virus Infection and Antigen Presenting Cell Functionality in Mice		Mouse	150	C					
Efficacy of Consecutive Vaccinations with rVSV Vectors Against Sudan and Zaire Ebola Viruses in Non-human Primate		NHP	17	E				X	
Assessment of Complement Activation on Prion Disease and Pathogenesis in Mice		Mouse	1536	D/E	X			X	
Third Passage of Anchored and Anchorless 22L Rodent Scrapie in Transgenic Mice		Mouse	64	E				X	
Evaluation of T-705 for the Treatment of Ebola Hemorrhagic Fever in Syrian Hamsters		Hamster	72	E				X	
Assessing the Therapeutic Potential of Human Anti-Ebola		NHP	10	E				X	

Virus Polyclonal IgG Antibodies Against the Development of Ebola Virus Disease in Non-human Primates											
Assessment of the T cell Response during Virulent Francisella Infection in Mice	Redacted by agreement		Mouse	1721	C					X	
Treatment of Prion Disease with Oral Statin Therapy in Mice			Mouse	504	C/D/E	X				X	
Understanding the Cell-type Specific Role of MAVS in Protection from TBEV Infection in the Mouse Model			Mouse	776	C/E					X	
Modulating Effects of the Ebola Virus L Gene Upstream Open Reading Frame on Virulence in Mice			Mouse	76	C/E					X	
The Mechanism of Regulatory T cells (Treg) Suppression of B cell Responses during Friend Virus (FV) Infection in Mice			Mouse	576	C					X	
The Role of T Follicular Regulatory Cells in Inhibiting B cell Response Against Friend Virus in Mice			Mouse	144	C						
Virulence Determinants of Spotted Fever Group Rickettsia in Guinea Pigs			Guinea Pig	50	C					X	
Protective Efficacy of an Inactivated Ebola Whole Virus Vaccine Against ZEBOV Guinea and Analysis of the Host Signatures Associated with Protection in NHPs			NHP	32	E					X	
Efficacy of a Monoclonal Antibody Treatment Against Ebola Viruses in Mice			Mouse	400	C/E					X	
Efficacy of Modified Vaccinia Ankara (MVA) Vectored Middle East Respiratory Syndrome Coronavirus Vaccine in Non-human Primates			NHP	12	E					X	
Efficacy Testing of a Vaccine Candidate for 'Middle East Respiratory Syndrome'			NHP	8	E					X	

Coronavirus (MERS-CoV) in Rhesus Macaques											
Treatment of Chronic HIV Infection in Humanized Mice with Different Subtypes of Human Interferon Alpha	Redacted by agreement		Mouse	392	C					X	
The Role of NK cells in IFNα14, IFNα17, and IFNα21-mediated Protection from HIV in Humanized Mice			Mouse	264	C					X	
Identification of Immune Cells Required for Protection Against Tularemia in Mice			Mouse	1084	C					X	
Innate Immunity and Retrovirus-induced Neurological Disease in Mice			Mouse	500	C/E					X	X
Efficacy of Interferon Gamma Treatment Against Ebola Virus in Guinea Pigs			Guinea Pig	24	E					X	
Contributions of IL10 to Disease in Humanized Mice Infected with Ebola Virus			Mouse	12	E					X	
Therapeutic Vaccination Against Trachoma in Cynomolgus Monkeys			NHP	18	C					X	
Evaluation of Amodiaquine and Artesunate for the Treatment of Ebola Hemorrhagic Fever in Rodent Models			Mouse Hamster	80 80	E					X	
The Role of B cells and CD86 in Regulatory T cell Responses During Persistent Viral Infection in Mice			Mouse	528	C						
Activation of Glia and Neurons by Virus Infection and Innate Immune Stimulation in Cultured Murine Cells from Mice			Mouse	837	C						X
Treatment of Relapsed HIV Infection in Humanized Mice with Different Subtypes of Human Interferon Alpha			Mouse	216	C					X	
Testing of Recombinant Attenuated Salmonella Vaccines Against Lassa Virus Infection in Mastomys natalensis			Mastomys	194	C			X		X	

Role of the Kinesin Motor During Prion Spread in a Mouse Model	Redacted by agreement	Mouse	476	D/E	X			X	
Antisense oligonucleotides to Delay or Prevent Onset of Prion Disease in Mice		Mouse	854	D/E	X	X		X	
Efficacy Testing of Neutralizing Monoclonal Antibodies Against 'Middle East Respiratory Syndrome' coronavirus (MERS-CoV) in Common Marmosets		NHP	30	E				X	
Determining the Role of Subcapsular Sinus Macrophages in Y. pestis Infection in Mice		Mouse	160	C				X	
Efficacy of Modified Vaccinia Ankara (MVA)-based Vaccine Against Ebola Virus in Rodent Models		Guinea Pig Hamster	50 50	E				X	
Species Barrier to EVD in Humanized Mice Infected with Reston Virus or Mouse-adapted Ebola Virus		Mouse	417	C/E				X	
The Mechanism of CD86 Induction in Friend Virus-Infected B cells in Mice		Mouse	1400	C					
Pathobiological Role of Macrophages/Monocytes in Ebola Virus Pathogenesis in Mice		Mouse	266	C/E				X	
Assessment of Chronic Wasting Disease Transmission to Humans Using Two Transgenic Mouse Models		Mouse	128	C/E				X	
Pathogenicity of Zaire Ebolavirus Isolates from West Africa 2014 in IFNAR-/- Mice		Mouse	264	E				X	
Assessment of Prion Disinfectants by RT-QulC Analysis and Mouse Bioassay		Mouse	308	E	X			X	
Assessing T-705 as a Post-exposure Countermeasure to Lujo Virus Infection in Strain 13 Guinea Pigs		Guinea Pig	60	C/E				X	
Production of Antibodies Against Foamy Virus and Simian Adenovirus in Rabbits		Rabbit	12	C					

Further Development of hDPP4 Mice MERS-CoV Animal Model	Redacted by agreement	Mouse	190	E					X	
Infection of Several Transgenic Mouse Strains Expressing Human Prion Protein Using Human TSE Agents		Mouse	85	E					X	
Cell-specific MAVS Responses and LACV Pathogenesis in Mice		Mouse	960	C/E					X	
Understanding the Cell-type Specific Role of MAVS in Protection from Ebola Virus Infection in the Mouse Model		Mouse	712	C/E					X	
Optimization of Spike SynCon DNA Vaccine for Severe Middle East Respiratory Syndrome Coronavirus (MERS-CoV) in the Rhesus Macaque Model		NHP	20	E					X	
Determining the Role of MAVS in Host Susceptibility to 1918 Influenza Virus in the Mouse Model		Mouse	344	C/E					X	
Efficacy Testing of a New Neutralizing Monoclonal Antibody (LCA60) Against MERS-CoV in Common Marmosets		NHP	12	E					X	
IFN-ART Cure of HIV Infection in TKO BLT Mice		Mouse	196	C					X	
Ornithodoros Tick Colony Feeding and Maintenance on Mice		Mouse	600	C						X
Ixodes Tick Colony Feeding and Maintenance on Mice and Rabbits		Mouse Rabbit	120 36	C						
Infectious Cycle Relapsing Fever Spirochetes in Mice		Mouse	900	C					X	
Investigating the Mechanisms of Development and Progression of Salmonella Meningitis in Mice		Mouse	783	C/E					X	
Efficacy of a Modified Vaccinia Ankara (MVA) Based Vaccine Against Ebola Virus in the Macaque Model		NHP	12	E					X	
T cell Responses to Lassa Virus in Mastomys natalensis		Mastomys	96	C					X	

Natural Route of Transmission of MERS-CoV in hDPP4 Transgenic Mice	Redacted by agreement	Mouse	142	E					X	
Immunotherapeutic Blockade of PD-1 and SIRPα to Restore Immune Cell Function in a Mouse Model of Murine Retrovirus Infection		Mouse	360	C						
Protective Efficacy of VSV-CCHF Vaccine in IFNAR-/- Mice		Mouse	90	E					X	
Amplification and Isolation of a Unique Rodent Cytomegalovirus in Mastomys natalensis		Mastomys	27	C					X	
Determination of the Presence of Infectivity in Murine Prion Samples Prepared for Mass Spectrometry Analysis		Mouse	48	E					X	
The Mobilization of Endogenous Retroviruses in Mice During Friend 57 MuLV Infection		Mouse	252	C						
In Vivo Imaging of Yersinia pestis Dissemination in Mice After Infection by Flea Bite		Mouse	130	C					X	
Modeling Salmonella Typhimurium Infection in the Mouse Gallbladder		Mouse	62	C					X	X
Investigating the Requirements of Monocytes for the Dissemination of Salmonella enterica Serovar Typhimurium in Infected Mice		Mouse	519	C/E					X	
Establishment of a Lethal Mouse Model for Ebola Infection Suitable for Both Vaccine and Therapeutic Treatments		Mouse	864	E					X	
Assessing T-705 as a Post-exposure Countermeasure to Lassa Virus Infection in Cynomolgus Macaques		NHP	40	E					X	
Tracking Interferon Stimulated Gene Expression in HIV Infected Humanized Mice Treated with Interferon Alpha		Mouse	432	C					X	
Modulation of Inflammation by Synthetic PE:PC Liposomes in Mice		Mouse	3105	C/E					X	

Evaluation of the Effect of Ixodid Tick Salivary Gland Extract on Powassan Virus (POWV) Infection in Peromyscus leucopus Mice	Redacted by agreement	Mouse	124	C/E				X	
The Role of Transcription Factor Foxo3 on Virus-specific and Non-specific CD4 and CD8 T Cell Responses to a Friend Retrovirus Infection		Mouse	468	C					
Establishment of a Non-human Primate Disease (Common Marmoset) Model for Zika Virus Infection		NHP	8	E				X	
Pathogenicity and Mortality of Zaire Ebolavirus (Mouse-adapted) in Balb/c Substrain Mice		Mouse	132	E				X	
Establishment of a Mouse Disease Model for Zika Virus Infection		Mouse	472	C/E				X	
Maintenance of Experimental Flea Colonies Using Mice (2016 – 2019)		Mouse	6600	C/E				X	X
Development of a Mouse Model to Study how Zika Virus Affects the Developing Brain		Mouse	1254	C/D/E	X			X	
Plethysmograph Training Program (NHP)		NHP	40	C					
Mouse Model of Chlamydia trachomatis Genital Infection		Mouse	90	C				X	
Immune Responses of Zika Virus Infection in Adult Mice and the Impact of Pregnancy or Dengue Infection on these Responses		Mouse	1388	C/E				X	
Treatment of La Crosse (LACV)-Induced Neurological Disease in Mice with FDA-approved Drugs Identified in Neuronal Apoptosis Screen		Mouse	870	E				X	
Refining the Rhesus Macaque Model for Hantavirus Cardiopulmonary Syndrome Using Sin Nombre Virus		NHP	4	E				X	
Efficacy Testing of Intravenous GS-5734 in the Rhesus Macaque Model of MERS-CoV Infection		NHP	30	E				X	

Production and Titration of Rat-passaged Prion Stocks	Redacted by agreement	Rat	96	C/E				X	
Prion Infection in Transgenic Mice Expressing Human Apolipoprotein E		Mouse	240	C/D/E				X	
Experimental Infection of Three Bat Species with Bat Coronaviruses		Bat	72	E				X	
Pathogenesis of Klebsiella pneumoniae ST258 in a Murine Bacteremia Model		Mouse	95	C/E				X	
Production of Polyclonal Rabbit Sera Against Nipah Virus in Rabbits		Rabbit	8	C				X	
Antibody Production in Rabbits Against Simbu Serogroup Orthobunyaviruses Inactivated with H_2O_2		Rabbit	22	C				X	
Infectivity of Olfactory Mucosa Tissue Samples from CJD Patients in Human Prion Protein Transgenic Mice		Mouse	126	C/E				X	
Preparation of Plasmodium yoelii Stocks in Mice		Mouse	30	E				X	
Establishing a Malaria Mouse Model for the Use of Ebola Co-infection Studies		Mouse	228	E				X	
Determining Host Responses in the Syrian Hamster Model Upon Immunization with Recombinant Vesicular Stomatitis Virus Vectored Vaccines		Hamster	120	C				X	
Stimulation of B Cells by huBAFF, huIL-6, and anti-CEACAM1 to Improve Antibody Responses in HIV infected humanized mice		Mouse	240	D				X	
Cure of Latent HIV Infection in Humanized Mice Using Anti-retroviral Therapy (ART) and Ixazomib (MLN2238		Mouse	162	C				X	
Production of Friend Virus Stocks in Mice		Mouse	120	C					

Identification of Immunogenic Proteins in Mice Immune to Virulent Francisella tularensis	Redacted by agreement	Mouse	50	C					X	
Efficacy of Chimpanzee Adenovirus (ChAdOx1-MERS-S) Expressing MERS-CoV Spike Vaccine, Using Transgenic hDPP4 Mice		Mouse	40	E					X	
Competence of B. burgdorferi Variants in the Mouse/Tick Infectious Cycle		Mouse	864	C					X	
Evaluation of Virulence and Attenuation of Various Salmonella Mutants in Mice		Mouse	1180	C/E					X	
Transmission of MERS-CoV within Immunocompromised hDPP4 Transgenic Mice		Mouse	154	E					X	
Mapping a Susceptibility Allele for Ebola Hemorrhagic Fever Pathogenesis and Resistance in Mice		Mouse	144	C/E					X	
Effect of NK/T cell Depletion on Andes Virus Pathogenesis in Hamsters		Hamster	30	C/E					X	
Tissues from TSE-Infected Mice and Hamsters for Use in Biochemical and Biophysical Analysis		Mouse Hamster	1560 394	C/E					X	
Innate Immune Responses and Zika Virus Pathogenesis in the CNS in Mice		Mouse	2256	C/E	X				X	
Evaluation of the Antiviral Compound Griffithsin Against Middle East Respiratory Syndrome Coronavirus (MERS-CoV) in Rhesus Macaques		NHP	8	E					X	
Tracking Microglia, Monocytes, and Monocyte-derived Macrophages Following Ocular or Intracerebral Scrapie Infection of Mice		Mouse	192	D/E					X	
Microglial Involvement in Prion Pathogenesis and Neuroinflammation in Mice		Mouse	536	D/E	X				X	

Localization of T cells during Tularemia in Mice	Redacted by agreement	Mouse	512	C/E				X	
Establishment of an "Old World" Non-human Primate Disease Model for Zika Virus Infection		NHP	16	E				X	
Protective Efficacy of Humanized Monoclonal Antibody Therapy Against Ebola Virus in Hamsters		Hamster	120	C/E				X	
Defining the Effect of Unique Host Genetic Backgrounds and Sex in Ebola Virus Pathogenicity in Mice and Linking Genetic Loci to Phenotype		Mouse	2760	D/E				X	
Nature of the Protective CD8 T cell Response During Tularemia in Mice		Mouse	1560	C/E				X	
Analysis of Disease Progression of Crimean-Congo Hemorrhagic Fever (CCHF) in Cynomolgus Macaques		NHP	28	E				X	
Determining the Efficacy of a GMP VSV-Lassa Vaccine in the Cynomolgus macaque Model of Lassa Fever		NHP	42	E				X	
Pre- and Post-exposure Treatment with the VSV-MARV Vaccine Against Marburg Hemorrhagic Fever in Macaques		NHP	28	E				X	
Protective Efficacy of the Novel VSV-Makona Vaccination Against Lethal EBOV Infection in Macaques		NHP	20	E				X	
Protective Efficacy of the rVSV-EBOV-HA Vaccine Against Highly Pathogenic H5N1 Influenza A Virus Infection in Mice		Mouse	340	C/E				X	
Determining the Efficacy of GMP-VSV-Lassa GPC Vaccine in the Hartley Guinea Pig Model of Lassa Fever		Guinea Pig	60	E				X	
MERS-CoV Disease Severity in Older hDPP4 Mice		Mouse	14	E				X	
Zika Virus (ZIKV) Infection and Immunity in TKO-BLT Mice		Mouse	216	C/E				X	

Model of Microcephaly Following Vaginal Inoculation of Pregnant Mice with Zika Virus	Redacted by agreement	Mouse	1144	C/E				X	
Normal Laboratory Animal Blood and Tissue Donors to Support Ongoing Research (2016)		Mouse Rat Hamster Rabbit Guinea pig Poultry NHP Ferret Mastomy Wild Mouse Bat Goat Sheep Swine	25000 60 150 30 60 30 100 60 200 200 25 10 10 10	C					
Efficacy of a New VSV-NiV Vaccine Against Nipah Virus Bangladesh in Syrian Hamsters		Hamster	130	E				X	
Establishment of a Microcephaly Model Following Mother-to-Fetus Transmission of Zika Virus in Cynomolgus Macaques		NHP	32	C/D	X			X	
Comparison of Age-Dependent Pathogenesis and Neurological Disease Induced by La Crosse (LAC), Tahyna (TAH), Jamestown Canyon (JC), Snowshoe Hare (SSH), and Inkoo (INK) Viruses in Mice		Mouse	1224	C/E				X	
Comparison of Two Different Nipah Viruses in African Green Monkeys		NHP	8	E				X	
Establishment of a Mouse Model for Lassa Virus Infection		Mouse	124	C/E				X	
Evaluation of Viral Variants of La Crosse Virus (LACV) and Zika Virus (ZIKV) that Mediate Neuroinvasion (LACV) and Placental Crossing (ZIKV) in Mice		Mouse	362	C/E	X			X	
Establishing the Protective Efficacy of VSV-LASV vaccine in Mastomys natalensis		Mastomys	136	C				X	

Protective Efficacy of a Tetravalent Modified Vaccinia Ankara Based Vaccine Against Hemorrhagic Fever Viruses in the Guinea Pigs	Redacted by agreement	Guinea Pig	80	E				X	
Antibody Production in Rabbits		Rabbit	4	C				X	
Infectivity Cycle of Borrelia burgdorferi Mutants in the Mouse Tick-Mouse Model of Infection and Transmission		Mouse Rabbit	900 45	C				X	
Intravital Microscopy to Examine the Dissemination of Salmonella Typhimurium in a Mouse Model of Infection		Mouse	98	D/E				X	X
Production of Rabbit Antibody Against K. pneumoniae Capsule		Rabbit	8	C					
Prion Infection in Transgenic Mice Expressing Human tau		Mouse	160	C/D/E				X	
Genetic Content and Virulence of Coxiella burnetii in Guinea Pigs		Guinea Pig	60	C/E				X	
Immunogenicity and Efficacy Testing of a Conditionally-attenuated Murine Cytomegalovirus-based Ebola Virus Vaccine in Mice		Mouse	140	E				X	
Modulation of Host Metabolism for Protection Against Tularemia in Mice		Mouse	180	E				X	
Inactivation of Rodent Prions in Mice by Reactive Oxygen Species		Mouse	660	D/E	X			X	
Natural Host Immunity and the Infectious Cycle of Borrelia burgdorferi in Mice		Mouse	142	C				X	
Repressor of Toxins (Rot) and D-alanine Transfer Protein (DltB) Contribute to the Pathogenesis of Staphylococcus aureus Skin and Soft Infections in Rabbits: a Pilot Study		Rabbit	24	E				X	
The Effect of Maintenance Blood Feeding and Time After Infection on the Efficiency of Early Phase Transmission of Yersinia pestis by Oropsylla montana to Mice		Mouse	146	E				X	

Depletion of CD4 and CD8 T cells to determine the cytotoxic Contribution of Each Subset in a Mouse Model of Murine Retrovirus Infection	Redacted by agreement	Mouse	140	C					X	
Investigating the Effect of Pregnancy on Acute and Chronic Immune Responses and Viral Load in a Model of Murine Retrovirus Infection		Mouse	672	C					X	

(1) Please provide a description / definition of any pain/distress classification used within this Appendix.
(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.*

Summary of Animal Housing and Support Sites

Redacted by agreement

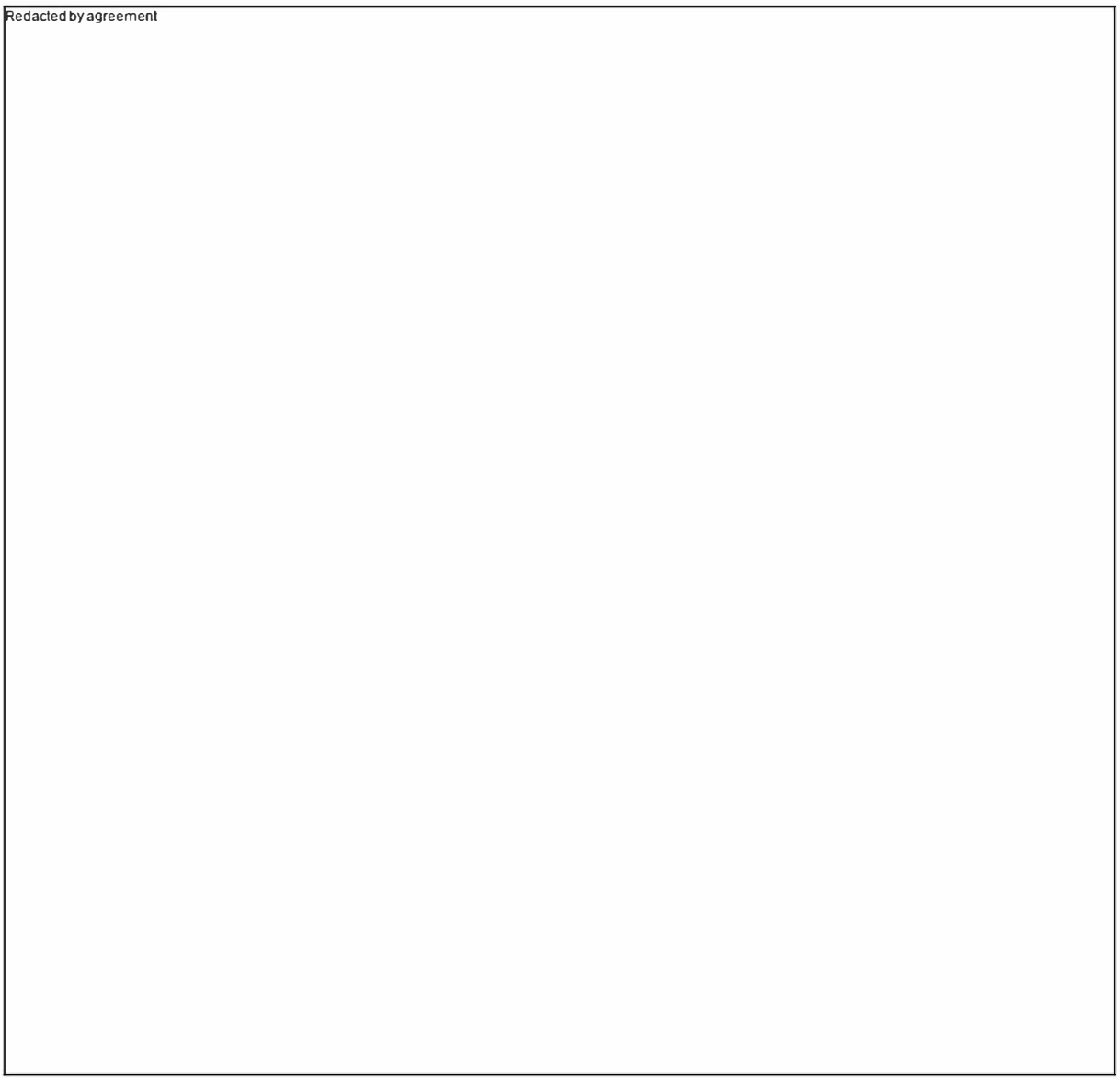
Redacted by agreement

Redacted by agreement

Redacted by agreement

Redacted by agreement

Redacted by agreement



PRE-PLACEMENT EVALUATION

Work Location: _____ ☐Regular ☐Short Stay/Summer Student
At NIH through _____ (date)

Working with: ☐ Patients ☐ HBBF ☐ Animals: _____
☐ Other: _____ ☐ Authorization for TX of a minor signed

PE I

I. IMMUNIZATION/DISEASE HISTORY

Items followed by (*) require medical documentation

Immunization Record Provided: ☐ Y ☐ N

A. Tuberculosis Screening:

Country of Birth: ☐ U.S. ☐ Other: _____
Received BCG ☐ Y ☐ N
Date of last: ☐ TST*: _____ Result _____ ☐ IGRA*: _____ Result*: _____
☐ CXR*: _____ Result*: _____
☐ INH Therapy recommended (if positive): When: _____ For how long: _____

B. Tetanus/Pertussis

Date of last ☐ Td ☐ Tdap: _____ ☐ Declined

C. Hepatitis B	**YES**	**NO**	
Required for occupational exposure	☐	☐	
Prior series complete	☐	☐	Date Completed: _____
If incomplete, note dates administered:			# 1: _____ #2: _____
Documented positive titer	☐	☐	Date: _____
History of disease	☐	☐	
Medical exemption	☐	☐	

D. Rubeola			
DOB after 1950	☐	☐	
Works in Bldg. 10	☐	☐	
Patient contact	☐	☐	
NHP contact (or mice @BRC)	☐	☐	
Documented positive titer			
Rubeola*	☐	☐	Date: _____
Mumps*	☐	☐	Date: _____
Rubella*	☐	☐	Date: _____
MMR Vaccination after 1980/Dates admin*	☐	☐	# 1: _____ #2: _____

E. Varicella			
MD documented history of disease*	☐	☐	Date: _____
Documented positive titer*	☐	☐	Date: _____
Vaccination after 1994/Dates administered*:	☐	☐	# 1: _____ #2: _____

F. Influenza

Immunization received for current season* ☐ ☐ Date: _____

*NAME:*_____ *Last 4:*_____ *DATE:*_____

NO. OF ATTACHED SHEETS:

MEDICAL RECORD	REPORT OF MEDICAL HISTORY	DATE OF EXAM

NOTE: This information is for official and medically-confidential use only and will not be released to unauthorized persons

1. NAME OF PATIENT *(Last, first, middle)*			2. IDENTIFICATION NUMBER	3. GRADE
4a. HOME STREET ADDRESS *(Street or RFD; City or Town; State; and ZIP Code)*			5. EXAMINING FACILITY	
4b. CITY	4c. STATE	4d. ZIP CODE		

6. PURPOSE OF EXAMINATION

7. STATEMENT OF PATIENT'S PRESENT HEALTH AND MEDICATIONS CURRENTLY USED *(Use additional pages if necessary)*

a. PRESENT HEALTH	b. CURRENT MEDICATION	REGULAR OR INTERM.
c. ALLERGIES *(Include insect bites/stings and common foods)*		
	d. HEIGHT	e. WEIGHT
8. PATIENT'S OCCUPATION	9. ARE YOU *(Check one)* ☐ RIGHT HANDED ☐ LEFT HANDED	

10. PAST/CURRENT MEDICAL HISTORY

CHECK EACH ITEM	YES	NO	DON'T KNOW	CHECK EACH ITEM	YES	NO	DON'T KNOW	CHECK EACH ITEM	YES	NO	DON'T KNOW
Household contact with anyone with tuberculosis				Shortness of breath				Bone, joint or other deformity			
				Pain or pressure in chest				Loss of finger or toe			
Tuberculosis or positive TB test				Chronic cough				Painful or "trick" shoulder or elbow			
Blood in sputum or when coughing				Palpitation or pounding heart							
				Heart trouble				Recurrent back pain or any back injury			
Excessive bleeding after injury or dental work				High or low blood pressure							
				Cramps in your legs				"Trick" or locked knee			
Suicide attempt or plans				Frequent indigestion				Foot trouble			
Sleepwalking				Stomach, liver or intestinal trouble				Nerve Injury			
Wear corrective lenses				Gall bladder trouble or gallstones				Paralysis *(including infantile)*			
Eye surgery to correct vision								Epilepsy or seizure			
Lack vision in either eye				Jaundice or hepatitis				Car, train, sea or air sickness			
Wear a hearing aid				Broken bones				Frequent trouble sleeping			
Stutter or stammer				Adverse reaction to medication				Depression or excessive worry			
Wear a brace or back support				Skin diseases				Loss of memory or amnesia			
Scarlet fever				Tumor, growth, cyst, cancer				Nervous trouble of any sort			
Rheumatic fever				Hernia				Periods of unconsciousness			
Swollen or painful joints				Hemorrhoids or rectal disease				Parent/sibling with diabetes, cancer, stroke or heart disease			
Frequent or severe headaches				Frequent or painful urination							
Dizziness or fainting spells				Bed wetting since age 12				X-ray or other radiation therapy			
Eye trouble				Kidney stone or blood in urine				Chemotherapy			
Hearing loss				Sugar or albumin in urine				Asbestos or toxic chemical exposure			
Recurrent ear infections				Sexually transmitted diseases							
Chronic or frequent colds				Recent gain or loss of weight				Plate, pin or rod in any bone			
Severe tooth or gum trouble				Eating disorder (anorexia bulimia, etc.)				Easy fatigability			
Sinusitis								Been told to cut down or criticized for alcohol use			
Hay fever or allergic rhinitis				Arthritis, Rheumatism, or Bursitis							
Head injury								Used illegal substances			
Asthma				Thyroid trouble or goiter				Used tobacco			

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Prescribed by ICMR/GSA
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11. FEMALES ONLY

CHECK EACH ITEM	YES	NO	DON'T KNOW	DATE OF LAST MENSTRUAL PERIOD	DATE OF LAST PAP SMEAR	DATE OF LAST MAMMO-GRAM
Treated for a female disorder						
Change in menstrual pattern						

CHECK EACH ITEM. IF "YES" EXPLAIN IN BLANK SPACE TO RIGHT. LIST EXPLANATION BY ITEM NUMBER.

ITEM	YES	NO
12. Have you been refused employment or been unable to hold a job or stay in school because of:		
a. Sensitivity to chemicals, dust, sunlight, etc.		
b. Inability to perform certain motions.		
c. Inability to assume certain positions.		
d. Other medical reasons *(If yes, give reasons.)*		
13. Have you ever been treated for a mental condition? *(If yes, specify when, where, and give details.)*		
14. Have you ever been denied life insurance? *(If yes, state reason and give details.)*		
15. Have you had, or have you been advised to have, any operation. *(If yes, describe and give age at which occurred.)*		
16. Have you ever been a patient in any type of hospital? *(If yes, specify when, where, why, and name of doctor and complete address of hospital.)*		
17. Have you consulted or been treated by clinics, physicians, healers, or other practitioners within the past 5 years for other than minor illnesses? *(If yes, give complete address of doctor, hospital, clinic, and details.)*		
18. Have you ever been rejected for military service because of physical, mental, or other reasons? *(If yes, give date and reason for rejection.)*		
19. Have you ever been discharged from military service because of physical, mental, or other reasons? *(If yes, give date, reason, and type of discharge; whether honorable, other than honorable, for unfitness or unsuitability.)*		
20. Have you ever received, is there pending, or have you ever applied for pension or compensation for existing disability? *(If yes, specify what kind, granted by whom, and what amount, when, why.)*		
21. Have you ever been arrested or convicted of a crime, other than minor traffic violations. *(If yes, provide details.)*		
22. Have you ever been diagnosed with a learning disability? *(If yes, give type, where, and how diagnosed.)*		

23. LIST ALL IMMUNIZATIONS RECEIVED

I certify that I have reviewed the foregoing information supplied by me and that it is true and complete to the best of my knowledge. I authorize any of the doctors, hospitals, or clinics mentioned above to furnish the Government a complete transcript of my medical record for purposes of processing my application for this employment or service. I understand that falsification of information on Government forms is punishable by fine and/or imprisonment.

24a. TYPED OR PRINTED NAME OF EXAMINEE	24b. SIGNATURE	24c. DATE

NOTE: HAND TO THE DOCTOR OR NURSE, OR IF MAILED MARK ENVELOPE "TO BE OPENED BY MEDICAL OFFICER ONLY".

25. PHYSICIAN'S SUMMARY AND ELABORATION OF ALL PERTINENT DATA *(Physician shall comment on all positive answers in Items 7 through 11. Physician may develop by interview any additional medical history deemed important, and record any significiant findings here.)*

26a. TYPED OR PRINTED NAME OF PHYSICIAN OR EXAMINER	26b. SIGNATURE	26c. DATE

II. COHORT PROGRAMS *Enrolled in:*

☐ AEP: ☐ Small ☐ Large ☐ NHP ☐ NHP tissues
☐ Hep B: ☐ Exempt ☐ Decline ☐ Participating
☐ Tuberculosis Screening Program ☐ TB Quiz Completed

III. COMPLETED TASKS

☐ Vital signs and vision testing completed as ordered
☐ Forms completed and reviewed

Handouts *(Given & Discussed)*	**Labs** *(Drawn)*	**Forms** *(Given with Instructions)*	**Other**
☐ AEP PACKET	☐ Anti-HBS	☐ 750-2	☐ AUDIOMETRY
☐ HBBF EXPOSURE	☐ RUBEOLA TITER	☐ Short Stay/Summer Clearance Form	☐ CXR
☐ OMS/EAP BROCHURE	☐ MUMPS TITER		
☐ STANDARD PRECAUTIONS	☐ RUBELLA TITER		
☐ TB INFO	☐ VARICELLA TITER		
	☐ TB IGRA		

☐ OTHER: _____

☐ **Immunizations Administered** (see record)
☐ **TST Placed** (see record)

☐ **Computer Entries Completed** ☐ **No Labs**

IV. DISPOSITION

☐ FFD: No obvious medical contraindication to position as proposed.
☐ Return for PE II (Date) _____
☐ Needs TST read ☐ IGRA Pending
☐ *Needs prior to clearance:* _____

COMMENTS _____

_____

_____

_____

SIGNATURE _____ *DATE* _____

PE II

PPD Read: Date_____ ☐ Negative ☐ Positive _____*mm*
☐ CXR Ordered ☐ IGRA Drawn
☐ Forms completed and reviewed
☐ FFD: No obvious medical contraindication to position as proposed.

COMMENTS: _____

_____

_____

Forms: ☐ 750 -2 given with instructions
☐ Summer/Short Stay Clearance Form given with instructions

SIGNATURE _____ *DATE* _____

NO. OF ATTACHED SHEETS:

MEDICAL RECORD	REPORT OF MEDICAL HISTORY	DATE OF EXAM

NOTE: This information is for official and medically-confidential use only and will not be released to unauthorized persons

1. NAME OF PATIENT *(Last, first, middle)*			2. IDENTIFICATION NUMBER	3. GRADE
4a. HOME STREET ADDRESS *(Street or RFD; City or Town; State; and ZIP Code)*			5. EXAMINING FACILITY	
4b. CITY	4c. STATE	4d. ZIP CODE		
6. PURPOSE OF EXAMINATION				

7. STATEMENT OF PATIENT'S PRESENT HEALTH AND MEDICATIONS CURRENTLY USED *(Use additional pages if necessary)*

a. PRESENT HEALTH	b. CURRENT MEDICATION	REGULAR OR INTERM.
c. ALLERGIES *(Include insect bites/stings and common foods)*		
	d. HEIGHT	e. WEIGHT
8. PATIENT'S OCCUPATION	9. ARE YOU *(Check one)* ☐ RIGHT HANDED ☐ LEFT HANDED	

10. PAST/CURRENT MEDICAL HISTORY

CHECK EACH ITEM	YES	NO	DON'T KNOW	CHECK EACH ITEM	YES	NO	DON'T KNOW	CHECK EACH ITEM	YES	NO	DON'T KNOW
Household contact with anyone with tuberculosis				Shortness of breath				Bone, joint or other deformity			
				Pain or pressure in chest				Loss of finger or toe			
Tuberculosis or positive TB test				Chronic cough				Painful or "trick" shoulder or elbow			
Blood in sputum or when coughing				Palpitation or pounding heart							
				Heart trouble				Recurrent back pain or any back injury			
Excessive bleeding after injury or dental work				High or low blood pressure							
				Cramps in your legs				"Trick" or locked knee			
Suicide attempt or plans				Frequent indigestion				Foot trouble			
Sleepwalking				Stomach, liver or intestinal trouble				Nerve Injury			
Wear corrective lenses				Gall bladder trouble or gallstones				Paralysis *(including infantile)*			
Eye surgery to correct vision								Epilepsy or seizure			
Lack vision in either eye				Jaundice or hepatitis				Car, train, sea or air sickness			
Wear a hearing aid				Broken bones				Frequent trouble sleeping			
Stutter or stammer				Adverse reaction to medication				Depression or excessive worry			
Wear a brace or back support				Skin diseases				Loss of memory or amnesia			
Scarlet fever				Tumor, growth, cyst, cancer				Nervous trouble of any sort			
Rheumatic fever				Hernia				Periods of unconsciousness			
Swollen or painful joints				Hemorrhoids or rectal disease				Parent/sibling with diabetes, cancer, stroke or heart disease			
Frequent or severe headaches				Frequent or painful urination							
Dizziness or fainting spells				Bed wetting since age 12				X-ray or other radiation therapy			
Eye trouble				Kidney stone or blood in urine				Chemotherapy			
Hearing loss				Sugar or albumin in urine				Asbestos or toxic chemical exposure			
Recurrent ear infections				Sexually transmitted diseases							
Chronic or frequent colds				Recent gain or loss of weight				Plate, pin or rod in any bone			
Severe tooth or gum trouble				Eating disorder (anorexia bulimia, etc.)				Easy fatigability			
Sinusitis								Been told to cut down or criticized for alcohol use			
Hay fever or allergic rhinitis				Arthritis, Rheumatism, or Bursitis							
Head injury								Used illegal substances			
Asthma				Thyroid trouble or goiter				Used tobacco			

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Treated for a female disorder						
Change in menstrual pattern						

CHECK EACH ITEM. IF "YES" EXPLAIN IN BLANK SPACE TO RIGHT. LIST EXPLANATION BY ITEM NUMBER.

ITEM	YES	NO
12. Have you been refused employment or been unable to hold a job or stay in school because of:		
a. Sensitivity to chemicals, dust, sunlight, etc.		
b. Inability to perform certain motions.		
c. Inability to assume certain positions.		
d. Other medical reasons *(If yes, give reasons.)*		
13. Have you ever been treated for a mental condition? *(If yes, specify when, where, and give details.)*		
14. Have you ever been denied life insurance? *(If yes, state reason and give details.)*		
15. Have you had, or have you been advised to have, any operation. *(If yes, describe and give age at which occurred.)*		
16. Have you ever been a patient in any type of hospital? *(If yes, specify when, where, why, and name of doctor and complete address of hospital.)*		
17. Have you consulted or been treated by clinics, physicians, healers, or other practitioners within the past 5 years for other than minor illnesses? *(If yes, give complete address of doctor, hospital, clinic, and details.)*		
18. Have you ever been rejected for military service because of physical, mental, or other reasons? *(If yes, give date and reason for rejection.)*		
19. Have you ever been discharged from military service because of physical, mental, or other reasons? *(If yes, give date, reason, and type of discharge; whether honorable, other than honorable, for unfitness or unsuitability.)*		
20. Have you ever received, is there pending, or have you ever applied for pension or compensation for existing disability? *(If yes, specify what kind, granted by whom, and what amount, when, why.)*		
21. Have you ever been arrested or convicted of a crime, other than minor traffic violations. *(If yes, provide details.)*		
22. Have you ever been diagnosed with a learning disability? *(If yes, give type, where, and how diagnosed.)*		

23. LIST ALL IMMUNIZATIONS RECEIVED

I certify that I have reviewed the foregoing information supplied by me and that it is true and complete to the best of my knowledge. I authorize any of the doctors, hospitals, or clinics mentioned above to furnish the Government a complete transcript of my medical record for purposes of processing my application for this employment or service. I understand that falsification of information on Government forms is punishable by fine and/or imprisonment.

24a. TYPED OR PRINTED NAME OF EXAMINEE	24b. SIGNATURE	24c. DATE

NOTE: HAND TO THE DOCTOR OR NURSE, OR IF MAILED MARK ENVELOPE "TO BE OPENED BY MEDICAL OFFICER ONLY".

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26a. TYPED OR PRINTED NAME OF PHYSICIAN OR EXAMINER	26b. SIGNATURE	26c. DATE

BSP Medical Qualification Assessment (MQA)

Participant:_____ **Date:** _____

Visit Reason: ☐ Initial ☐ Annual ☐ Status Change **Location:** ☐ Bethesda ☐ Frederick ☐ RML

Medical Clearances	Clearance Expiration Date	Last Vaccine Date	Not Cleared (√)		
			In Progress	Declined	Unable
ABSL/BSL-4 laboratory					
ABSL/BSL-4 infrastructure					
ABSL/BSL-3 laboratory					
ABSL/BSL-3 infrastructure					
Administrative support spaces					
Bacteria					
Bacillus anthracis[1]					
B.anthracis (Sterne strain)					
Clostridium botulinum (neurotoxin producing)					
Coxiella burnetii					
Francisella tularensis					
Mycobacterium tuberculosis					
Rickettsia prowazekii					
Yersinia pestis					
Viruses					
Alphavirus: Chikungunya (CHIKV), Eastern, Venezuelan, or Western Equine Encephalitis Virus (EEEV, VEEV, WEEV)					
Arenavirus: Chapare, Guanarito, Junin, Lassa, Lujo, Machupo, Sabia					
Bunyavirus: Crimean Congo Hemorrhagic Fever Virus (CCHFV), hantaviruses, Rift Valley Fever Virus, Severe Fever with Thrombocytopenia Syndrome Virus (SFTSV)					
Coronavirus: Middle East Respiratory Syndrome Coronavirus (MERS-CoV), Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV)					
Filovirus: Ebola, Marburg					
Flavivirus: Alkhurma, Dengue Virus (DENV), Kyasanur Forest Disease, Langat, Omsk Hemorrhagic Fever Virus, Powassan, Saint Louis Encephalitis, West Nile Virus (WNV)					
Flavivirus: Japanese Encephalitis Virus (JEV)[1]					
Flavivirus: Tick-borne Encephalitis Virus (TBEV)[2]					
Flavivirus: Yellow Fever[3]					
Henipavirus: Cedar, Hendra, Nipah					
Influenza: 1918[1], High Path Influenza[1] (HPI), non-HPI[1]					
Newcastle Disease Virus (NDV)					
Orthopox: Monkeypox[2]					

1: Booster dose required every year
2: Booster dose required every 3 years
3: Booster dose required every 10 years

●MS Healthcare Provider: _____ **Date:** _____

BSP Medical Evaluation Form

Name: _____ **Date:** _____

Visit Type: ☐ Initial ☐ Annual ☐ Status change

Job title:
Employer:

Based on the MQR, the worker requires access to areas registered to use/store the following agents:

☐ *Bacillus anthracis*[1]
☐ *Bacillus anthracis* (Sterne strain)
☐ *Clostridium Botulinum* (neurotoxin producing)
☐ *Coxiella burneti*
☐ *Francisella tularensis*
☐ *Mycobacterium tuberculosis*
☐ *Rickettsia prowazekii*
☐ *Yersinia pestis*
☐ Alphavirus: Chikungunya Virus (CHIKV), Eastern Venezuelan, or Western Equine Encephalitis Virus (EEEV,VEEV, or WEEV)
☐ Arenavirus: Chapare, Guanarito, Junin, Lassa, Lujo, Machupo, Sabia
☐ Bunyavirus: Crimean-Congo Hemorrhagic Fever Virus (CCHFV), hantaviruses, Rift Valley Fever Virus, Severe Fever with Thrombocytopenia Syndrome Virus (SFTSV)
☐ Coronavirus: Middle East Respiratory Syndrome Coronavirus (MERS-CoV), Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV)
☐ Filovirus: Ebola, Marburg
☐ Flavivirus: Alkhurma, Dengue Virus (DENV) Kyasanur Forest Disease, Langat, Omsk Hemorrhagic Fever Virus, Powassan, Saint Louis Encephalitis, West Nile Virus (WNV)
☐ Flavivirus: Japanese Encephalitis Virus (JEV)[1]
☐ Flavivirus: Tick-borne Encephalitis Virus (TBEV)[2]
☐ Flavivirus: Yellow Fever[3]
☐ Henipavirus: Cedar, Hendra, Nipah
☐ Influenza: 1918[1], High Past Influenza (HPI)[1], non-HPI[1]
☐ Newcastle Disease Virus
☐ Orthopox: Monkeypox[2]
☐ Other: _____

1: Booster dose required every year
2: Booster dose required every 3 years
3: Booster dose required every 10 years

Work environment: ☐ ABSL/BSL-4 laboratory ☐ ABSL/BSL-4 infrastructure ☐ ABSL/BSL-3 laboratory ☐ ABSL/BSL-3 infrastructure ☐ Administrative support spaces

Will work in a BSL-4 suit? ☐ No ☐ Yes (*if yes and this is an initial BSP visit, offer audiometric testing*)

Clearance type ☐ Direct handling of agents ☐ Access to active areas ☐ No access to active areas

Worker's description of work responsibilities (*describe any discrepancies with MQR assertions*)

Immunizations *(required, if working with the agent in a BSL-3 laboratory)*

	Date of last dose?	Series complete/take?	Booster dose due? *(date)*
Anthrax[1]	_____	☐ Yes ☐ No	_____
Influenza[1]	_____		_____
JEV[1]	_____	☐ Yes ☐ No	_____
TBEV[2]	_____	☐ Yes ☐ No	_____
Td	_____		_____
Tdap[3]	_____		_____
Vaccinia	_____	☐ Yes ☐ No	_____
Yellow Fever[3]	_____		_____
Other (specify)	_____	☐ Yes ☐ No	_____

Respirator fit testing/training previously cleared? ☐ Yes ☐ No Date cleared: _____

Animal contact ☐ None ☐ Small ☐ Large ☐ NHP ☐ NHP tissues

Previously enrolled in AEP? ☐ N/A ☐ Yes ☐ Enrolled today
If NHP contact
☐ Last TST/IGRA Date: _____ Result: _____
☐ Rubeola titer Date: _____ Result: _____

Save serum (*due q 5 yrs*) Date of last: _____
Due now? ☐ No ☐ Yes

Lipid profile (*only for BSL-4. Due q 5 yrs. Due q yr, if last risk score was >9.*) Date of last: _____
Due now? ☐ No ☐ Yes

HR: _____ BP: _____/_____ RR: _____ Height: _____' _____" Weight: _____ BMI: _____

Vision Testing

Acuity	Near Vision		Distant Vision	
	Uncorrected	Corrected	Uncorrected	Corrected
OD	_____	_____	_____	_____
OS	_____	_____	_____	_____
OU	_____	_____	_____	_____

Depth perception

1) B	4) T	7) R
2) L	5) T	8) L
3) B	6) L	9) R

Score: _____ / 9

Peripheral Vision (*Circle*) Pass Fail

Color vision (*initial visit only*)

1) 12 _____	6) 7 _____	11) 2 _____
2) 8 _____	7) 45 _____	12) 35 _____
3) 5 _____	8) 2 _____	13) 96 _____
4) 29 _____	9) X _____	14) X _____
5) 74 _____	10) 16 _____	

Score: ____/ 14

Date: _____

Comments or concerns:

_____ Date: _____
(*BSP Provider's signature*)

Social History (*for annual visit – enter changes from last visit*)

Those living at home (their age and health status)

Other family responsibilities (e.g., ill child, elderly/ill parent, etc.)

Travel, outside recreational activities, hobbies

Past Medical History (*for annual visit – enter changes from last visit*)

History of adverse reactions to medications (*specify type of reaction to each*)

Prior hospitalizations, surgeries, urgent care/ER visits (*describe*)

Febrile illness: (*describe*)
If yes, did the participant report it to OMS? ☐ Yes ☐ No

Occupational injury (*describe*)
If yes, did the participant report it to OMS? ☐ Yes ☐ No

Possible exposure (*describe*)
If yes, did the participant report it to OMS? ☐ Yes ☐ No

Current Medical History (*for annual visit – enter changes from last visit*)

Current medical conditions

Any reason to suspect immune suppression (e.g., HIV infection, some cancers, treatment with steroids, splenectomy, frequent infections requiring antibiotic treatment, diabetes, etc.)

Current medications (prescription, OTC, and supplements)

Changes in medications or dosage

Allergies/changes in allergies (e.g., animal proteins, latex)

Review of Systems (*for annual visit – enter changes from last visit*)

HEENT (e.g., headaches, hearing problems, vision problems, sleep apnea/CPAP, chronic sinus problems)

Cardiovascular (e.g., HTN, CAD, angina, DOE)

Pulmonary (e.g., persistent cough, smoking history, asthma, hemoptysis)

Musculoskeletal (e.g., previous back injuries, knee injuries, repetitive motion injury, arthritis, fibromyalgia)

Gastrointestinal (e.g., GERD, history of gastric ulcer disease, Crohn's disease, IBS)

GU/GYN (e.g., kidney stones, menstrual disorders, pregnant)

Metabolic (e.g., thyroid disease, diabetes)

Dermatological (e.g., eczema, psoriasis)

Neurological (e.g., head injury w/sequelae, seizures, tremors, stroke, aneurysm, multiple sclerosis)

Psychological (depression, anxiety, claustrophobia, history of hypnosis, attempted suicide)

Past history of either alcohol or drug abuse? ☐ Yes ☐ No
If yes, explain:

Current alcohol use (*check each consumed and the quantity in an average week since the last visit*)

☐ Beer: _____

☐ Wine: _____

☐ Liquor: _____

Current recreational drug use (*details*)

During the last year: (*Explain all positive responses to the following questions*)

- Have you had five or more drinks on at least one occasion? ☐ Yes ☐ No
  If yes, specify the beverage type and quantity.
- Did you drink excessively as often as once per month? ☐ Yes ☐ No
  If yes, specify the frequency of excessive drinking.
- Have you had a feeling of guilt or remorse after drinking or doing drugs? ☐ Yes ☐ No
- Has a friend or family member ever told you about things you said or did while you were drinking or doing drugs that you could not remember? ☐ Yes ☐ No
- Have you failed to do what was expected from you because of drinking or drug use? ☐ Yes ☐ No

Cardiac Clearance (*BSL-4, ABSL-4, critical infrastructure for a BSL-4*)

Age _____
Gender _____
Total cholesterol _____HDL _____
Smoker ☐ Yes ☐ No
Systolic BP _____
Currently on any medication to treat hypertension ☐ Yes ☐ No

10 year risk _____ (*greater than 20% triggers further cardiac evaluation*)

Behavioral Health Assessment

Received? ☐ Yes ☐ No

Actions Taken

- ☐ Reviewed and confirmed data entry in CAM
- ☐ EAP services discussed
- ☐ First aid discussed in detail
- ☐ Activation of emergency medical response system discussed
- ☐ Need to report all accidents discussed
- ☐ Need to report all fevers discussed
- ☐ Need to report all health-related changes that could interfere with safe and effective performance in a BSL-3 or BSL-4 laboratory, prior to the annual visit, discussed
- ☐ For participants in MD, discussed the potential need to enroll in a clinical protocol for care in the SCSU at the Clinical Center in the event of significant exposure to a BSL-3 or -4 agent or a suspected laboratory acquired infection. If care is recommended, will the worker agree to enroll in the study?
  ☐ Yes ☐ Maybe ☐ No If maybe or no, explain: _____
  ☐ Handout describing the clinical protocol provided
- ☐ For participants in MT, discussed the possible need for hospitalization at St. Patrick's Hospital in Missoula to care in the event of a significant exposure to a BSL-3 or -4 agent or a suspected laboratory acquired infection. If care is recommended, will the worker agree to hospitalization at St. Patrick Hospital?
  ☐ Yes ☐ Maybe ☐ No If maybe or no, explain: _____
- ☐ Relevant, pathogen-specific counseling and related informational handouts provided
- ☐ Supplies provided
  - ☐ Wallet card
  - ☐ Thermometer (*provided to participants who handle BSL-3 or -4 agents*)
  - ☐ Oseltamivir 75 mg tab #10, prescription given (*provided to participants who handle HPI*)
- ☐ MQA completed

Comments (*describe the steps taken to resolve any discrepancies between the MQR and the worker's history*)

Recommendations

- ☐ Issue medical clearance for work in:
  - ☐ ABSL/BSL-4 laboratory
  - ☐ ABSL/ BSL-4 infrastructure
  - ☐ ABSL/BSL-3 laboratory
  - ☐ ABSL/ BSL-3 infrastructure
  - ☐ Administrative support space

- ☐ Hold medical clearance for specific pathogen (*explain*)

- ☐ Hold medical clearance for participation in the BSP (*explain*)

_____ Date: _____

(*BSP Provider's signature*)

Meetings arranged by Redacted by

Distribution List: NIAID RML ACUC

ANIMAL CARE AND USE COMMITTEE (ACUC)

Name	Lab	Affiliation	Email	Phone	Comment	Start Year
Redacted by agreement					Reviewer	Feb-11
					Reviewer	Sep-11
Gardner, Don	RMVB	Chief, RMVB	dgardner@niaid.nih.gov	Redacted by agreement	Reviewer	Jan-14
Redacted by agreement					Reviewer	Oct-14
					Vice-Chair	12/1/2012; designated VC on 5/14/2014
					Reviewer	Jul-15
					Reviewer	Jul-15
					Reviewer	Sep-15
					Reviewer	Oct-14
					Reviewer	Jul-10
					Reviewer	Jun-06
					Alternate for S Best	Oct-14
					Reviewer	Jul-15
					Reviewer	Jun-15
Steele-Mortimer, Olivia	**LB**	**Senior Investigator**	**omortimer@niaid.nih.gov**	Redacted by agreement	**Chair**	**5/23/2011; designated chair on 10/1/2011**
Redacted by agreement						Oct-14
					Member	Jan-16
					Ex Officio	
					Ex Officio	
					Ex Officio	
					Ex Officio	
					Ex Officio	
					Ex Officio	
					Ex Officio	

NATIONAL INSTITUTES OF HEALTH
ANIMAL STUDY PROPOSAL
(03/11/2016)

Leave Blank
PROPOSAL # _____
APPROVAL DATE

A. ADMINISTRATIVE DATA:

Institute or Center: NIH/NIAID/RML

Principal Investigator:

Building/Room: E-Mail: Telephone: FAX:

Emergency Treatment and Animal Care instructions shall be provided on the attached form at the end of this document.

Division, Laboratory, or Branch:

Project Title:

Initial Submission [ ] Renewal [ ] or Modification [ ] of Proposal Number_____
List the names of all individuals authorized to conduct procedures involving animals under this proposal and identify key personnel (i.e., Co-investigator(s)): A brief summary of the training and/or experience for procedures each individual will be expected to perform in this ASP must be documented and available to the ACUC. The name(s) of the supervisor, mentor, or trainer who will provide assurance each individual is/has achieved proficiency in those procedures shall be included in that documentation.

Principal Investigator:
Responsible Investigator (Required if PI is not an NIAID Employee):
Co-Investigator:
Non-RML Investigators:
RMVB Personnel (T & E form not required):

B. ANIMAL REQUIREMENTS:

Species: Age/Weight/Size: Sex:

Stock or Strain:

Source(s): Holding Location(s):

Animal Procedure Location(s):

Estimated Number of Animals:

Year 1 Year 2 Year 3 =TOTAL

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

D. STUDY OBJECTIVES: Provide no more than a 300 word summary of the objectives of this work. Why is this work important/interesting? How might this work benefit humans and/or animals? This should be written so that a non-scientist can easily understand it. Please eliminate or minimize abbreviations, technical terms, and jargon. Where they are necessary, they should be defined.

1) Explain briefly in non-scientific terms:

2) Explain briefly in scientific terms:

3) Explain briefly in scientific language, the hypothesis and the specific aims of this study:

E. RATIONALE FOR ANIMAL USE:

1) Explain your rationale for animal use.

2) Justify the appropriateness of the species selected.

3) Justify the number of animals to be used. (Use additional sheets if necessary)

F. DESCRIPTION OF EXPERIMENTAL DESIGN AND ANIMAL PROCEDURES:

Briefly explain the experimental design and specify all animal procedures. This description should allow the ACUC to understand the experimental course of an animal from its entry into the experiment to the endpoint of the study. Specifically address the following: (Use additional sheets if necessary.)

1) **Injections, Inoculations, or Instillations** (substances, e.g., infectious agents, adjuvants, medications, drugs, etc.; dose, sites, volume, route, diluent, and schedules). ACUCs will address non-pharmaceutical grade compounds IAW Guidelines for the Use of Non-Pharmaceutical Grade Compounds in Laboratory Animals

2) **Blood Withdrawals** (volume, frequency, withdrawal sites, and methodology)

3) **Minor surgical procedures (those which do not invade a body cavity):**

4) **Non-Survival Surgical Procedures** (Provide details of survival surgical procedures in Section G.)

5) **Radiation** (dosage and schedule)

6) **Methods of Restraint** (e.g., restraint chairs, collars, vests, harnesses, slings, etc.)

7) **Animal Identification Methods** (e.g., ear tags, tattoos, collar, cage card, etc.)

8) **Other Procedures** (e.g., survival studies, tail biopsies, etc.)

9) **Potentially Painful or Distressful Effects**, if any, the animals are expected to experience (e.g., pain or distress, ascites production, etc.) For Column E studies provide: 1) a description of the procedure(s) producing pain and/or distress; 2) scientific justification why pain and/or distress cannot be relieved.

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

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

None ____ Major_____ Minor_____

1. Identify and describe the surgical procedure(s) to be performed. Include the aseptic methods to be utilized. (Use additional sheets if necessary):
2. Who will perform surgery and what are their qualifications and/or experience?
3. Where will surgery be performed, Building and Room?_____
4. Describe post-operative care required, including consideration of the use of post-operative analgesics, and identify the responsible individual:
5. Has survival surgery been performed on any animal prior to being placed on this study? Y/N_____ If yes, please explain:
6. Will more than one survival surgery be performed on an animal while on this study?
   Y/N_____ If yes, please justify:

H. RECORDING PAIN OR DISTRESS CATEGORY -

The ACUC is responsible for applying U.S. Government Principle IV.: Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals. Check the appropriate category or categories and indicate the approximate number of animals in each. Sum(s) should equal total from Section B.

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

NUMBER OF ANIMALS USED EACH YEAR			Year 1	Year 2	Year 3
	USDA Column C	Minimal, Transient, or No Pain or Distress			
	USDA Column D	Pain or Distress Relieved By Appropriate Measures			
	USDA Column E	Unrelieved Pain or Distress			

Describe your consideration of alternatives to procedures listed for Column D and E, and your determination that alternatives were not available. [Note: Principal investigators must certify in paragraph N.5. that no valid alternative was identified to any described procedures which may cause more than momentary pain or distress, whether it is relieved or not.] Delineate the methods and sources used in the search below. **Database references must include the databases (2 or more) searched, the date of the search, period covered, and keywords used.**

I. ANESTHESIA, ANALGESIA, TRANQUILIZATION: For animals indicated in Section H, Column D, specify the anesthetics, analgesics, sedatives or tranquilizers that are to be used. Include the name of the agent(s), the dosage, route, and schedule of administration. ACUCs will address non-pharmaceutical grade compounds IAW Guidelines for the Use of Non-Pharmaceutical Grade Compounds in Laboratory Animals. None ____

J. METHOD OF EUTHANASIA OR DISPOSITION OF ANIMALS AT END OF STUDY: Indicate the proposed method, and if a chemical agent is used, specify the dosage and route of administration. If the method(s) of euthanasia include those not recommended by the AVMA Guidelines on Euthanasia, provide justification why such methods must be used. Indicate the method of carcass disposal if not as MPW.
None ____

K. HAZARDOUS AGENTS: None ____
Use of hazardous agents requires the approval of an RML safety specialist. If you have any questions, please contact the RML Biosafety Staff, Radiation Safety Officer, or Occupational Safety and Health Manager.

Biological Agents with Pathogenic Potential: **NONE** ___ (check if none) For guidance, see ORS/DOHS Biological Safety and Compliance. Include the RML Institutional Biosafety Committee's risk-assessment language or attach a copy of the registration documents.		
Agent:	PRD #:	ABSL:
Additional occupational health and/or animal facility handling safety considerations.		

Recombinant DNA: **NONE** ___ (check if none) For guidance, see NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules FAQs. Include the RML Institutional Biosafety Committee's risk-assessment language or attach a copy of the registration documents.		
Recombinant DNA:	RD #:	ABSL:
Additional occupational health and/or animal facility handling safety considerations.		

Ionizing Radiation: (Radionuclides & radiation producing equipment) **NONE** ___ (check if none) For guidance, see ORS/DRS/Policies/Radiation Safety Protocols Animal Studies Proposal Requirements
☐ Yes, I will use radionuclides or radiation producing equipment as part of the experimental procedures on the ASP and all operators will be registered with Division of Radiation Safety. If an irradiator is to be used, then all individual users must comply with Division of Radiation Safety requirements for irradiator training, and all individual assessors will comply with applicable security requirements for escorts and proxy card access approval.
List of Radionuclides:
Radiological safety considerations:

Hazardous Chemicals or Drugs: **NONE** ___ (check if none) For guidance, see NIH Policy Manual 3034 – Working with Hazardous Chemicals Material safety data sheets for hazardous chemicals and drugs must be maintained readily accessible to laboratory and animal facility employees (Title 29, Part 1910.1200(b)(3)(ii), CFR)
List of Agents:
Additional occupational health and/or animal facility handling safety considerations:

L. BIOLOGICAL MATERIAL/ANIMAL PRODUCTS FOR USE IN ANIMALS (e.g., List cells/tissues, sera/antibodies, viruses/parasites/bacteria, and non-synthetic biochemicals that will be introduced into research animals.): None ____

Material:	Source:	Sterile?	
		Y	N
If derived from rodents, has the material been tested, e.g. MAP/RAP/HAP/PCR? (If Yes, attach copy of results)			
Have the tested materials been passed through rodents outside of the animal facility in question?			
Is the material derived from the original MAP/RAP/HAP/PCR tested sample?			
I certify that to the best of my knowledge that the above is complete and correct, and that the material remains uncontaminated with rodent pathogens.			

M. SPECIAL CONCERNS OR REQUIREMENTS OF THE STUDY: List any special housing, equipment, animal care (i.e., special caging, water, feed, or waste disposal, etc.). Include justification for exemption from participation in the environmental enrichment plan for nonhuman primates or exercise for dogs. None ____

N. PRINCIPAL INVESTIGATOR CERTIFICATIONS:

1. I certify that I have attended an approved NIH investigator training course.
   Month/Year of Initial Course Completion:_____ ; Month/Year(s) of Refresher Training: _____
2. I certify that I have determined that the research proposed herein is not unnecessarily duplicative of previously reported research.
3. I certify that all individuals working on this proposal who have animal contact are participating in the NIH Animal Exposure Program (or equivalent, as applicable, for contract personnel).
4. I certify that the individuals listed in Section A are authorized to conduct procedures involving animals under this proposal, have completed the course "Using Animals in Intramural Research: Guidelines for Animal Users" will complete refresher training as required, and received training in the biology, handling, and care of this species; aseptic surgical methods and techniques (if necessary); the concept, availability, and use of research or testing methods that limit the use of animals or minimize distress; the proper use of anesthetics, analgesics, and tranquilizers (if necessary); and procedures for reporting animal welfare concerns. I further certify that I am responsible for the professional conduct of all personnel listed in Section A.
5. **FOR ALL COLUMN D AND COLUMN E PROPOSALS (see Section H):** I certify that I have reviewed the pertinent scientific literature and the sources and/or databases (2 or more) **as noted in Section H,** and have found no valid alternative to any procedures described herein which may cause more than momentary pain or distress, whether it is relieved or not.
6. I will obtain approval from the ACUC before initiating any significant changes in this study.

By signing the attached signature page, I certify the above.

Column E Explanation Form For Regulated Species

Though Column E studies do involve pain and/or distress, properly selected endpoints are applied to minimize pain and/or distress and adverse effects to the animals while accomplishing the scientific goals.

This form is intended as an aid to completing the Column E explanation. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. **Registration Number: 51-F-0016**

2. **Number of animals used under Column E conditions in this study.**

3. **Species (common name) of animals used in this study.**

4. **Explain the procedure producing pain and/or distress, including reason(s) for species selected. (*from ASP Section F*)**

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results *(from ASP, Section F).* Provide summary of supportive care measures (if applicable).**

INSTRUCTIONS FOR EMERGENCY ANIMAL TREATMENT AND CARE

Principal Investigator: Date form completed:
Protocol Number:
Office Phone:
Home Phone:

Protocol Title:

Use a separate form if ***care is different*** for each species
Species: **Species**:
Species: **Species:**

Animal Housing Location: Bldg
Use separate form if care differs by location Bldg
Bldg

List of Procedures: (surgery, tumor implant, catheter**):**

Primary Point of Contact (P.O.C.) in Case of Emergency:
Work Tel: **Home Tel**: **Pager or Cell #**:
Alternate Point of Contact in Case of Emergency:
Work Tel: **Home** **Pager or Cell #**:
Potential or Expected Complications:

Circumstances Requiring Contact:

Treatment (indicate appropriate response):

Treatment determined by **veterinarian**: [ ] Yes [ ] No
If **NO**, specify **restrictions** as follows

Specific treatment as follows:
What **drugs** are **contraindicated?** Criteria for **Euthanasia** (indicate appropriate response)

At Vet discretion if poor condition, severe pain or distress: [ ] Yes [ ] No
If NO, specify treatments **or** restrictions:

- Notify P.O.C. *[ ] Yes [ ] No
- Requested **euthanasia agent** and **route of administration**:
- Specific **criteria** for **euthanasia**:

If Euthanasia is performed or animals are found dead:
a. Contact P.O.C. [ ] Yes [ ] No
b. Refrigerate carcass [ ] Yes [ ] No
c. Dispose of carcass [ ] Yes [ ] No
d. Submit to DVR for necropsy [ ] Yes [ ] No
CAN number to use for submission:

Additional Comments:

Principal Investigator:

_____
Signature Date

*** The veterinarian will take the appropriate action in an emergency if no response from the PI/POC is received within 30 minutes after an attempt at notification is made.**

RML ACUC
Thursday January 26, 2017
1:30 PM
MINUTES

I. CALL TO ORDER – 1335

Members	Present	Absent
Dr. Steele-Mortimer – Chair	X	
Dr. Gardner – Attending Veterinarian	X	
Redacted by agreement	X	
	X	
	X	
	X	
	X	
	X	
		X
	X	
	X	
		X
		X
	X	
	X	
	X	

Guests	Present
Redacted by agreement	X
	-
	-
	X
	X

Coordinator	Present
Redacted by agreement	X

II. APPROVAL OF MINUTES- Tabled for next month

III. FACILITIES UPDATE- Power outages occurred in Redacte in December. Breakers were tripping, due to faulty sensors. There were no animal welfare concerns that resulted and there have been no further incidences since that time. Redacted renovation started and are due to be finished by late spring.

IV. ADDENDA APPROVED, ANNUAL REVIEW (via electronic memo**), APPROVED PROTOCOLS FINALIZED,**

Addenda Approved

Addendum #	Approved via	P.I	Title	Approved
Redacted by agreement	DMR	Redacted by agreement	Establishment of a lethal mouse model for Ebola infection suitable for both vaccine and therapeutic treatment	12/20/2016
	FCR/DMR		Analysis of Disease Progression of Crimean-Congo Hemorrhagic Fever (CCHF) in Cynomolgus Macaques	12/23/2016
	DMR		Production and titration of rat-passaged prion stocks	12/23/2016
	Admin		Defining the Effect of Unique Host Genetic Backgrounds and Sex in Ebola Virus Pathogenicity in Mice and Linking Genetic Loci to Phenotype	12/23/2016
	DMR		Testing of Recombinant Attenuated Salmonella Vaccines against Lassa virus infection in *Mastomys natalensis*	01/03/2017
	FCR		Determining the efficacy of GMP VSV-Lassa GPC vaccine in the Hartley guinea pig model of Lassa fever	01/03/2017
	DMR		IFN-ART Cure of HIV infection in TKO BLT mice	01/05/2017
	DMR		Effect of NK/T cell depletion on Andes virus pathogenesis in hamsters	01/06/2017
	DMR		Understanding the cell-type specific role of MAVS in protection from Ebola virus infection in the mouse model	01/10/2017
	DMR		Investigating the mechanisms of development and progression of Salmonella meningitis in mice	01/10/2017
	DMR		Cell-specific MAVS responses and LACV pathogenesis in mice	01/13/2017
	DMR		Defining the Effect of Unique Host Genetic Backgrounds and Sex in Ebola Virus Pathogenicity in Mice and Linking Genetic Loci to Phenotype	01/19/2017
	DMR		Establishment of a microcephaly model following mother to fetus transmission of Zika virus in Cynomolgus macaques	01/19/2017

Annual Review of Approved Protocols (via electronic memo)

Protocol #	P.I	Title	Approved	Expires
Redacted by agreement		Modulation of inflammation by Synthetic PE:PC liposomes in mice	01/13/2016	01/13/2019
		Antibody production against Phlebovirus NSs Protein in Rabbits	01/14/2015	Closed out
		The role of Mitochondria in Neuronal Degeneration of Scrapie-infected Mice	01/07/2015	01/07/2018
		Injection of Human Jakob disease (CJD) Isolates of the Genotype Met/Val Into Transgenetic Mice Expressing the Human Prion Protein	01/07/2015	01/07/2018
		Efficacy of rVACV-COP/MERS-S vaccine using transgenic DPP4 mice	01/15/2016	Closed out
		Analysis of colonization of C. trachomatis to the lower genital tract in mice	3/13/2015	Closed out
		Production of prion infected tissues in mice	01/29/2105	01/29/2018
		Aerosol Challenge and the generation of aerosols by ebola virus in Cynomolgus macaques	01/08/2015	Closed out
		Evaluation of FX06 for the treatment and prevention of hantavirus pulmonary syndrome in Syrian hamsters	01/29/2015	01/29/2018
		Assessing the therapeutic potential of human anti-Sin Nombre virus polyclonal IgG antibodies against the development of hantavirus pulmonary syndrome in non-human primates	01/29/2015	01/29/2018
		Contribution of capsule in Francisella tularensis mediated suppression of pulmonary inflammation in mice	01/12/2015	Closed out
		Defining post-vaccination immune response of VSV vector vaccines in hamsters	02/05/2015	02/05/2018
		Efficacy of computationally predicted Ebola antiviral compound in mice	01/29/2015	01/29/2018
		Understanding the role of MAVS in protection from TBEV infection in the mouse model	01/27/2015	01/27/2018

Protocols Approved and Finalized

Protocol #	P.I	Title	Approved	Expires
Redacted by agreement		Establishing the protective efficacy of VSV-LASV vaccine in Mastomys natalensis	12/28/2016	12/28/2019
		Protective efficacy of a tetravalent modified vaccinia Ankara-based vaccine against hemorrhagic fever viruses in the Guinea Pig	12/27/2016	12/27/2019
		Antibody Production in Rabbits	01/03/2017	01/03/2020
		Infective Cycle of *Borrelia burgdorferi* Mutants in the Mouse-Tick-Mouse Model of Infection and Transmission	01/05/2017	01/05/2020
		Using intravital microscopy to examine the dissemination of Salmonella Typhimurium in a mouse model of infection	01/18/2017	01/18/2020

V. ADDENDUM FOR REVIEW BY FCR

(b)(5)

VI. NEW ANIMAL STUDY PROPOSALS –

(b)(5)

(b)(5)

VII. OTHER BUSINESS –

OLAW Response - Response was received and no additional actions are required

Unexpected Outcome Report Redacted by agreement – The PI self-reported an unexpected outcome and presented details at the meeting. There were unexpected deaths that the PI believed to be from an unidentified stressor or strain issue. The PI looked at bacterial loads in infected mice, histology is being performed and thus far, there is no indication the deaths has anything to do with inoculum or evidence of protocol failure during the experiment. The committee discussed the findings and no further action is needed. The Animal Program Administrator will request a health certificate from vendor. The committee decided this was not a reportable event.

ARAC Meeting – The chair provided feedback from the ARAC Meeting held on 01/25/2017 in which the ARAC's CO_2 euthanasia guideline was reviewed. Specifically where the word "Should" is used, this indicates there is room for flexibility in how this is interpreted by each Institute. For example, where it says containers should be cleaned after each use.

VIII. GUIDELINES AND POLICIES TO REVIEW –

RML ACUC Guideline for Online ASP Submission – Approved with minor changes
RML ACUC Guideline on Anesthesia and Analgesia – Tabled for DMR
RML ACUC Guideline on Euthanasia – Tabled for February's ACUC Meeting

IX. NEXT MEETING DATE –

- Thursday February 23, 2017 starting at 1:30 p.m. in Redacted by agreement

IIX. ADJOURNMENT - 1515

RML ACUC
Thursday, February 23, 2017
1:30 PM
MINUTES

IV. CALL TO ORDER – 1340

Members	Present	Absent
Dr. Steele-Mortimer – Chair	X	
Dr. Gardner – Attending Veterinarian	X	
Redacted by agreement		X
	X	
	X	
		X
		X
	X	
	X	
	X	
	X	
	X	
	X	
	X	
	X	

Guests	Present
Redacted by agreement	X
	-
	X
	X

Coordinator	Present
Redacted by agreement	X

V. **APPROVAL OF MINUTES-** December 2016, Jan 3 2017 and January 2017 minutes were approved as is

VI. **FACILITIES UPDATE-** Redacted by renovation is in progress. Redacted by agreement may have upgrading for AAALAC (hallways, etc).

IV. ADDENDA APPROVED, ANNUAL REVIEW (via electronic memo**), APPROVED PROTOCOLS FINALIZED,**

Addenda Approved

Addendum #	Approved via	P.I	Title	Approved
Redacted by agreement	DMR	Redacted by agreement	Immune responses of Zika virus infection in adult mice and the impact of pregnancy or Dengue infection on these responses	01/20/2017
	Admin (VVC) – additional urine collection		Establishment of a microcephaly model following mother-to-fetus transmission of Zika virus in Cynomolgus macaques	01/24/2017
	Admin – Addition of personnel		Effect of NK-T cell depletion on Andes virus pathogenesis in hamsters	01/25/2017
	FCR		Mapping a susceptibility allele for Ebola hemorrhagic fever pathogenesis and resistance in Mice	01/30/2017
	Admin – Addition of personnel		Species barrier to EVD in humanized mice infected with Reston Virus or Mouse-adapted Ebola virus	02/06/2017
	DMR		Infectious cycle of Relapsing Fever Spirochetes in mice	02/07/2017
	DMR		Microglial Involvement in Prion Pathogenesis and Neuroinflammation in Mice	02/14/2017
	Admin – Addition of personnel		Pathobiological role of macrophages/monocytes in Ebola virus pathogenesis in mice	02/15/2017

Annual Review of Approved Protocols (via electronic memo)

Protocol #	P.I	Title	Approved	Expires
Redacted by agreement		Assessing T-705 as a post-exposure countermeasure to Lassa virus infection in Cynomolgus macaques	01/05/2016	01/05/2019
		Antibody production in rabbits to antigens of Borrelia species	01/06/2015	01/06/2018
		Surveillance of natural foci of African Hemorrhagic Fever Viruses (HFVs)	01/27/2015	01/27/2018
		Global Surveillance of Known and Potential Zoonotic Foci for Pathogens to Assess Human Risk	01/27/2015	01/27/2018
		The mobilization of endogenous retroviruses in mice during Friend 57 MuLV infection	12/03/2015	12/03/2018
		Pathogenicity and mortality of Zaire ebolavirus (mouse-adapted) in Balb/c substrain mice	02/29/2016	03/01/2019
		Evaluation of the effect of ixodid tick salivary gland extract on Powassan virus (POWV) infection	02/02/2016	02/02/2019
		Prion Pathogenesis in Mice Following Stereotactic Intracerebral Inoculation	02/03/2014	Closed out - Expired
		Establishment of a nonhuman primate disease (common marmoset) model for Zika virus infection	02/26/2016	02/26/2019
		Efficacy of sodium stibogluconate against tularemia in mice	01/29/2015	Closed out
		Tracking Interferon Stimulated Gene Expression in HIV infected humanized mice treated with Interferon alpha	01/06/2016	01/06/2019
		Infective Cycle of Borrelia burgorferi mutants in the Mouse-Tick Model of Infection and Transmission	01/31/2014	Closed out – Expired
		Post-exposure Efficacy of rVSV/ZEBOV in Rhesus Macaques Against Challenge with a West African Zaire Ebolavirus Strain	01/07/2015	Closed out
		Immunization of Mice with Live-Attenuated Y. pestis and Intravital Microscopy of Immunized Mice	01/16/2015	01/16/2018
		Establishment of a mouse disease model for Zika virus infection	03/02/2016	03/02/2019
		The role of transcription factor Fox3 on virus specific and non-specific CD4 and CD8 T cell responses to a Friend retrovirus infection	02/11/2016	02/11/2019
		Efficacy of consecutive vaccinations with rVSV vectors against Sudan and Zaire ebola viruses in nonhuman primates	03/06/2015	03/06/2018
		Production of TKO-BLT mice	03/02/2015	03/02/2018
		Friend virus infection and Antigen Presenting Cell functionality in mice	03/06/2015	03/06/2018
		Assessing T-705 as a post exposure countermeasure to Lassa virus in Guinea Pigs	03/04/2014	Closed out – Expired

Redacted by agreement	Assessment of Complement activation on prion disease and pathogenesis in mice	03/09/2015	03/09/2018
	Third passage of anchored and anchorless 22L rodent scrapie in transgenic mice	03/09/2015	03/09/2018

Protocols Approved and Finalized

Protocol #	P.I	Title	Approved	Expires
Redacted by agreement		Production of rabbit antibody against *K. pneumoniae* capsule	01/25/2017	01/25/2020
		Prion infection in transgenic mice expressing human Tau	01/30/2017	01/30/2020
		Genomic Content and Virulence of Coxiella burnetii in Guinea Pigs	02/07/2017	02/07/2020
		Immunogenicity and efficacy testing of a conditionally-attenuated murine cytomegalovirus-based Ebola virus vaccine in mice	02/10/2017	02/10/2020
		Modulation of host metabolism for protection against tularemia in mice	02/13/2017	02/13/2020
		Inactivation of rodent prions in mice by reactive oxygen species	02/14/2017	02/14/2020

V. ADDENDUM FOR REVIEW BY FCR

(b)(5)

VI. NEW ANIMAL STUDY PROPOSALS –

(b)(5)

(b)(5)

(b)(5)

(b)(5)

VII. OTHER BUSINESS –
The spring semi-annual walkthrough will be scheduled for Tuesday April 4th at 1:30

VIII. GUIDELINES AND POLICIES TO REVIEW – None

IX. NEXT MEETING DATE –

- Thursday March 23, 2017 starting at 1:30 p.m. in Redacted by agreement

IIX. ADJOURNMENT – 16:00

SEMIANNUAL REPORT

ANIMAL CARE AND USE
PROGRAM REVIEW AND FACILITY INSPECTION
OF THE

National Institute of Allergy and Infectious Disease, RML

OCTOBER 2016

Section A – Site Visits & Program Review

1) Inspections of the ***IC name*** animal facilities (AF), satellite holding facilities (SF), USDA-defined study areas for regulated species (SA) and areas where any surgical manipulations (Surg) are performed (as applicable) were conducted as indicated below:

Location	Type	Date	ACUC Members
Redacted by agreement	AF	10/13/2016	Redacted by agreement
(ABSL-3)	AF	10/13/2016	Gardner, Redacted by agreement Redacted
Redacted by agreement (Rodent Quarantine)	AF	10/13/2016	Closed for renovations. No animals are currently housed in this facility.
Redacted by agreement (Surgery)	Surg.	10/13/2016	Closed for renovations. No animals are currently housed in this facility.
Redacted by agreement (Quarantine & ABSL-4)	AF	10/13/2016	Gardner, Redacted by agreement Redacted by
Redacted by agreement Rodent Facility)	AF, Surg.	10/13/2016	Redacted Steele-Mortimer, Redacted by Redacted

2) Visits by at least one member of the ACUC to all remaining areas where animal activities were performed were conducted. These visits occurred during the previous six months and findings and corrective actions are described in this or the previous semiannual report.

3) Additionally, the AAALAC Program Description and the Guide for the Care & Use of Laboratory Animals, 8th Edition were used as the basis for review of the animal care and use program.

Section B – Regulatory Compliance:

Except as noted in Sections E, F, and G below, the facilities and program are in full compliance with the Public Health Service Policy, the Animal Welfare Act Regulations and the Guide, which were used as the basis for this evaluation.

Section C – Program Changes:

The following administrative and procedural changes have occurred since the program was last evaluated:

1) Administrative/Procedural Changes:

The RML ACUC has implemented the use of a new Animal Study Proposal submission and repository system.

2) Key Personnel Changes - ACUC Chair, ACUC Attending Vet, APD, or Program Manager:

Role (ACUC Chair, ACUC AV, IC APD,	Name	Action

or IC Animal Program Manager)		(joined or departed)
Animal Program Training Coordinator	Redacted by agreement	Joined

3) Animal Facility/Area Changes:

N/A

Section D – Guide Departures & USDA Exceptions:

Departures from the standards of the *Guide* and exceptions to the USDA *Animal Welfare Act Regulations,* which have been approved by the Animal Care and Use Committee, include the following:

1. Departures from the Guide:
   N/A

2. Exceptions to the AWAR:

Species	***9CFR title/section***	***Description and Rationale***
Non-human Primates	2.31 d). iv). A). Institutional Animal Care and Use Committee (Column E Procedures)	40 non-human primates infected with viral hemorrhagic fever (VHF) viruses and other ABSL-4 agents have been used in approved research studies evaluating mechanisms of pathogenesis, as well as comparing various vaccine candidates and treatment strategies. All animals are monitored daily for signs of disease. Clearly defined clinical endpoints are established and utilized if clinical disease occurs prior to scheduled euthanasia in the study design. As these are infectious disease models, NSAIDS and other pain modulating drugs cannot be used due to known effects on the disease process and the viral and immune parameters being measured. Therefore, these animals are listed as "column E" for these studies.
Guinea Pigs	2.31 d). iv). A). Institutional Animal Care and Use Committee (Column E Procedures)	4 Guinea pigs infected with VHF viruses and other ABLS-4 agents have been used in approved research efforts for the generation of models of human disease and vaccine development. All animals are monitored daily for signs of disease. Clearly defined clinical endpoints are established and utilized if clinical disease occurs prior to scheduled euthanasia in the study design. As these are infectious disease models, NSAIDS and other pain modulating drugs cannot be used due to known effects on the disease process and the viral and immune parameters being measured. Therefore, these animals are listed as "column E" for these studies.
Hamsters	2.31 d). iv). A). Institutional Animal Care and Use Committee (Column E Procedures)	52 hamsters infected with ABLS-4 agents have been used in approved research efforts for the generation of models of human disease and vaccine development. All animals are monitored daily or signs of disease. Clearly defined clinical endpoints are established and utilized if clinical disease occurs prior to scheduled euthanasia in the study design. As these are infectious disease models, NSAIDS and other pain modulating drugs cannot be used due to known effects on the disease process and the viral and immune parameters being measured. Therefore, these animals are listed as "column E" for these studies.
Non-human primates	3.81 Environmental Enrichment to Promote Psychological Well Being (Singly Housed NHP).	122 non-human primates on approved infectious disease research proposals have been singly-housed for the duration of the studies. The avoidance of direct contact between infected animals and therefore the potential for cross contamination, along with the need to protect individuals from harmful interactions with other animals during the disease process requires single-housing. None of the singly-housed animals are isolated and all are able to see, hear, and smell members of their own species housed in the same room
Non-human primates	3.81 Environmental Enrichment to Promote Psychological Well Being (Singly Housed NHP).	121 non-human primates displaying aggressive behavior, for medical and/or clinical treatment, or quarantine purposes have been singly-housed temporarily or long term, based on assessment by the veterinary staff. None of the singly-housed animals are isolated and all are able to see, hear, and smell members of their own species housed in the same room.

Section E – Previous Deficiencies & Plans:

The committee validated that the plans and schedules for deficiencies noted during the previous ***RML NIAID*** program review, and facilities and laboratory inspections were achieved within the time intervals projected on the previous semiannual report.

All deficiencies from the previous report were completed as scheduled.

Section F – Current Deficiencies & Plans:

Deficiencies found *over the past 6 months* during ***RML NIAID*** program review, facility inspections, and laboratory inspections, are as follows:

	Deficiency	[1]M/S	Location	Correction Plan	Responsible Party	Scheduled Completion Date (mm/dd/yy)	[2]Status: C/P
1	No enrichment noted in mouse cages	M	Redacted by agreement	Enrichment will be provided unless stated in the ASP	RMVB	10/20/2016	C
2	Expired iodine scrub in the NHP bite/scratch kits	M		Iodine will be replaced	RMVB	10/20/2016	C
3	Rack washer emergency exit sign placed too high to read easily and should be placed at eye level	M		Sign will be repositioned to be at eye level	RMVB	10/20/2016	C
4	Unlabeled bottle of isoflurane	M		Bottle will be disposed of	RMVB	10/13/2016	C
5	Expired vacutainers	M		Vacutainers will be disposed of or labeled clearly as expired	RMVB	10/20/2016	C
6	Exhaust Hood overdue for testing	M		DOHS has been notified and hood should be tested soon	DOHS	10/31/2016	C
7	Ethanol bottle was not properly labeled	M		Ethanol will be labelled properly	LPVD	10/20/2016	C
8	Bell jar was dirty	M		SOPs will be followed	LPVD	10/20/2016	C
9	Insect were found in the sticky aspect of the ceiling tiles near entrance/exit door	M		DOHS has been contacted and pest control will be put into place	DOHS	10/25/2016	C
10	(b)(5)						
11	Bedding found on shelves	M	Redacted by agreement	Bedding will be stored properly	RMVB	10/20/2016	C
12	Anesthesia machine without calibration sticker	M		DOHS has been notified and stations should be certified soon	DOHS	10/25/2016	C
13	(b)(5)						
14	Sharps container was full	M	Redacted by agreement	All sharps containers will be appropriately disposed of	LPVD	10/20/2016	C

15	Bottles of experimental compounds in the fridge were not labeled with dates	M	Redacted by agreement	Experimental compounds will be labelled properly	LPVD	10/20/2016	C

[1]M=minor; S=significant [2]C=corrected; P=pending

Section G – Reportable Events:

PHS Policy (i.e. OLAW) reportable events that occurred in the last 6 months or that are still awaiting final disposition are as follows: **[ ] None**

SA 1st noted	Description of event	Current Status
Fall 2016	Unapproved experimental procedures: research activities conducted beyond established study endpoints	Closed
Fall 2016	Animals kept on study beyond the established study endpoint	Memo sent to OLAW

Section H – Shared & Central Facilities:

This semiannual report also encompasses review and oversight of animals and animal activities which were present or occurred in shared or central facilities. Deficiencies were noted and transmitted directly to the facility, and if necessary, to the responsible Animal Care and Use Committee. These reviews were conducted as indicated below:
This section does not apply to this IC.

Section I – Minority Report

There is not a minority report filed with this semiannual report.

NIAID, RML ACUC Member Signatures:

Redacted by agreement

Olivia Steele-Mortimer, Chair, ACUC

Redacted by agreement

Redacted by agreement

Don Gardner, Attending Veterinarian

Redacted by agreement

(Revised - 07/2016)

10/31/2016

Member Name	Degree/Credentials	Position Title	PHS Policy Membership Role	New Member
Olivia Steele-Mortimer	PhD	Principal Investigator	Chair	☐
Donald Gardner	DVM, DACLAM	Branch Chief	Attending Veterinarian	☐
Redacted by agreement				☐
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Olivia Steele-Mortimer, Ph.D.
Redacted by agreement
Hamilton, MT 59840
phone Redacted by agreement

Attending Veterinarian Phone #: Redacted by agreement

NATIONAL INSTITUTES OF HEALTH
Facilities and Animal Species Inventory Table
Assurance Number: A-4149-01

IC Name: National Institute of Allergy and Infectious Diseases/RML

Fall Semiannual Report Submission Date: October 31, 2016

Spring Program Review Date(s):	4/19/16					

Fall Program Review Date(s):	10/13/16					

Bldg/Area/Rm	Facility Insp. Date(s) Spring / Fall		AF/SF; Gross Sq. Ft.	Species Housed			Average Daily Inventory		
Redacted by agreement	4/19/16	10/13/16	AF; 23000	1 Mice	2 Peromyscus	3 Hamsters	1 7,287	2 181	3 182
				4 Rats	5 Guinea pigs	6 Rabbits	4 26	5 39	6 6
	"	"	"	1 NHP-Squirrel	2 NHP-Cynos	3	1 2	2 61	3
				4	5	6	4	5	6
	4/19/16	10/13/16	AF; 8900	1 Mice	2 Peromyscus	3 Mastomys	1 155	2 1	3 98
				4	5	6	4	5	6
	4/19/16	10/13/16	AF; 1600	1 Mice	2 Hamsters	3 Rats	1 1,043	2 91	3 12
				4 NHP-cynos	5	6	4 2	5	6
	4/19/16	10/13/16	AF; 1600	1 NHP-cynos	2 NHP-rhesus	3 NHP-AGMs	1 19	2 18	3 4
				4	5	6	4	5	6

NATIONAL INSTITUTES OF HEALTH
Facilities and Animal Species Inventory Table
Assurance Number: A-4149-01

IC Name: National Institute of Allergy and Infectious Diseases/RML

Fall Semiannual Report Submission Date: October 31, 2016

10/31/2016

Bldg/Area/Rm	Facility Insp. Date(s) Spring / Fall		AF/SF; Gross Sq. Ft.	Species Housed			Average Daily Inventory		
Redacted by agreement	4/19/16	10/13/16	AF; 3000	1 Mice	2 Peromyscus	3 Hamsters	1 188	2 5	3 5
				4 Bats	5 NHP-cynos	6 NHP-rhesus	4 2	5 5	6 8
	"	"	"	1 NHP-AGMs	2	3	1 1	2	3
				4	5	6	4	5	6
				1	2	3	1	2	3
				4	5	6	4	5	6
				1	2	3	1	2	3
				4	5	6	4	5	6
				1	2	3	1	2	3
				4	5	6	4	5	6

Semiannual Report Attachment 3
Supplemental Information
National Institute of Allergy and Infectious Diseases/RML
Fall 2016

A. **NIH ASP Template Implementation:**
Has your IC implemented the current NIH Animal Study Proposal Template (2014 version or later)?

☒ Yes
☐ No If no, when do you anticipate it will be implemented?

B. **Zebrafish Incubators:**

a. Does your IC incubate zebrafish embryos >96 hours post fertilization? (See NIH Animal Program Director Guidelines for Zebrafish Larvae Incubators for additional information.)

☐Yes
☒N/A – No zebrafish used; or no incubators for >96 hours post fertilization.

b. If Yes, to above question:

i. Provide the incubator Building/Room numbers:
ii. Are these incubators visited by your IC ACUC during semiannual program review and included on the Inventory Table?
☐Yes
☐No

C. **IC Policy and Procedure Review:**

OLAW requires that IACUCs review policies, drug formularies, SOPs, and other guidance documents at appropriate intervals of no less than once every three years to ensure that they are appropriate and accurate. (NOT-OD-14-126; FAQ D.14)

a. How frequently does your IC ACUC review the following documents (i.e., semiannually, annually, every 2 years, every 3 years)?

i. IC ACUC SOPs: every three years or as deemed necessary
ii. IC ACUC Policies: every three years or as deemed necessary
iii. IC Animal Care/Veterinary SOPs: every three years or as deemed necessary
iv. IC Animal Care/Veterinary Policies: every three years or as deemed necessary

b. How is the document review performed?

i. ☒ Full Committee Review
ii. ☐ Designated Member Review
iii. ☐ Agent of the IC ACUC
iv. ☐ Other (please explain):

D. **Performance Standards:**

Provide a description of ACUC approved performance standards. *For additional information and examples, see the "Guide Departures & Performance Standards" document developed by OACU.*

In Redacted by agreement *Mus musculus* are co-housed with *Peromyscus maniculatus* and *P. leucopus*. In the temporary rodent quarantine room Redacted by *Mastomys natalensis* are housed in the same room as *Mus musculus*. In Redacted by agreement *Mesocricetus auratus* are housed in the same room as *Rattus norvegicus*. In addition, multiple species of rodents are housed in the animal holding rooms of the maximum containment laboratory Redacted by agreement In all above cases, all animals are housed in individually-ventilated caging.

Heating, Ventilation and Air Conditioning (HVAC) System Summary

Summarize the heating, ventilation and air conditioning (HVAC) information for each animal facility, including all satellite facilities, indicating: a) source(s) of air, b) air recirculation rates if other than 100% fresh air, c) air exchange rates, d) relative pressure differentials, e) humidity control, and f) date of most recent measurement/evaluation. 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, etc.). Air exchange rates within animal holding rooms and cage washing facilities are required. 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. HVAC information should be provided from assessments obtained within the past 12 months.

Room No.	Use	Air Source %Fresh/Recirculated	Treatment Filtered/Absorbers, etc.	Air Changes	Pressure	Humidity Control	Date Assessed
Redacted by agreement	Rodent	100 % Fresh	Filtered	16.7	-	Y	9/1/16
	Rodent	100 % Fresh	Filtered	14.4	-	Y	9/1/16
	Rodent	100 % Fresh	Filtered	14.1	-	Y	9/1/16
	Rodent	100 % Fresh	Filtered	12.8	-	Y	9/1/16
	Rodent	100 % Fresh	Filtered	15.7	-	Y	9/1/16
	Rodent	100 % Fresh	Filtered	19.2	-	Y	9/1/16
	Rodent	100 % Fresh	Filtered	13.1	-	Y	9/1/16
	Rodent	100 % Fresh	Filtered	19.2	-	Y	9/1/16
	Rodent	100 % Fresh	Filtered	14.0	-	Y	9/1/16
	Rodent	100 % Fresh	Filtered	15.5	-	Y	9/1/16
	Rodent	100% Fresh	Filtered	16.0	-	Y	9/1/16
	NHP Proc. Rm	100% Fresh	Filtered	15.0	-	Y	9/1/16
	NHP	100 % Fresh	Filtered	14.6	-	Y	9/1/16
	NHP	100 % Fresh	Filtered	13.2	-	Y	9/1/16

Redacted by agreement	NHP	100 % Fresh	Filtered	12.8	-	Y	9/1/16
	NHP	100 % Fresh	Filtered	14.7	-	Y	9/1/16
	NHP	100 % Fresh	Filtered	12.8	-	Y	9/1/16
	NHP	100 % Fresh	Filtered	13.4	-	Y	9/1/16
	NHP	100 % Fresh	Filtered	15.2	-	Y	9/1/16
	Rabbit	100 % Fresh	Filtered	14.4	-	Y	9/1/16
	Rodent	100 % Fresh	Filtered	14.3	-	Y	9/1/16
	Rodent	100 % Fresh	Filtered	15.8	-	Y	9/1/16
	Rodent	100 % Fresh	Filtered	16.8	-	Y	9/1/16
	Rodent	100 % Fresh	Filtered	15.6	-	Y	9/1/16
	Rodent	100 % Fresh	Filtered	14.7	-	Y	9/1/16
	Rodent	100 % Fresh	Filtered	14.7	-	Y	9/1/16
	Rodent	100 % Fresh	Filtered	17.2	-	Y	9/1/16
	Rodent	100 % Fresh	Filtered	15.1	-	Y	9/1/16
	Rodent	100 % Fresh	Filtered	15.8	-	Y	9/1/16
	Necropsy Room	100% Fresh	Filtered	59.9	-	Y	9/1/16
	Rodent	100 % Fresh	Filtered	21.5	-	Y	9/1/16
	Rodent	100 % Fresh	Filtered	22.1	-	Y	9/1/16
	Rodent	100 % Fresh	Filtered	21.9	-	Y	9/1/16
	Rodent	100 % Fresh	Filtered	20.9	-	Y	9/1/16
	Anteroom	100 % Fresh	Filtered	11.40	-	Y	1/1/17

Redacted by agreement	Rodent	100 % Fresh	Filtered	14.90	-	Y	1/1/17
	Proc. Room	100% Fresh	Filtered	28.44	-	Y	1/1/17
	Rodent	100 % Fresh	Filtered	15.01	-	Y	1/1/17
	Anteroom	100 % Fresh	Filtered	13.25	-	Y	1/1/17
	Rodent	100 % Fresh	Filtered	14.88	-	Y	1/1/17
	Proc. Room	100% Fresh	Filtered	28.53	-	Y	1/1/17
	Proc. Room	100% Fresh	Filtered	28.39	-	Y	1/1/17
	Rodent	100 % Fresh	Filtered	15.02	-	Y	1/1/17
	Anteroom	100 % Fresh	Filtered	12.51	-	Y	1/1/17
	Rodent	100 % Fresh	Filtered	17.64	-	Y	1/1/17
	Rodent	100 % Fresh	Filtered	15.08	-	Y	1/1/17
	Rodent	100 % Fresh	Filtered	14.93	-	Y	1/1/17
	Anteroom	100 % Fresh	Filtered	15.16	-	Y	1/1/17
	Proc. Room	100% Fresh	Filtered	28.48	-	Y	1/1/17
	Rodent	100 % Fresh	Filtered	15.03	-	Y	1/1/17
	Rodent	100 % Fresh	Filtered	15.07	-	Y	1/1/17
	Proc. Room	100% Fresh	Filtered	23.21	-	Y	1/1/17
	Rodent	100 % Fresh	Filtered	15.19	-	Y	1/1/17
	Quar. Corridor	100% Fresh	Filtered	7.10	-	Y	1/1/17
	Quarantine	100 % Fresh	Filtered	22.0	-	Y	1/1/17
	Quarantine	100 % Fresh	Filtered	22.0	-	Y	1/1/17
	Quarantine	100 % Fresh	Filtered	23.0	-	Y	1/1/17

Redacted by agreement	Quarantine	100 % Fresh	Filtered	21.0	-	Y	1/1/17
	Quarantine	100 % Fresh	Filtered	22.0	-	Y	1/1/17
	Quar. Proc. Rm.	100% Fresh	Filtered	9.00	-	Y	1/1/17
	Proc. Corridor	100% Fresh	Filtered	6.56	-	Y	1/1/17
	Necropsy	100% Fresh	Filtered	83.10	-	Y	1/1/17
	ABSL-4	100 % Fresh	Filtered	22.70	-	Y	1/1/17
	ABSL-4	100 % Fresh	Filtered	22.00	-	Y	1/1/17
	Proc. Corridor	100% Fresh	Filtered	8.80	-	Y	1/1/17
	ABSL-4	100 % Fresh	Filtered	15.60	-	Y	1/1/17
	ABSL-4	100 % Fresh	Filtered	15.60	-	Y	1/1/17
	ABSL-4	100 % Fresh	Filtered	15.15	-	Y	1/1/17
	Necropsy	100% Fresh	Filtered	77.60	-	Y	1/1/17
	ABSL-4	100 % Fresh	Filtered	15.30	-	Y	1/1/17
	ABSL-4	100 % Fresh	Filtered	15.38	-	Y	1/1/17
	Proc. Corridor	100% Fresh	Filtered	6.56	-	Y	12/31/13
	ABSL-4	100 % Fresh	Filtered	15.62	-	Y	12/18/13
	ABSL-4	100 % Fresh	Filtered	18.73	-	Y	12/18/13
	Necropsy	100% Fresh	Filtered	70.65	-	Y	12/31/13
	Quarantine						
	Quarantine						
	Quarantine						
	Quarantine						
	Quarantine						

Redacted by agreement	Quarantine
	Prep/recovery
	Operating rm.
	Surgeons prep
	Autoclave rm.
	Supply Storage

* denotes rooms that are currently under remodel and are non-operational.

Redacted by agreement is currently under renovation. HVAC values will be available upon completion.

Aquatic Systems Summary – Part II

NOT APPLICABLE

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):

(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, etc.

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

Primary Enclosures and Animal Space Provisions

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

Species	Dimensions of Enclosure (cage, pen, tank*, corral, paddock, etc.)	Maximum Number Animals/Enclosure	Guiding Document Used to determine the Institution's Space Standards (Guide, Ag Guide, ETS 123, Other)	Enclosure Composition & Description**
Mice	75 in^2 x 5.5"H 180 in^2 x 5.5"H 81 in^2 x 5"H	5 adults 10 adults 5 adults	Guide, AWAR	Polycarbonate IVCs Polyethylene terephthalate disposable IVCs.
Hamsters	72 in^2 x 5.5"H 210 in^2 x 7.5"H 141 in^2, 7"H	4 adult dwarf hamsters 6 adult hamsters 6 adult hamsters	Guide, AWAR	Polycarbonate IVCs Polyethylene terephthalate disposable IVCs.
Rabbits	25"W x 24"D x 16"H	1 adult	Guide, AWAR	Stainless steel with removable dividers to make single cage of two, 8 single cages per rack.

Guinea Pigs	25"W x 25"D x 10"H 17"W x 12"D x 12"H 141 in^2, 7" H	6 adults 1 adult 1 adult, 2 juveniles	Guide, AWAR	High Temperature plastic with perforated floor, 8 cages per stainless steel rack. Polycarbonate IVCs Polyethylene terephthalate disposable IVCs.
Rats	210 in^2, 7.5" H 141 in^2, 7" H	3 adults, 5 juveniles 2 adults	Guide, AWAR	Polycarbonate IVCs Polyethylene terephthalate disposable IVCs.
NHPs	4.7 sq. ft. x 32" H 6.3 sq. ft. x 32"H	2 Group 1 NHPs 1 adult, 2 juveniles	Guide, AWAR	Aluminum or stainless steel 1 over 1 racks.
NHPs	6.8 sq. ft. x 32"H 30 sq. ft. x 7'8"H	1 adult, 2 juveniles 6 adults, 10 juveniles	Guide, AWAR	Stainless steel biplex convertible quad caging and large gang cages.
Ferrets	33"W x 23"D x 18"H (5.2 sq. ft.) 17"W x 12"D x 12"H	2 adults	Guide, AWAR	Stainless steel, 2 x 3 cage, ventilated, isolator rack, w/ squeeze mechanism for ABSL-3/4 work. Polycarbonate IVCs
Swine	24 sq. ft. free standing raised pens	4 swine (under 25 kg) or 2 swine 25-50 kg.	Guide, AWAR	Stainless steel or aluminum pens.
Sheep/goats	24 sq. ft. free standing raised pens	2 sheep/goats (under 25 kg), or 1 animal 25-50 kg.	Guide, AWAR	Stainless steel or aluminum pens.

Bats	6.3 sq. ft. x 32"H	4 Rousettus aegyptiacus	Association of Zoos and Aquarium Bat Taxon Advisory Group, Guide, AWAR	Stainless steel 1 over 1 racks.

*For aquatic species, provide tank volume.

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

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	Other Comments
Micro-environment			
Solid-bottom cages (static)	Mechanical Washer	At least weekly	
Solid-bottom cages (IVC)	Mechanical Washer	Every other week	
Suspended wire-bottom or slotted floor cages	Mechanical washer and/or high pressure steam	Every other week	
Cage lids	Mechanical Washer	Every other week	
Filter tops	Mechanical Washer	Every other week	
Cage racks and shelves	Mechanical Washer	quarterly	
Cage pans under suspended cages	Mechanical Washer	Rabbit and Guinea pigs are washed twice weekly, NHP pans are rinsed daily and washed/sanitized at least every other week.	
Play pens, floor pens, stalls, etc.	High-pressure sprayers	Daily	Large animal pens in ABSL4
Corrals for primates or outdoor paddocks for livestock	N/A	N/A	N/A
Aquatic, amphibian, and reptile tanks and enclosures	N/A	N/A	N/A
Feeders	Mechanical Washer	Every other week	
Watering Devices	Mechanical Washer	Watering devices on/in cages are sanitized every other week.	Redacted by agreement automatic watering systems disinfected and flushed with sodium hypochlorite monthly.
Exercise devices and manipulanda used in environmental enrichment programs, etc.	Mechanical Washer	Sanitized at least every other week.	At every cage change
Transport cages	Mechanical Washer	After each use	

Operant Conditioning & Recording Chambers, Mechanical Restrains Devices (chairs, slings, etc.)	Mechanical Washer or hand washing	After each use	Rabbit restrainer
Euthanasia Chambers	Mechanical Washer or hand washing	After each use	

Area	**Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)**	**Washing/ Sanitizing Frequency**	**Other Comments**
Macro-Environment			
ANIMAL ROOMS			
Floors	Mopped or chemical disinfection with wash down (ABSL-4)	Daily	Rodent ABSL-4 floors sanitized weekly or after cage changes
Walls	Chemical disinfection/water hose wash down	Minimum of quarterly	
Ceilings	Chemical disinfection/water hose wash down	Minimum of quarterly	
Ducts/Pipes	Chemical disinfection/water hose wash down	Minimum of quarterly	
Fixtures	Chemical disinfection/water hose wash down	Minimum of quarterly	
CORRIDORS			
Floors	Mopped	Daily	Except on weekends
Walls	Chemical disinfection/water hose wash down	Minimum of quarterly	
Ceilings	Chemical disinfection/water hose wash down	Minimum of quarterly	
Ducts/Pipes	Chemical disinfection/water hose wash down	Minimum of quarterly	

Fixtures	Chemical disinfection/water hose wash down	Minimum of quarterly	
SUPPORT AREAS (e.g., surgery, procedure rooms, etc.) Complete for each area:			
Floors	Mopped	Procedure Areas: Daily Surgery: Daily (when in use)	Except on weekends
Walls	Chemical disinfection/water hose wash down	Procedure Areas: Quarterly Surgery: Weekly (when in use)	
Ceilings	Chemical disinfection/water hose wash down	Procedure Areas: Quarterly Surgery: Weekly (when in use)	
Ducts/Pipes	Chemical disinfection/water hose wash down	Procedure Areas: Quarterly Surgery: Weekly (when in use)	
Fixtures	Chemical disinfection/water hose wash down	Procedure Areas: Quarterly Surgery: Weekly (when in use)	
IMPLEMENTS (note whether or not shared)			
Mops	Mechanical Washer	Sanitized weekly	Rinsed/washed after every use
Mop buckets	Mechanical Washer	Sanitized weekly	Rinsed/washed after every use
Aquaria nets	N/A	N/A	N/A
Vehicle(s): ATVs	Pressure Washer or hand washed	After each use	
Other transport equipment (list): Filtered Rodent Cages, Draped NHP Transport Cages, Carts	Mechanical Washer	After each use	