

**Memorandum to:** [REDACTED], Associate Vice Chancellor for Research

**From:** Institutional Animal Care and Use Committee

**Subject:** Semiannual Report of the Program Review and Facility Inspection

**Date:** October 5, 2021

This report summarizes the IACUC's results of its most recent program review and facility inspection, as required by the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals ([Policy](#)), Section [IV.B.1.-3.](#), the *Guide for the Care and Use of Laboratory Animals* ([Guide](#)), and the Animal Welfare Act ([AWA](#)) regulations, as applicable. Submission of semiannual reports to the Institutional Official is a condition of this institution's Animal Welfare Assurance with the NIH Office of Laboratory Animal Welfare (OLAW).

**Since the last review, the following changes have occurred in the institution's program for animal care and use (PHS Policy [IV.A.1.a.-i.](#)):**

Membership changes - None

**I. Description of the Nature and Extent of the Institution's Adherence to the PHS Policy, the *Guide*, and the AWA**

Departures from the PHS Policy, the *Guide*, and the AWA.

Select A or B:

☐ A. There were no departures during this reporting period.

☒ B. The following departures have been reviewed and approved by the IACUC:

*Guide: The space recommendations presented here are based on professional judgment and experience. They **should** be considered the minimum for animals housed under conditions commonly found in laboratory animal housing facilities. Recommended Minimum Space for Commonly Used Laboratory Rodents Housed in Groups. Rats in groups >500, Floor Area/Animal in<sup>2</sup> ≥70 in<sup>2</sup> Table 3.2. (pages 56-57)*

Approved departure (1): Pair housing of rats exceeding 500 grams to maintain social housing. The arrangement exceeds the *Guides'* minimum space recommendations for laboratory rodents.

Approved departure (2): Group housing of rat littermates three to a cage and aged out to 16 weeks. At approximately three months of age, the arrangement exceeds the *Guides'* minimum space recommendations for laboratory rodents.

*Guide: Food and Fluid Regulation – Body weights **should** be recorded at least weekly and more often for animals requiring greater restrictions. (page 31)*

Approved departures: Nonhuman primate studies requiring food restriction are approved for weight checks approximately every two weeks and every month for animals whose food is not restricted but is scheduled. More frequent weighing will occur if an animal displays reduced appetite or becomes ill and the veterinary staff will be consulted.

## II. Deficiencies in the Institution's Animal Care and Use Program

Animal Care and Use Program Review Date(s): July 02, 2021

Select A or B:

☒ A. There were no deficiencies in the program during this reporting period.

☐ B. The following deficiencies have been identified:

The IACUC conducted its semiannual review of the institution's animal care and use program on July 2, 2021 using the OLAW Semiannual Program and Facilities Review Checklist as a guide for the review (Section VI). *Discussion comments are noted in blue font.*

No deficiencies were noted during the review.

## III. Deficiencies in the Institution's Animal Facility

Animal Facility Inspection Date(s): June 29, 2021

Select A or B:

☐ A. There were no deficiencies in the animal facility during this reporting period.

☒ B. The following deficiencies have been identified:

A separate table is included at the end of the OLAW Semiannual Program and Facilities Review Checklist (Section VII) that describes and identifies a plan and schedule for correction of each deficiency found in the Center for Comparative of Research (CCR) at the time of inspections on June 29<sup>th</sup>. All deficiencies recognized from this inspection were categorized as "minor".

## IV. Minority Views

Select A or B:

☒ A. No minority views were submitted or expressed.

☐ B. The following minority views were expressed:

## V. Status of AAALAC Accreditation

The status of UMMC's program of laboratory animal care and use that includes the G. V. (Sonny) Montgomery Veterans Affairs Medical Center, has not changed since the last report. "Full accreditation" status was verified by letter from AAALAC, International dated June 30, 2021.

## VI. Signatures

Names of IACUC Members	Signatures
[REDACTED]	[REDACTED]
[REDACTED]	
[REDACTED]	
[REDACTED]	
[REDACTED]	
[REDACTED]	
[REDACTED]	
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[REDACTED]	
[REDACTED]	

\*alternate member for [REDACTED]  
\*\*alternate member for [REDACTED]  
\*\*\*VA representative member

\*Due to COVID restrictions, digital signatures and email acknowledgment were accepted and are on file in the Office of Animal Welfare.

# Semiannual Program Review and Facility Inspection Checklist

## VI. Semiannual Program Review Checklist <sup>i</sup>

### Institutional Policies and Responsibilities

Date: 07/02/2021

1. Animal Care and Use Program <sup>NEW</sup>	A*	M	S	C	NA
• Responsibility for animal well-being is assumed by all members of the program ( <i>Guide, p 1</i> ) [must]	X				
• IO has authority to allocate needed resources ( <i>Guide, p 13</i> )	X				
• Resources necessary to manage program of veterinary care are provided ( <i>Guide, p 14</i> ) [must]	X				
• Sufficient resources are available to manage the program, including training of personnel in accord with regulations and the <i>Guide</i> ( <i>Guide, pp 11, 15</i> )	X				
• Program needs are regularly communicated to IO by AV and/or IACUC ( <i>Guide, p 13</i> )	X				
• Responsibilities for daily animal care and facility management are assigned to specific individual(s) when a full-time veterinarian is not available on site ( <i>Guide, p 14</i> ) [must]					X
• Inter-institutional collaborations are described in formal written agreements ( <i>Guide, p 15</i> )	X				
• Written agreements address responsibilities, animal ownership, and IACUC oversight ( <i>Guide, p 15</i> )	X				
2. Disaster Planning and Emergency Preparedness <sup>NEW</sup>	A*	M	S	C	NA
• Disaster plans for each facility to include satellite locations are in place ( <i>Guide, p 35, p 75</i> ) [must]	X				
• Plans include provisions for euthanasia ( <i>Guide, p 35</i> ) [must]	X				
• Plans include triage plans to meet institutional and investigators' needs ( <i>Guide, p 35</i> )	X				
• Plans define actions to prevent animal injury or death due to HVAC or other failures ( <i>Guide, p 35</i> )	X				
• Plans describe preservation of critical or irreplaceable animals ( <i>Guide, p 35</i> )	X				
• Plans include essential personnel and their training ( <i>Guide, p 35</i> )	X				
• Animal facility plans are approved by the institution and incorporated into overall response plan ( <i>Guide, p 35</i> )	X				
• Law enforcement and emergency personnel are provided a copy and integration with overall plan is in place ( <i>Guide, p 35</i> )	X				
3. IACUC <sup>NEW</sup>	A*	M	S	C	NA
• Meets as necessary to fulfill responsibilities ( <i>Guide, p 25</i> ) [must]	X				
• IACUC Members named in protocols or with conflicts recuse themselves from protocol decisions ( <i>Guide, p 26</i> ) [must]	X				
• Continuing IACUC oversight after initial protocol approval is in place ( <i>Guide, p 33</i> )	X				
• IACUC evaluates the effectiveness of training programs ( <i>Guide, p 15</i> )	X				
4. IACUC Protocol Review - Special Considerations	A*	M	S	C	NA
• Humane endpoints are established for studies that involve tumor models, infectious diseases, vaccine challenge, pain modeling, trauma, production of monoclonal antibodies, assessment of toxicologic effects, organ or system failure, and models of cardiovascular shock ( <i>Guide, p 27</i> )	X				
• For pilot studies, a system to communicate with the IACUC is in place ( <i>Guide, p 28</i> )	X				
• For genetically modified animals, enhanced monitoring and reporting is in place ( <i>Guide, p 28</i> )	X				

• Restraint devices are justified in the animal use protocols ( <i>Guide, p 29</i> ) [must]	X				
• Alternatives to physical restraint are considered ( <i>Guide, p 29</i> )	X				
• Period of restraint is the minimum to meet scientific objectives ( <i>Guide, p 29</i> )	X				
• Training of animals to adapt to restraint is provided ( <i>Guide, p 29</i> )	X				
• Animals that fail to adapt are removed from study ( <i>Guide, p 29</i> )	X				
• Appropriate observation intervals of restrained animals are provided ( <i>Guide, p 29</i> )	X				
• Veterinary care is provided if lesions or illness result from restraint ( <i>Guide, p 30</i> ) [must]	X				
• Explanations of purpose and duration of restraint are provided to study personnel ( <i>Guide, p 30</i> )	X				
• Multiple surgical procedures on a single animal are justified and outcomes evaluated ( <i>Guide, p 30</i> )	X				
• Major versus minor surgical procedures are evaluated on a case-by-case basis ( <i>Guide, p 30</i> )	X				
• Multiple survival procedure justifications in non-regulated species conform to regulated species standards ( <i>Guide, p 30</i> )	X				
• Animals on food/fluid restriction are monitored to ensure nutritional needs are met ( <i>Guide, p 31</i> )	X				
• Body weights for food/fluid restricted animals are recorded at least weekly ( <i>Guide, p 31</i> )	X				
• Daily written records are maintained for food/fluid restricted animals ( <i>Guide, p 31</i> )	X				
• Pharmaceutical grade chemicals are used , when available, for animal-related procedures ( <i>Guide, p 31</i> )	X				
• Non-pharmaceutical grade chemicals are described, justified, and approved by IACUC ( <i>Guide, p 31</i> )	X				
• Investigators conducting field studies know zoonotic diseases, safety issues, laws and regulations applicable in study area ( <i>Guide, p 32</i> )					X
• Disposition plans are considered for species removed from the wild ( <i>Guide, p 32</i> )					X
• Toe-clipping only used when no alternative, performed aseptically and with pain relief ( <i>Guide, p 75</i> )	X				

## 5. IACUC Membership and Functions

	A*	M	S	C	NA
• IACUC is comprised of at least 5 members, appointed by CEO (PHS Policy, <i>IV.A.3.</i> )	X				
• Members include a veterinarian, a scientist, a nonscientist, and a nonaffiliated non-lab animal user ( <i>Guide, p 24</i> ) <sup>ii</sup>	X				
• IACUC authority and	X				
• IACUC conducts semiannual evaluations of institutional animal care and use program (PHS Policy, <i>IV.B.</i> )	X				
• Conducts semiannual inspections of institutional animal facilities (PHS Policy, <i>IV.B.</i> )	X				
• IACUC organizationally reports to the Institutional Official (PHS Policy, <i>IV.A.1.b.</i> )	X				
• Methods for reporting and investigating animal welfare concerns are in place ( <i>Guide, p 23</i> ) [must]	X				
• Reviews and investigates concerns about animal care and use at institution <sup>iii</sup> (PHS Policy, <i>IV.B.</i> )	X				
• Procedures are in place for review, approval, and suspension of animal activities <sup>iv</sup> (PHS Policy, <i>IV.B.</i> )	X				
• Procedures are in place for review and approval of significant changes to approved activities (PHS Policy, <i>IV.B.</i> )	X				
• Policies are in place for special procedures (e.g., genetically modified animals, restraint, multiple survival surgery, food and fluid regulation, field investigations, agricultural animals) ( <i>Guide, p 27-32</i> )	X				
• Requests for exemptions from major survival surgical procedure restrictions are made to USDA/APHIS* ( <i>Guide, p 30</i> ) [must]	X				

## 6. IACUC Training NEW

A\* M S C NA

• All IACUC members should receive:					
○ Formal orientation to institution's program ( <i>Guide, p 17</i> )	X				
○ Training on legislation, regulations, guidelines, and policies ( <i>Guide, p 17</i> )	X				
○ Training on how to inspect facilities and labs where animal use or housing occurs ( <i>Guide, p 17</i> )	X				
○ Training on how to review protocols as well as evaluate the program ( <i>Guide, p 17</i> )	X				
○ Ongoing training/education ( <i>Guide, p 17</i> )	X				

## 7. IACUC Records and Reporting Requirements<sup>vi</sup>

**A\* M S C NA**

• Semiannual report to the IO (PHS Policy, <a href="#">IV.B.</a> )					
○ Submitted to IO every 6 months -	X				
○ Compiles program review and facility inspection(s) results (includes all program and facility deficiencies)	X				
○ Includes minority IACUC views	X				
○ Describes IACUC-approved departures from the <i>Guide</i> or PHS Policy and the reasons for each departure <sup>vii</sup>	X				
○ Distinguishes significant from minor deficiencies	X				
○ Includes a plan and schedule for correction for each deficiency identified <sup>viii</sup>	X				
• Reports to OLAW (PHS Policy, <a href="#">IV.F.</a> )					
○ Annual report to OLAW documents program changes, dates of the semiannual program reviews and facility inspections and includes any minority views	X				
○ Promptly advises OLAW of serious/ongoing <i>Guide</i> deviations or PHS Policy noncompliance ( <a href="#">NOT-OD-05-034</a> )	X				
○ Institute must promptly advise OLAW of any suspension of an animal activity by the IACUC ( <a href="#">NOT-OD-05-034</a> )	X				
• Reports to U.S. Department of Agriculture (USDA) or Federal funding agency <sup>ix</sup>					
○ Annual report to USDA contains required information including all exceptions/exemptions	X				
○ Reporting mechanism to USDA is in place for IACUC-approved exceptions to the regulations and standards	X				
○ Reports are filed within 15 days for failures to adhere to timetable for correction of significant deficiencies	X				
○ Promptly reports suspensions of activities by the IACUC to USDA and any Federal funding agency	X				
• Records (PHS Policy, <a href="#">IV.E.</a> )					
○ IACUC meeting minutes and semiannual reports to the IO are maintained for 3 years	X				
○ Records of IACUC reviews of animal activities include all required information*	X				
○ Records of IACUC reviews are maintained for 3 years after the completion of the study	X				

## 8. Veterinary Care (See also next section - Veterinary Care)

**A\* M S C NA**

• An arrangement for veterinarian(s) with training or experience in lab animal medicine is in place including backup veterinary care <sup>xi</sup>	X				
• Veterinary access to all animals is provided ( <i>Guide, p 14</i> ) <b>[must]</b>	X				
• Direct or delegated authority is given to the veterinarian to oversee all aspects of animal care and use ( <i>Guide, p 14</i> ) <b>[must]</b>	X				
• Veterinarian provides consultation when pain and distress exceeds anticipated level in protocol ( <i>Guide, p 5</i> ) <b>[must]</b>	X				
• Veterinarian provides consultation when interventional control is not possible ( <i>Guide, p 5</i> ) <b>[must]</b>	X				
• If part time /consulting veterinarian, visits meet programmatic needs ( <i>Guide, p 14</i> )					X
• Regular communication occurs between veterinarian and IACUC ( <i>Guide, p 14</i> )	X				
• Veterinarian(s) have experience and training in species used ( <i>Guide, p 15</i> ) <b>[must]</b>	X				
• Veterinarian(s) have experience in facility administration/management ( <i>Guide, p 15</i> )	X				

9. Personnel Qualifications and Training							A*	M	S	C	NA
• All personnel are adequately educated, trained, and/or qualified in basic principles of laboratory animal science. Personnel included: [must]											
○ Veterinary/other professional staff ( <i>Guide</i> , p 15-16)							X				
○ IACUC members ( <i>Guide</i> , p 17)							X				
○ Animal care personnel ( <i>Guide</i> , p 16)							X				
○ Research investigators, instructors, technicians, trainees, and students ( <i>Guide</i> , pp 16-17)							X				
• Continuing education for program and research staff provided to ensure high quality care and reinforce training ( <i>Guide</i> , pp 16-17)							X				
• Training is available prior to starting animal activity ( <i>Guide</i> , p 17)							X				
• Training is documented ( <i>Guide</i> , p 15) –							X				
• Training program content includes: ( <i>Guide</i> , p 17)											
○ Methods for reporting concerns ( <i>Guide</i> , p 17)							X				
○ Humane practices of animal care (e.g., housing, husbandry, handling) <sup>xii</sup>							X				
○ Humane practices of animal use (e.g., research procedures, use of anesthesia, pre- and post-operative care, aseptic surgical techniques and euthanasia ( <i>Guide</i> , p 17)) <sup>xiii</sup>							X				
○ Research/testing methods that minimize numbers necessary to obtain valid results (PHS Policy, IV.A.1.g.)							X				
○ Research/testing methods that minimize animal pain or distress (PHS Policy, IV.A.1.g.)							X				
○ Use of hazardous agents, including access to OSHA chemical hazard notices where applicable ( <i>Guide</i> , p 20)							X				
○ Animal care and use legislation ( <i>Guide</i> , p 17)							X				
○ IACUC function ( <i>Guide</i> , p 17)							X				
○ Ethics of animal use and Three R's ( <i>Guide</i> , p 17)							X				
10. Occupational Health and Safety of Personnel							A*	M	S	C	NA
• Program is in place and is consistent with federal, state, and local regulations ( <i>Guide</i> , p 17) [must]							X				
• Program covers all personnel who work in laboratory animal facilities ( <i>Guide</i> , p 18)							X				
• Changing, washing, and showering facilities are available as appropriate ( <i>Guide</i> , p 19)							X				
• Hazardous facilities are separated from other areas and identified as limited access ( <i>Guide</i> , p 19)							X				
• Personnel training is provided based on risk (e.g., zoonoses, hazards, personal hygiene, special precautions, animal allergies) ( <i>Guide</i> , p 20)							X				
• Personal hygiene procedures are in place (e.g., work clothing, eating/drinking/smoking policies) ( <i>Guide</i> , p 20)							X				
• Procedures for use, storage, and disposal of hazardous biologic, chemical, and physical agents are in place ( <i>Guide</i> , p 21)							X				
• Personal Protective Equipment for the work area is appropriate and available ( <i>Guide</i> , p 21)							X				
• Program for medical evaluation and preventive medicine for personnel includes:											
○ Pre-employment evaluation including health history ( <i>Guide</i> , p 22)							X				
○ Immunizations as appropriate (e.g., rabies, tetanus) and tests as appropriate ( <i>Guide</i> , p 22)							X				
○ Zoonosis surveillance as appropriate (e.g., Q-fever, tularemia, Hantavirus, plague) ( <i>Guide</i> , p 23)							X				
○ Procedures for reporting and treating injuries, including accidents, bites, allergies, etc. ( <i>Guide</i> , p 23)							X				
○ Promotes early diagnosis of allergies including preexisting conditions ( <i>Guide</i> , p 22)							X				
○ Considers confidentiality and other legal factors as required by federal, state and local regulations ( <i>Guide</i> , p 22) [must]							X				



○ If serum samples are collected, the purpose is consistent with federal and state laws ( <i>Guide, p 22</i> ) <b>[must]</b>	X				
• Waste anesthetic gases are scavenged ( <i>Guide, p 21</i> )	X				
• Hearing protection is provided in high noise areas ( <i>Guide, p 22</i> )	X				
• Respiratory protection is available when performing airborne particulate work ( <i>Guide, p 22</i> )	X				
• Special precautions for personnel who work with nonhuman primates, their tissues or body fluids include:					
○ Tuberculosis screening provided for all exposed personnel ( <i>Guide, p 23</i> )	X				
○ Training and implementation of procedures for bites, scratches, or injuries associated with macaques ( <i>Guide, p 23</i> )	X				
○ PPE is provided including gloves, arm protection, face masks, face shields, or goggles ( <i>Guide, p 21</i> )	X				
○ Injuries associated with macaques are carefully evaluated and treatment implemented ( <i>Guide, p 23</i> )	X				
• Occupational safety and health of field studies is reviewed by OSH committee or office ( <i>Guide, p 32</i> )					X

#### 11. Personnel Security **NEW** **A\* M S C NA**

• Preventive measures in place include pre-employment screening, and physical and IT security ( <i>Guide, p 23</i> )	X				
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#### 12. Investigating & Reporting Animal Welfare Concerns **NEW** **A\* M S C NA**

• Methods for investigating and reporting animal welfare concerns are established ( <i>Guide, p 23</i> ) <b>[must]</b>	X				
• Reported concerns and corrective actions are documented ( <i>Guide, p 24</i> )	X				
• Mechanisms for reporting concerns are posted in facility and at applicable website with instructions ( <i>Guide, p 24</i> )	X				
○ Includes multiple contacts ( <i>Guide, p 24</i> )	X				
○ Includes anonymity, whistle blower policy, nondiscrimination and reprisal protection ( <i>Guide, p 24</i> )	X				

\* **A** = acceptable

**M** = minor deficiency

**S** = significant deficiency (is or may be a threat to animal health or safety)

**C** = change in program (PHS Policy [IV.A.1.a.-i.](#)) (include in semiannual report to IO and in annual report to OLAW)

**NA** = not applicable

#### NOTES: General Facilities Observations:

#### UMMC

- EH&S performed a risk assessment of the CCR environments and identified the need for two plumbed eye-wash stations in rooms housing hazardous studies with mice. The rooms are not plumbed and would require a financial commitment to meet the recommendations. The CCR has requested the use of portable, self-contained stations. Discussions with EH&S continue to identify if the portable stations will need the regulatory requirements.
- The HVAC in the [REDACTED] building continues to have problems. The CCR works closely with Physical Facilities to address issues as they arise. The system is scheduled to be replaced by Summer 2022.
- The cage washer in the [REDACTED] building is over 12 years of age. Problems with the unit are increasing and service is difficult due to age of unit and outdated parts. Physical Facilities and contractors are working with the CCR to keep the unit running but replacement needs to be a priority.



## General Laboratory Observations and Training Opportunities:

- Several labs are not documenting training of personnel. Re-educate investigators on use of Personnel Training form.
- Surgical records for rodent surgeries are not consistent. Re-educate investigators on requirements for records and distribute template forms.
- Rodent Surgical techniques and aseptic procedure inconsistent. IACUC review and update Rodent Survival Surgery Guidelines and re-educate investigators.
- Several labs using heating pads without temperature control (setting are low/medium/high). IACUC needs to establish policy on use of store bought heating pads and educate investigators.

## VAMC

- The cage washer is non-functional. Only *Xenopus* frogs are housed at the VAMC. Rodents are housed at UMMC for effective management of time and resources.

## Veterinary Care

### Date:

1. Clinical Care and Management <span>NEW</span>	A*	M	S	C	NA
• Veterinary program offers high quality of care and ethical standards ( <a href="#">Guide, p 105</a> ) <span>[must]</span>	X				
• Veterinarian provides guidance to all personnel to ensure appropriate husbandry, handling, treatment, anesthesia, analgesia, and euthanasia ( <a href="#">Guide, p 106</a> )	X				
• Veterinarian provides oversight to surgery and perioperative care ( <a href="#">Guide, p 106</a> )	X				
• Veterinary care program is appropriate for program requirements ( <a href="#">Guide, pp 113-114</a> )	X				
• Veterinarian(s) is familiar with species and use of animals and has access to medical and experimental treatment records ( <a href="#">Guide, p 114</a> )	X				
• Procedures to triage and prioritize incident reports are in place ( <a href="#">Guide, p 114</a> )	X				
• Procedures are in place to address:					
o Problems with experiments to determine course of treatment in consultation with investigator( <a href="#">Guide, p 114</a> )	X				
o Recurrent or significant health problems with the IACUC and documentation of treatments and outcomes ( <a href="#">Guide, p 114</a> )	X				
o Veterinary review and oversight of medical and animal use records ( <a href="#">Guide, p 115</a> )	X				
• Procedures established for timely reporting of animal injury, illness, or disease ( <a href="#">Guide, p 114</a> ) <span>[must]</span>	X				
• Procedures established for veterinary assessment, treatment, or euthanasia ( <a href="#">Guide, p 114</a> ) <span>[must]</span>	X				
• Veterinarian is authorized to treat, relieve pain, and/or euthanize ( <a href="#">Guide, p 114</a> ) <span>[must]</span>	X				
2. Animal Procurement and Transportation/Preventive Medicine	A*	M	S	C	NA
• Procedures for lawful animal procurement are in place ( <a href="#">Guide, p 106</a> ) <span>[must]</span>	X				
• Sufficient facilities and expertise are confirmed prior to procurement ( <a href="#">Guide, p 106</a> )	X				
• Procurement is linked to IACUC review and approval ( <a href="#">Guide, p 106</a> )	X				
• Random source dogs and cats are inspected for identification ( <a href="#">Guide, p 106</a> )					X

• Population status of wildlife species is considered prior to procurement ( <i>Guide, p 106</i> )					X
• Appropriate records are maintained on animal acquisition ( <i>Guide, p 106</i> )	X				
• Animal vendors are evaluated to meet program needs and quality ( <i>Guide, p 106</i> )	X				
• Breeding colonies are based on need and managed to minimize numbers ( <i>Guide, p 107</i> )	X				
• Procedures for compliance with animal transportation regulations, including international requirements, are in place ( <i>Guide, p 107</i> ) <b>[must]</b>	X				
• Transportation is planned to ensure safety, security and minimize risk ( <i>Guide, p 107</i> )	X				
• Movement of animals is planned to minimize transit time and deliveries are planned to ensure receiving personnel are available ( <i>Guide, pp 107- 108</i> )	X				
• Appropriate loading and unloading facilities are available ( <i>Guide, p 109</i> )	X				
• Environment at receiving site is appropriate ( <i>Guide, p 109</i> )	X				
• Policies in place on separation by species, source, and health status ( <i>Guide, pp 109, 111-112</i> )	X				
• Procedures in place for quarantine to include zoonoses prevention ( <i>Guide, p 110</i> )	X				
• Quarantined animals from different shipments are handled separately or physically separated ( <i>Guide, p 110</i> )	X				
• Procedures in place for stabilization/acclimation ( <i>Guide, pp 110-111</i> )	X				
• Policies in place for isolation of sick animals ( <i>Guide, p 112</i> )	X				
• Program is in place for surveillance, diagnosis, treatment and control of disease to include daily observation ( <i>Guide, p 112</i> )	X				
• Diagnostic resources are available for preventive health program ( <i>Guide, p 112</i> )	X				

### 3. Surgery

	A*	M	S	C	NA
• Surgical outcomes are assessed and corrective changes instituted ( <i>Guide, p 115</i> )	X				
• Researchers have appropriate training to ensure good technique ( <i>Guide, p 115</i> ) <b>[must]</b>	X				
• Pre-surgical plans are developed and include veterinary input (e.g., location, supplies, anesthetic and analgesic use, peri-operative care, recordkeeping) ( <i>Guide, p 116</i> )	X				
• Aseptic surgery is conducted in dedicated facilities or spaces, unless exception justified and IACUC approved ( <i>Guide, p 116</i> )	X				
• Surgical procedures including laparoscopic procedures are categorized as major or minor ( <i>Guide, pp 117-118</i> )	X				
• For nonsurvival surgery, the site is clipped, gloves are worn and instruments and area are clean ( <i>Guide, p 118</i> )	X				
• Aseptic technique is followed for survival surgical procedures ( <i>Guide, pp 118-119</i> )	X				
• Effective procedures for sterilizing instruments and monitoring expiration dates on sterile packs are in place ( <i>Guide, p 119</i> )	X				
• Procedures for monitoring surgical anesthesia and analgesia are in place ( <i>Guide, p 119</i> )	X				
• For aquatic species, skin surfaces are kept moist during surgical procedures ( <i>Guide, p 119</i> )	X				
• Post-operative monitoring and care are provided by trained personnel and documented (e.g., thermoregulation, physiologic function, analgesia, infection, removal of skin closures) ( <i>Guide, pp 119-120</i> )	X				

### 4. Pain, Distress, Anesthesia and Analgesia

	A*	M	S	C	NA
• Guidelines for assessment and categorization of pain, distress and animal wellbeing are provided during training ( <i>Guide, p 121</i> )	X				
• Selection of analgesics and anesthetics is based on professional veterinary judgment ( <i>Guide, p 121</i> )	X				
• Painful procedures are monitored to ensure appropriate analgesic management ( <i>Guide, p 122</i> )	X				
• Nonpharmacologic control of pain is considered as an element of postprocedural care ( <i>Guide, p 122</i> )	X				

<ul style="list-style-type: none"> <li>Procedures are in place to assure antinoception before surgery begins (<i>Guide</i>, <a href="#">p 122</a>) <b>[must]</b></li> </ul>	X				
<ul style="list-style-type: none"> <li>Guidelines for selection and use of analgesics and anesthetics are in place and regularly reviewed and updated (<i>Guide</i>, <a href="#">p 122</a>)</li> </ul>	X				
<ul style="list-style-type: none"> <li>Special precautions for the use of paralytics are in place to ensure anesthesia<sup>xiv</sup> (<i>Guide</i>, <a href="#">p 123</a>)</li> </ul>	X				

## 5. Euthanasia

	A*	M	S	C	NA
<ul style="list-style-type: none"> <li>Methods are consistent with AVMA Guidelines on Euthanasia unless approved by the IACUC (<i>Guide</i>, <a href="#">p 123</a>)</li> </ul>	X				
<ul style="list-style-type: none"> <li>Standardized methods are developed and approved by the veterinarian and IACUC that avoid distress and consider animal age and species (<i>Guide</i>, <a href="#">pp 123-124</a>)</li> </ul>	X				
<ul style="list-style-type: none"> <li>Training is provided on appropriate methods for each species and considers psychological stress to personnel (<i>Guide</i>, <a href="#">p 124</a>)</li> </ul>	X				
<ul style="list-style-type: none"> <li>Procedures and training are in place to ensure death is confirmed (<i>Guide</i>, <a href="#">p 124</a>) <b>[must]</b></li> </ul>	X				

## 6. Drug Storage and Control **NEW**

	A*	M	S	C	NA
<ul style="list-style-type: none"> <li>Program complies with federal regulations for human and veterinary drugs(<i>Guide</i>, <a href="#">p 115</a>) <b>[must]</b></li> </ul>	X				
<ul style="list-style-type: none"> <li>Drug records and storage procedures are reviewed during facility inspections (<i>Guide</i>, <a href="#">p 115</a>)</li> </ul>	X				
<ul style="list-style-type: none"> <li>Procedures are in place to ensure analgesics and anesthetics are used within expiration date (<i>Guide</i>, <a href="#">p 122</a>) <b>[must]</b></li> </ul>	X				
<ul style="list-style-type: none"> <li>Anesthetics and analgesics are acquired, stored, and their use and disposal are recorded legally and safely (<i>Guide</i>, <a href="#">p 122</a>)</li> </ul>	X				

\* **A** = acceptable

**M** = minor deficiency

**S** = significant deficiency (is or may be a threat to animal health or safety)

**C** = change in program (PHS Policy [IV.A.1.a.-i.](#)) (include in semiannual report to IO and in annual report to OLAW)

**NA** = not applicable



## VII. Semiannual Program Review and Facility Inspection Report

Date: 6/29/21

Members in Attendance: 13

Deficiency Category*	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete /Verified
M		<b>Item Identified:</b> Johnson Control box damaged <b>Required Action:</b> schedule repair		9/30/21: WO was issued and controller is now repaired	9/13/21
M		<b>Item Identified:</b> IWF cards not properly completed <b>Required Action:</b> complete as required		9/30/21: corrected	9/30/21
M		<b>Item Identified:</b> feed container sanitization not dated <b>Required Action:</b> sanitize and date feed container  <b>Item Identified:</b> improper labeling of food container <b>Required Action:</b> label as required		9/30/21: Problem was corrected, but now has re-appeared. Current listing is dated 8/10/21, should have been sanitized on 9/10/21  PI small food containers also out of date: dated to exp 8/15/21	9/30/21
M		<b>Item Identified:</b> IWF cards not completed <b>Required Action:</b> complete IWF as required		9/30/21: corrected	9/13/21
		<b>Item Identified:</b> expired food <b>Required Action:</b> replace		9/30/21: OK, corrected	9/13/21
M		<b>Item Identified:</b> IWF cards not completed <b>Required Action:</b> complete IWF as required		9/30/21: corrected	9/21/21
M		<b>Item Identified:</b> expired food <b>Required Action:</b> replace		9/30/21: corrected	9/21/21

M	████	<b>Item Identified:</b> expired heparin, expired sterilant <b>Required Action:</b> discard	████	9/30/21: corrected	9/13/21
		<b>Item Identified:</b> feed container sanitization not dated <b>Required Action:</b> sanitize and date feed container	████	9/30/21: Corrected and currently in-date	9/13/21
M	████	<b>Item Identified:</b> IWF card not completed <b>Required Action:</b> complete IWF card as required <b>Item Identified:</b> improper labeling of container <b>Required Action:</b> label as required	████	9/30/21: Corrected	9/30/21
M	████	<b>Item Identified:</b> IWF card not completed <b>Required Action:</b> complete IWF cards as required	████	9/30/21: corrected, cards on individual cages with overall log on wall	9/13/21
M	████	<b>Item Identified:</b> IWF cards not completed <b>Required Action:</b> complete IWF cards as required	████	9/30/21:	
M	████	<b>Item Identified:</b> quarterly sanitation not documented <b>Required Action:</b> sanitize and document	████	9/30/21: Corrected, room not due for quarterly san. Until October	9/13/21
M	████	<b>Item Identified:</b> overcrowded cages <b>Required Action:</b> separate and maintain colony	████	9/30/21: corrected	9/13/21
M	████	<b>Item Identified:</b> IWF cards not completed <b>Required Action:</b> complete IWF cards as required	████	9/30/21:corrected	9/13/21
		<b>Item Identified:</b> cage cards need updating <b>Required Action:</b> update as required	████	9/30/21: corrected	9/13/21
		<b>Item Identified:</b> IWF cards not completed <b>Required Action:</b> complete IWF cards as required	████	9/30/21: corrected	9/13/21
M	████	<b>Item Identified:</b> unlabeled bottles <b>Required Action:</b> label and date appropriately	████	9/30/21: corrected	9/13/21
M	████	<b>Item Identified:</b> expired antibiotic ointment <b>Required Action:</b> discard	████	9/30/21: corrected	9/13/21

M		<b>Item Identified:</b> overcrowded cages <b>Required Action:</b> separate animals and maintain breeding colony to avoid overcrowding		9/30/21: corrected	9/13/21
M		<b>Item Identified:</b> expired saline <b>Required Action:</b> discard		9/30/21: corrected	9/13/21
M		<b>Item Identified:</b> rust stains on wall by cage wash <b>Required Action:</b> schedule maintenance		9/30/21: Problem persists: this is a dead-end conduit (no electricity) that has a persistent H2O leak. Numerous attempts to diagnose & correct have failed.	9/30/21
M		<b>Item Identified:</b> bug infestation in ceiling <b>Required Action:</b> treatment is ongoing		9/30/21: OK, problem solved in this room	9/13/21
M		<b>Item Identified:</b> bug infestation in ceiling <b>Required Action:</b> treatment is ongoing		9/30/21: Improvement, Bay Pest Services have aided efforts to control spiders, yet resolution not achieved due to inability to spray or use insecticides in fish room	9/30/21

		<b>Individual Laboratory Inspections</b> <b>Date of Inspection: December 2020</b> <b>Teams of two or more IACUC Members conducted inspection.</b>			
M		<b>Item Identified:</b> No training documentation <b>Required Action:</b> Maintain training records		9/30/21: training records discussed	9/30/21



		<b>Item Identified:</b> surgical records lacked information <b>Required Action:</b> maintain complete surgical records		during visit; example sent	
M		<b>Item Identified:</b> no way to monitor temperature in room <b>Required Action:</b> obtain monitoring device and maintain temperature log		9/30/21: monitoring device obtained	7/29/21
NA		<b>Item Identified:</b> vaporizer past due for service but noted as not in use <b>Required Action:</b> suggest that unit is stored away until ready to use and serviced		9/30/21: confirmed that no surgical procedures has occurred in the past 6+ months	NA
		VA			

- \* **A** = acceptable                      **NA** = not applicable  
**M** = minor deficiency  
**S** = significant deficiency (is or may be a threat to animal health or safety)  
**C** = change in program (PHS Policy [IV.A.1.a.-i.](#)) (include in semiannual report to IO and in annual report to OLAW)
- ✓ Check if repeat deficiency

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<sup>i</sup> The PHS Policy requires that Assured institutions comply with the regulations (9 CFR, Subchapter A) issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act, as applicable. The endnotes below are specific USDA regulatory requirements that differ from or are in addition to the PHS Policy. This list is not intended to be all inclusive. For additional information please refer to 9 CFR Subchapter A - Animal Welfare.

<sup>ii</sup> Part 2 Subpart C - Research Facilities

- 2.31(b)(2) - “The Committee shall be composed of a Chairman and at least two additional members;... at least one shall not be affiliated in any way with the facility...such person will provide representation for general community interests in the proper care and treatment of animals.” [PHS policy requires 5 members]

<sup>iii</sup> 2.32(c)(4) - “...No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act.” [USDA requirement additional to PHS Policy]

<sup>iv</sup> 2.31(d)(5) - “...shall conduct continuing reviews of activities...not less than annually.” [PHS Policy requires a complete new review every 3 years utilizing all the criteria for initial review]

<sup>v</sup> 2.31(d)(1)(x) - “...no animal will be used in more than one major operative procedure from which it is allowed to recover unless...(it is) justified for scientific reasons...(or is) required as routine veterinary procedure...or other special circumstances as determined by the Administrator on an individual basis.” [this last point is an additional USDA justification for multiple survival surgeries]

<sup>vi</sup> 2.36 - “...each reporting facility shall submit an annual report to the APHIS, AC sector supervisor for the State where the facility is located on or before December 1 of each calendar year.” [The USDA annual report has a list of requirements which differ from PHS annual report]

<sup>vii</sup> 2.36(b)(3) - “...exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the IACUC. A summary of all such exceptions must be attached to the facility’s annual report.” [Refers to USDA annual report]

<sup>viii</sup> 2.31(c)(3) - “...Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the institutional official, to APHIS and any Federal agency funding that activity.” [PHS Policy requires prompt reporting to OPRR of serious or continuing noncompliance with the PHS Policy or serious deviations from the provisions of the *Guide*]

<sup>ix</sup> 2.36 - “...each reporting facility shall submit an annual report to the APHIS, AC sector supervisor for the State where the facility is located on or before December 1 of each calendar year.” [The USDA annual report has a list of requirements which differ from PHS annual report]

<sup>x</sup> In addition to PHS requirements for IACUC review/application for funding, USDA regulations require:

2.31(d)(1)(ii) - “The principal investigator (PI) consider alternatives to procedures that cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources...used to determine that alternatives were not available.”

2.31(d)(1)(iii) - “The PI has provided written assurance that the activities do not unnecessarily duplicate previous experiments.”

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2.31(d)(1)(iv) - “Procedures that may cause more than momentary or slight pain or distress to the animals will:

- involve in their planning, consultation with the attending veterinarian or his or her designee; [PHS Policy does not specify veterinary consultation]
- not include paralytics without the use of anesthesia;”

2.31(d)(1)(x) - “No animal will be used in more than one major operative procedure from which it is allowed to recover, unless justified for scientific reasons by the principal investigator, in writing...”

<sup>xi</sup> 2.33(a)(1) - “In the case of a part-time attending veterinarian or consultant arrangements, the formal arrangements shall include a written program of veterinary care and regularly scheduled visits to the research facility.” [USDA requirement additional]

<sup>xii</sup> 2.32(c) - “Humane methods of animal maintenance and experimentation, including the basic needs of each species, proper handling and care for the various species of animals used by the facility, proper pre-procedural and post-procedural care of animals, and aseptic surgical methods and procedures.”

<sup>xiii</sup> 2.32(c) - additional specifications include:

- “proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility”
- “methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility...”
- “utilization of services (e.g., National Agricultural Library, National Library of Medicine) to provide information on appropriate animal care and use, alternatives to the use of live animals in research , that could prevent unintended and unnecessary duplication of research involving animals, and regarding the intent and requirements of the Act.” [USDA training specifications are more detailed than PHS Policy].

<sup>xiv</sup> 2.31(d)(iv)(C) - “Procedures that may cause more than momentary or slight pain or distress to the animals will...not include the use of paralytics without anesthesia.”