

Memorandum to:

From: Institutional Animal Care and Use Committee

Subject: Semiannual Report of the Program Review and Facility Inspection

Date: June 17, 2021

This report summarizes the IACUC's results of its most recent program review and facility inspection for the Montana State University site conducted on 14,17,20,24,and 26 of May and 01 June 2021 as required by the *Guide for the Care and Use of Laboratory Animals (Guide)*, and the Animal Welfare Act (AWA) regulations, as applicable.

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

Departures from 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: *[include reason for each departure]*

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

Animal Care and Use Program Review Date(s):17,24 May 2021

Select A or B:

- ☒ A. There were no deficiencies in the program during this reporting period.
- ☐ B. Deficiencies identified during the program review are described in the attached table.

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III. Deficiencies in the Institution's Animal Facility

Animal Facility Inspection Date(s): 14,20,26 May, 1 June 2021

Select A or B:

- ☐ A. There were no deficiencies in the animal facility during this reporting period.
- ☒ B. Deficiencies identified during the animal facility inspection are described in the attached table.

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IV. Minority Views

Select A or B:

- ☒ A. No minority views were submitted or expressed.
- ☐ B. The following minority views were expressed:

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V. Status of AAALAC Accreditation

Full AAALAC Accreditation

DocuSigned by:

6/21/2021 | 4:50 PM MDT

Institutional Official
Vice President of Research, Economic Development & Graduate Education

IACUC Members

DocuSigned by:

_____, Chair

DocuSigned by:

_____, (Alternate)

DocuSigned by:

DocuSigned by:

_____, D.V.M, Attending Veterinarian

DocuSigned by:

DocuSigned by:

DocuSigned by:

DocuSigned by:

DocuSigned by:

(Alternate)

DocuSigned by:

DocuSigned by:

I. Semiannual Facilities Inspection/Program Review Report

DATE: JUNE 17, 2021

Dates: May 14, 17, 20, 24, 26, and June 1, 2021

Attendance: MB, SS, KH, KL, RB1, JK, RB2, TD, MT, KJ, RJ, ND, KJ2, LM

Deficiency Category*	✓	Location/Finding	Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
M		: A list of experimental protocol numbers contains outdated IACUC protocol numbers.	Update list with current protocol numbers	SW/BR		6/7/2021
M		Chemical Hazard signage on door is incomplete. One sign is blank.	Ensure chemical hazard signage is accurate and correct.	SW/BR		6/7/2021
M		Experimental cage cards have outdated IACUC Protocol number.	Label cages with correct protocol number.	AA, MH	6/30/2021	6/7/2021
M		Research staff is not aware of emergency veterinary coverage weekend schedule.	ARC will provide communication to research staff on emergency veterinary schedule and will update as necessary.	TD	6/30/2021	
M		a. Controlled substance Cabinet was unlocked b. Prefilled syringe was labeled "bup if needed".	a.b., Retrain ARC staff on controlled substance security and controlled substance labelling requirements.	RB	07/31/2021	
M		a. Animal room logs are incomplete. b. Water bottles and pouches are not labeled or identified with fill date, unable to determine how long they have been in the room. c. IVC rack labelling for broken ports/malfunctioning caging is unclear what shelf or port is bad.	a. Train JRL and ARC staff on animal room log record keeping. b. Removed unlabeled water sources. Replace with water source in which the fill date can be identified. c. Clarify/standardize "bad port" identification	TD/AR	07/31/2021	
M	✓	ARC General: Signage is out of date	Ensure all signage reflects current room status, MSU policies, ARC SOPs and/or IACUC Policies.	TD	6/30/2021	
M		Anesthesia machine out of calibration	Label machine "out of service" and obtain a calibrated machine from ARC if possible.	AA, MH		6/11/2021

- * **A** = acceptable
- M** = minor deficiency
- S** = significant deficiency (is or may be a threat to animal health or safety)
- ✓ Check if repeat deficiency

I. Semiannual Program Review Checklist ⁱ

Institutional Policies and Responsibilities

Date: 24 May 2021 Attendance: MB,ND,RJ,KL,LC

1. Animal Care and Use Program	A*	M	S	C	NA
• Responsibility for animal well-being is assumed by all members of the program (<i>Guide</i> , p 1) [must]	x				
• IO has authority to allocate needed resources (<i>Guide</i> , p 13)	x				
• Resources necessary to manage program of veterinary care are provided (<i>Guide</i> , p 14) [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</i> , pp 11, 15)	x				
• Program needs are regularly communicated to IO by AV and/or IACUC (<i>Guide</i> , p 13)	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</i> , p 14) [must]					x
• Inter-institutional collaborations are described in formal written agreements (<i>Guide</i> , p 15)	x				
• Written agreements address responsibilities, animal ownership, and IACUC oversight (<i>Guide</i> , p 15)	x				

2. Disaster Planning and Emergency Preparedness	A*	M	S	C	NA
• Disaster plans for each facility to include satellite locations are in place (<i>Guide</i> , p 35, p 75) [must]	x				
• Plans include provisions for euthanasia (<i>Guide</i> , p 35) [must]	x				
• Plans include triage plans to meet institutional and investigators' needs (<i>Guide</i> , p 35)	x				
• Plans define actions to prevent animal injury or death due to HVAC or other failures (<i>Guide</i> , p 35)	x				
• Plans describe preservation of critical or irreplaceable animals (<i>Guide</i> , p 35)	x				
• Plans include essential personnel and their training (<i>Guide</i> , p 35)	x				
• Animal facility plans are approved by the institution and incorporated into overall response plan (<i>Guide</i> , p 35)	x				
• Law enforcement and emergency personnel are provided a copy and integration with overall plan is in place (<i>Guide</i> , p 35)	x				

3. IACUC	A*	M	S	C	NA
• Meets as necessary to fulfill responsibilities (<i>Guide</i> , p 25) [must]	x				
• IACUC Members named in protocols or with conflicts recuse themselves from protocol decisions (<i>Guide</i> , p 26) [must]	x				
• Continuing IACUC oversight after initial protocol approval is in place (<i>Guide</i> , p 33)	x				
• IACUC evaluates the effectiveness of training programs (<i>Guide</i> , p 15)	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</i> , p 27)	x				
• For pilot studies, a system to communicate with the IACUC is in place (<i>Guide</i> , p 28)	x				
• For genetically modified animals, enhanced monitoring and reporting is in place (<i>Guide</i> , p 28)	x				
• Restraint devices are justified in the animal use protocols (<i>Guide</i> , p 29) [must]	x				
• Alternatives to physical restraint are considered (<i>Guide</i> , p 29)	x				
• Period of restraint is the minimum to meet scientific objectives (<i>Guide</i> , p 29)	x				
• Training of animals to adapt to restraint is provided (<i>Guide</i> , p 29)	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, IV.A.3.)	x				
• Members include a veterinarian, a scientist, a nonscientist, and a nonaffiliated non-lab animal user (<i>Guide, p 24</i>) ⁱⁱ	x				
• IACUC authority and resources for oversight and evaluation of institution's program are provided (<i>Guide, p 14</i>)	x				
• IACUC conducts semiannual evaluations of institutional animal care and use program (PHS Policy, IV.B.)	x				
• Conducts semiannual inspections of institutional animal facilities (PHS Policy, IV.B.)	x				
• IACUC organizationally reports to the Institutional Official (PHS Policy, IV.A.1.b.)	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 ⁱⁱⁱ (PHS Policy, IV.B.)	x				
• Procedures are in place for review, approval, and suspension of animal activities ^{iv} (PHS Policy, IV.B.)	x				
• Procedures are in place for review and approval of significant changes to approved activities (PHS Policy, IV.B.)	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 ^v (<i>Guide, p 30</i>) [must]	x				

6. IACUC Training

	A*	M	S	C	NA
• All IACUC members should receive:					
o Formal orientation to institution's program (<i>Guide, p 17</i>)	x				
o Training on legislation, regulations, guidelines, and policies (<i>Guide, p 17</i>)	x				

o Training on how to inspect facilities and labs where animal use or housing occurs (<i>Guide, p 17</i>)	X				
o Training on how to review protocols as well as evaluate the program (<i>Guide, p 17</i>)	X				
o Ongoing training/education (<i>Guide, p 17</i>)	X				

7. IACUC Records and Reporting Requirements^{vi}

A* M S C NA

• Semiannual report to the IO (PHS Policy, <i>IV.B.</i>)					
o Submitted to IO every 6 months	X				
o Compiles program review and facility inspection(s) results (includes all program and facility deficiencies)	X				
o Includes minority IACUC views	X				
o Describes IACUC-approved departures from the <i>Guide</i> or PHS Policy and the reasons for each departure ^{vii}	X				
o Distinguishes significant from minor deficiencies	X				
o Includes a plan and schedule for correction for each deficiency identified ^{viii}	X				
• Reports to OLAW (PHS Policy, <i>IV.F.</i>)					
o Annual report to OLAW documents program changes, dates of the semiannual program reviews and facility inspections and includes any minority views	X				
o Promptly advises OLAW of serious/ongoing <i>Guide</i> deviations or PHS Policy noncompliance (NOT-OD-05-034)	X				
o Institute must promptly advise OLAW of any suspension of an animal activity by the IACUC (NOT-OD-05-034)	X				
• Reports to U.S. Department of Agriculture (USDA) or Federal funding agency ^{ix}					
o Annual report to USDA contains required information including all exceptions/exemptions	X				
o Reporting mechanism to USDA is in place for IACUC-approved exceptions to the regulations and standards	X				
o Reports are filed within 15 days for failures to adhere to timetable for correction of significant deficiencies	X				
o Promptly reports suspensions of activities by the IACUC to USDA and any Federal funding agency	X				
• Records (PHS Policy, <i>IV.E.</i>)					
o IACUC meeting minutes and semiannual reports to the IO are maintained for 3 years	X				
o Records of IACUC reviews of animal activities include all required information ^x	X				
o 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 ^{xi}	X				
• Veterinary access to all animals is provided (<i>Guide, p 14</i>) [must]	X				
• Direct or delegated authority is given to the veterinarian to oversee all aspects of animal care and use (<i>Guide, p 14</i>) [must]	X				
• Veterinarian provides consultation when pain and distress exceeds anticipated level in protocol (<i>Guide, p 5</i>) [must]	X				
• Veterinarian provides consultation when interventional control is not possible (<i>Guide, p 5</i>) [must]	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>) [must]	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) ^{xii}	X				
○ Research/testing methods that minimize numbers necessary to obtain valid results (PHS Policy, IV.A.1.g.)	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) ^{xiii}	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				

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

ⁱ 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.

ⁱⁱ 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]

ⁱⁱⁱ 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]

^{iv} 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]

v 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]

vi 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]

vii 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]

viii 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*]

ix 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]

* 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."

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..."

xi 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]

^{xii} 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."

^{xiii} 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].

Veterinary Care Program Review

Date: 17 May 2021

Attendance: MJ,KH, RJ,RB,LC

1. Clinical Care and Management

	A*	M	S	NA
• Veterinary program offers high quality of care and ethical standards (<i>Guide, p 105</i>) [must]	x			
• Veterinarian provides guidance to all personnel to ensure appropriate husbandry, handling, treatment, anesthesia, analgesia, and euthanasia (<i>Guide, p 106</i>)	x			
• Veterinarian provides oversight to surgery and perioperative care (<i>Guide, p 106</i>)	x			
• Veterinary care program is appropriate for program requirements (<i>Guide, pp 113-114</i>)	x			
• Veterinarian(s) is familiar with species and use of animals and has access to medical and experimental treatment records (<i>Guide, p 114</i>)	x			
• Procedures to triage and prioritize incident reports are in place (<i>Guide, p 114</i>)	x			
o Problems with experiments to determine course of treatment in consultation with investigator(<i>Guide, p 114</i>)	x			
o Recurrent or significant health problems with the IACUC and documentation of treatments and outcomes (<i>Guide, p 114</i>)	x			
o Veterinary review and oversight of medical and animal use records (<i>Guide, p 115</i>)	x			
• Procedures established for timely reporting of animal injury, illness, or disease (<i>Guide, p 114</i>) [must]	x			
• Procedures established for veterinary assessment, treatment, or euthanasia (<i>Guide, p 114</i>) [must]	x			
• Veterinarian is authorized to treat, relieve pain, and/or euthanize (<i>Guide, p 114</i>) [must]	x			

2. Animal Procurement and Transportation/Preventive Medicine

	A*	M	S	NA
• Procedures for lawful animal procurement are in place (<i>Guide, p 106</i>) [must]	x			
• Sufficient facilities and expertise are confirmed prior to procurement (<i>Guide, p 106</i>)	x			
• Procurement is linked to IACUC review and approval (<i>Guide, p 106</i>)	x			
• Random source dogs and cats are inspected for identification (<i>Guide, p 106</i>)				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>) [must]	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	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>) [must]	x			

Veterinary Care Program Review

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Attendance: MJ,KH, RJ,RB,LC

• 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 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			
• Procedures are in place to assure antinociception before surgery begins (<i>Guide, p 122</i>)	x			
• Guidelines for selection and use of analgesics and anesthetics are in place and regularly reviewed and updated (<i>Guide, p 122</i>)	x			
• Special precautions for the use of paralytics are in place to ensure anesthesia ⁱ (<i>Guide, p 123</i>)				x

5. Euthanasia

A* M S NA

• Methods are consistent with AVMA Guidelines on Euthanasia unless approved by the IACUC (<i>Guide, p 123</i>)	x			
• Standardized methods are developed and approved by the veterinarian and IACUC that avoid distress and consider animal age and species (<i>Guide, pp 123-124</i>)	x			
• Training is provided on appropriate methods for each species and considers psychological stress to personnel (<i>Guide, p 124</i>)	x			
• Procedures and training are in place to ensure death is confirmed (<i>Guide, p 124</i>)	x			

6. Drug Storage and Control

A* M S NA

• Program complies with federal regulations for human and veterinary drugs (<i>Guide, p 115</i>)	x			
• Drug records and storage procedures are reviewed during facility inspections (<i>Guide, p 115</i>)	x			
• Procedures are in place to ensure analgesics and anesthetics are used within expiration date (<i>Guide, p 122</i>)	x			
• Anesthetics and analgesics are acquired, stored, and their use and disposal are recorded legally and safely (<i>Guide, p 122</i>)	x			

A = acceptable

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Veterinary Care Program Review

Date: 17 May 2021

Attendance: MJ,KH, RJ,RB,LC

M = minor deficiency

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

NA = not applicable

ⁱ 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."

Occupational Health and Safety

Date: 17 May 2021

Attendance: CC,JK,MB,KH,RB,LC

Occupational Health and Safety of Personnel	A*	M	S	NA
• Program is in place and is consistent with federal, state, and local regulations (<i>Guide, p 17</i>) [must]	x			
• Program covers <i>all</i> personnel who work in laboratory animal facilities (<i>Guide, p 18</i>)	x			
• Changing, washing, and showering facilities are available as appropriate (<i>Guide, p 19</i>)	x			
• Hazardous facilities are separated from other areas and identified as limited access (<i>Guide, p 19</i>)	x			
• Personnel training is provided based on risk (e.g., zoonoses, hazards, personal hygiene, special precautions, animal allergies) (<i>Guide, p 20</i>)	x			
• Personal hygiene procedures are in place (e.g., work clothing, eating/drinking/smoking policies) (<i>Guide, p 20</i>)	x			
• Procedures for use, storage, and disposal of hazardous biologic, chemical, and physical agents are in place (<i>Guide, p 21</i>)	x			
• Personal Protective Equipment for the work area is appropriate and available (<i>Guide, p 21</i>)	x			
○ Pre-(work) evaluation including health history (<i>Guide, p 22</i>)	x			
○ Immunizations as appropriate (e.g., rabies, tetanus) and tests as appropriate (<i>Guide, p 22</i>)	x			
○ Zoonosis surveillance as appropriate (e.g., Q-fever, tularemia, Hantavirus, plague) (<i>Guide, p 23</i>)	x			
○ Procedures for reporting and treating injuries, including accidents, bites, allergies, etc. (<i>Guide, p 23</i>)	x			
○ Promotes early diagnosis of allergies including preexisting conditions (<i>Guide, p 22</i>)	x			
○ Considers confidentiality and other legal factors as required by federal, state and local regulations (<i>Guide, p 22</i>) [must]	x			
○ If serum samples are collected, the purpose is consistent with federal and state laws (<i>Guide, p 22</i>) [must]				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			
○ Tuberculosis screening provided for all exposed personnel (<i>Guide, p 23</i>)	x			

Occupational Health and Safety

Date: 17 May 2021

Attendance: CC,JK,MB,KH,RB,LC

o Training and implementation of procedures for bites, scratches, or injuries associated with macaques (<i>Guide</i> , p 23)	x			
o PPE is provided including gloves, arm protection, face masks, face shields, or goggles (<i>Guide</i> , p 21)	x			
o Injuries associated with macaques are carefully evaluated and treatment implemented (<i>Guide</i> , p 23)	x			
• Occupational safety and health of field studies is reviewed by OSH committee or office (<i>Guide</i> , p 32)	x			
A* M S NA				

1. Personnel Security

• Preventive measures in place include pre-employment screening, and physical and IT security (<i>Guide</i> , p 23)	x			
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o species specific plans for housing including enrichment, behavior and activity are developed and reviewed regularly by IACUC, researchers and veterinarian (Guide, pp 53, 58, 60, 63)	x				
o animal care personnel receive training to identify abnormal animal behaviors (Guide, p 53)	x				
o stability of pairs or groups is monitored for incompatibility (Guide, p 64)	x				
o single housing is justified for social species (Guide, p 64)	x				
o single housing is limited to the minimum period necessary (Guide, p 64)	x				
o additional enrichment for single housed animals is provided (Guide, p 64)	x				
o single housing is reviewed regularly by IACUC and veterinarian (Guide, p 64)	x				
o habituation to routine procedures is part of enrichment program (Guide, p 64)	x				
• Sheltered or Outdoor Housing: (e.g., barns, corrals, pastures, islands)					
o weather protection and opportunity for retreat (Guide, p 54) [must]	x				
o appropriate size (Guide, p 54)	x				
o ventilation and sanitation of shelter (no waste/moisture build-up) (Guide, p 54)	x				
o animal acclimation (Guide, p 55)	x				
o social compatibility (Guide, p 55)	x				
o roundup/restraint procedures (Guide, p 55)	x				
o appropriate security (Guide, p 55)	x				
• Naturalistic Environments:					
o animals added /removed with consideration of effect on group (Guide, p 55)	x				
o adequate food, fresh water, and shelter ensured (Guide, p 55)	x				
• Food:					
o feeding schedule and procedures including caloric intake management (Guide, pp 65-67)	x				
o contamination prevention (Guide, p 65)	x				
o vendor quality control (Guide, p 66)	x				
o storage in sealed containers (Guide, p 66)	x				
o expiration date labeling (Guide, p 66)	x				
o vermin control (Guide, p 66)	x				
o rotation of stocks (Guide, p 66)	x				
• Water:					
o ad libitum unless justified (Guide, pp 67-68)	x				
o QC procedures (Guide, pp 67-68)		x			
• Bedding and Nesting Materials:					
o species appropriate (Guide, pp 68-69)	x				
o keeps animals dry (Guide, pp 68-69)	x				
o QC procedures (Guide, pp 68-69)	x				
o minimizes scientific variables (Guide, pp 68-69)	x				
• Sanitation:					
o frequency of bedding/substrate change (Guide, p 70)	x				
o cleaning and disinfection of microenvironment (Guide, pp 70-71)	x				
o cleaning and disinfection of macroenvironment (Guide, p 72)	x				
o assessing effectiveness (Guide, p 73)	x				
• Waste Disposal:					
o procedures for collection (Guide, pp 73-74)	x				
o procedures for storage and disposal (Guide, pp 73-74)	x				
o hazardous wastes are rendered safe before removal from facility (Guide, pp 73-74) [must]	x				
o animal carcasses (Guide, pp 73-74)	x				
• Pest Control:					
o regularly scheduled (Guide, p 74)	x				
o documented program including control of rodent pests and insecticide use (Guide, p 74)	x				
• Emergency, Weekend, and Holiday Animal Care:					
o care provided by qualified personnel every day (Guide, p 74)	x				
o provision for accessible contact information (Guide, p 74)		x			
o monitoring of backup systems (Guide, p 143)	x				
o veterinary care available after hours, weekends, and holidays (Guide, pp 74, 114) [must]	x				

o a disaster plan that takes into account both personnel and animals (<i>Guide, p 75</i>)	x				
• Identification:					
o cage/rack cards contain required information (<i>Guide, p 75</i>)		x			
o genotype information included and standardized nomenclature used when applicable (<i>Guide, p 75</i>)	x				
• Recordkeeping:					
o clinical records accessible and contain appropriate information (<i>Guide, pp 75-76</i>)	x				
o records are provided when animals are transferred between institutions (<i>Guide, p 75</i>)					x
• Breeding Genetics and Nomenclature:					
o appropriate genetic records, management and monitoring procedures (<i>Guide, p 76</i>)	x				
o phenotypes that affect wellbeing are reported to IACUC and effectively managed (<i>Guide, p 77</i>)	x				
• Storage:					
o adequate space for equipment, supplies, food, bedding and refuse (<i>Guide, p 141</i>)	x				
o bedding in vermin-free area and protected from contamination (<i>Guide, p 141</i>)	x				
o food in vermin-free, temperature and humidity controlled area and protected from contamination (<i>Guide, p 141</i>)	x				
o refuse storage is separate (<i>Guide, p 141</i>)	x				
o carcass and animal tissue storage is separate, refrigerated below 7°C and cleanable (<i>Guide, p 141</i>)	x				
• Personnel:					
o adequate space for locker rooms, administration and training (<i>Guide, p 135</i>)	x				

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NOTES:

Special Facilities: Procedure Areas, Non-survival Surgeries, Laboratories, Rodent Surgeries, Imaging, Whole Body Irradiation, Hazardous Agent Containment, Behavioral Studies

Date: 5/26

Location: Lab, Cooley, Leon Johnson, HSB

	A*	M	S	C	NA
• General Considerations:					
o labs used to house animals only when scientifically required and limited to minimum period necessary (<i>Guide, p 134</i>)	x				
o drug storage, control, and expiration dates (<i>Guide, pp 115, 122</i>)	x				
o sharps disposal (<i>Guide, p 74</i>)	x				
o anesthetic monitoring (<i>Guide, p 120</i>)	x				
o scavenging of anesthetic gases (<i>Guide, p 21</i>)	x				
o safety features (e.g., SOPs, safety signs, eyewash stations, secure gas cylinders) are in place (<i>Guide, p 19</i>)		x			
o carcass disposal (<i>Guide, pp 73-74</i>)	x				
• Additional Concerns for Survival Surgery: (rodent and minor procedures only)					
o rodent survival surgery clean and uncluttered, not used for anything else during surgery (<i>Guide, p 144</i>)					x
o records of peri-operative care (<i>Guide, p 120</i>)					x
o aseptic procedures (<i>Guide, pp 118-119</i>)					x
o autoclave monitoring procedures (<i>Guide, pp 119, 145</i>)					x
o storage of autoclaved materials (<i>Guide, p 145</i>)					x
o cold sterilization procedures are appropriate (<i>Guide, p 119</i>)					x
• Imaging/Whole Body Irradiation:					
o location of resource limits contamination risk (<i>Guide, p 147</i>)					x
o appropriate transportation methods are in place (<i>Guide, p 147</i>)					x
o gas anesthesia provision, scavenging and monitoring are appropriate (<i>Guide, p 147</i>)					x
o appropriate sensors and ventilation are provided for cryogen gases (<i>Guide, p 147</i>) [must]					x
o imaging console is located away from radiation source (<i>Guide, p 147</i>)					x
• Hazardous Agent Containment:					
o facility adheres to APHIS, USDA and CDC Select Agent Regulations and other federal, state and local regulations including security measures (<i>Guide, p 148</i>) [must]	x				
• Behavioral Studies:					
o facility minimizes airborne transmission of noise and ground-borne transmission of vibration (<i>Guide, p 149</i>)	x				
o floor coverings reduce sound transmission (<i>Guide, p 149</i>)	x				
o testing equipment allows for surface disinfection (<i>Guide, p 150</i>)	x				
o components that cannot be cleaned are not in ready contact with animals and kept covered when not in use (<i>Guide, p 150</i>)	x				
o housing areas are contiguous with testing areas when appropriate (<i>Guide, p 150</i>)	x				

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NOTES:

Special Facilities: Aseptic Surgery**Date: May 20, 2021****Location: ARC**

	A*	M	S	C	NA
• General Considerations:					
○ location minimizes traffic/contamination (<i>Guide, p 144</i>)	X				
○ functional components (surgical support, animal preparation, surgeon scrub, operating room, postoperative recovery) are designed and separated (physically or otherwise) (<i>Guide, p 144</i>)	X				
○ appropriate drug storage, control, expiration date monitoring (<i>Guide, pp 115, 122</i>)	X				
○ safe sharps disposal system (<i>Guide, p 74</i>)	X				
○ adequate records of anesthesia and perioperative care (<i>Guide, p 122</i>)	X				
○ aseptic procedures in use for all survival surgery (<i>Guide, pp 118-119</i>)	X				
• Operating Room:					
○ effective contamination control procedures (<i>Guide, p 144</i>)	X				
○ effective cleaning procedures/dedicated tools (<i>Guide, p 145</i>)	X				
○ interior surfaces smooth and impervious to moisture (<i>Guide, p 145</i>)	X				
○ HVAC system meets <i>Guide</i> requirements (<i>Guide, p 145</i>)	X				
○ lighting safe and appropriate (<i>Guide, p 145</i>)	X				
○ outlets safe and appropriate (<i>Guide, p 145</i>)	X				
○ scavenging of anesthetic gases implemented (<i>Guide, p 145</i>)	X				
• Surgical Support:					
○ facility for washing, sterilizing, storing instruments and supplies (<i>Guide, p 145</i>)	X				
○ autoclave monitoring procedures are implemented (<i>Guide, pp 119, 145</i>)	X				
○ storage of autoclaved materials maintains sterility (<i>Guide, p 145</i>)	X				
○ cold sterilization procedures are appropriate (<i>Guide, p 119</i>)	X				
• Animal Preparation: contains large sink to facilitate cleaning of animal and operative site (<i>Guide, p 145</i>)	X				
• Surgeon Scrub: outside operating room, non-hand-operated sink (<i>Guide, p 145</i>)	X				
• Postoperative Recovery: allows adequate observation, easily cleaned, supports physiologic functions, minimizes risk of injury (<i>Guide, p 145</i>)	X				
• Dressing Area: place for personnel to change (<i>Guide, p 145</i>)	X				

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NOTES:

	A*	M	S	C	NA
• Location:					
○ animal areas separate from personnel areas (<i>Guide</i> , p 134)	X				
○ separation of species (<i>Guide</i> , p 111)	X				
○ separation by disease status (<i>Guide</i> , p 111)	X				
○ security and access control (<i>Guide</i> , p 151)	X				
• Construction:					
○ corridors (<i>Guide</i> , p 136)	X				
○ animal room doors (<i>Guide</i> , pp 137, 150)	X				
○ exterior windows (<i>Guide</i> , p 137)	X				
○ floors (<i>Guide</i> , pp 137, 150)	X				
○ drainage (<i>Guide</i> , pp 138, 150)	X				
○ walls and ceilings (<i>Guide</i> , pp 138, 150)	X				
○ heating ventilation and air conditioning (<i>Guide</i> , pp 139, 150-151)	X				
○ power and lighting (<i>Guide</i> , pp 141, 150)	X				
○ noise control (<i>Guide</i> , p 142)	X				
○ vibration control (<i>Guide</i> , p 142)	X				
○ environmental monitoring (<i>Guide</i> , p 143)	X				
• Water Quality:					
○ standards for acceptable quality are established (<i>Guide</i> , p 78)	X				
○ chlorine, chloramines, chemical, and reactive bioproducts are removed or neutralized prior to use in aquatic systems (<i>Guide</i> , pp 78, 86) [must]	X				
• Life Support System:					
○ water source is based on appropriate controls and research requirements (<i>Guide</i> , p 79)	X				
○ biofilter is of sufficient size to process bioload (<i>Guide</i> , p 80) [must]	X				
• Temperature, Humidity and Ventilation/Illumination/Noise and Vibration:					
○ temperature and humidity (<i>Guide</i> , pp 43, 80-81)	X				
○ ventilation and air quality (<i>Guide</i> , pp 45, 81)	X				
○ illumination (<i>Guide</i> , pp 47, 81)	X				
○ noise and vibration (<i>Guide</i> , pp 49, 81)	X				
• Primary Enclosure:					
○ allows for normal physiological and behavioral needs (<i>Guide</i> , p 82)	X				
○ allows social interaction for social species (<i>Guide</i> , p 82)	X				
○ provides a balanced, stable environment (<i>Guide</i> , p 82)	X				
○ provides appropriate water quality and monitoring (<i>Guide</i> , p 82)	X				
○ allows access to food and waste removal (<i>Guide</i> , p 82)	X				
○ restricts escape and entrapment (<i>Guide</i> , p 82)	X				
○ allows undisturbed observation (<i>Guide</i> , p 82)	X				
○ constructed of nontoxic materials (<i>Guide</i> , p 82)	X				
○ prevents electrical hazards (<i>Guide</i> , p 82)	X				
○ space needs of species are evaluated by IACUC during program evaluations and facility inspections (<i>Guide</i> , p 83)	X				
• Environmental Enrichment, Social Housing, Behavioral and Social Management:					
○ enrichment elicits appropriate behaviors and is safe (<i>Guide</i> , p 83)	X				
○ semi-aquatic reptiles are provided terrestrial areas (<i>Guide</i> , p 83)					X
○ handling is kept to a minimum and appropriate techniques are in place at facility or protocol level (<i>Guide</i> , p 84)	X				
○ nets are cleaned, disinfected and managed to avoid contamination of systems (<i>Guide</i> , p 84)	X				
• Food:					

o storage to prevent contamination, preserve nutrients and prevent pests (<i>Guide, p 84</i>)	x				
o delivery ensures access to all , minimizing aggression and nutrient loss (<i>Guide, p 84</i>)	x				
o storage times are based on manufacturer recommendations or accepted practice (<i>Guide, p 84</i>)	x				
o a nutritionally complete diet is provided (<i>Guide, p 84</i>)	x				
• Substrate:					
o amount, type and presentation of substrate is appropriate for the system and the species (<i>Guide, p 85</i>)	x				
• Sanitation, Cleaning and Disinfection					
o frequency of tank/cage cleaning and disinfection is determined by water quality, permits adequate viewing and health monitoring (<i>Guide, p 86</i>)	x				
o cleaning and disinfection of macroenvironment (<i>Guide, p 86</i>)	x				
• Waste Disposal:					
o procedures for collection (<i>Guide, pp 73-74</i>)	x				
o hazardous wastes are rendered safe before removal from facility (<i>Guide, pp 73-74</i>) [must]	x				
o animal carcasses (<i>Guide, pp 73-74</i>)	x				
• Pest Control:					
o regularly scheduled (<i>Guide, p 74</i>)	x				
o documented program including control of pests and insecticide use (<i>Guide, p 74</i>)	x				
• Emergency, Weekend, and Holiday Animal Care:					
o care provided by qualified personnel every day (<i>Guide, pp 74, 87</i>)	x				
o provision for accessible contact information (<i>Guide, pp 74, 87</i>)	x				
o emergency response plans in place to address major system failures (<i>Guide, 87</i>)	x				
o veterinary care available after hours, weekends, and holidays (<i>Guide, pp 74, 114</i>) [must]	x				
• Identification:					
o cage/tank cards contain required information (<i>Guide, pp 75, 87</i>)	x				
o genotype information included and standardized nomenclature used when applicable (<i>Guide, pp 75, 87</i>)	x				
• Recordkeeping:					
o water quality parameters and frequency of testing recorded (<i>Guide, p 88</i>)	x				
o records kept on feeding, nonexpired food supplies, live cultures (<i>Guide, p 88</i>)	x				
• Storage:					
o adequate space for equipment, supplies, food, substrate and refuse (<i>Guide, p 141</i>)	x				
o substrate protected from contamination (<i>Guide, p 141</i>)	x				
o food in vermin-free, temperature and humidity controlled area and protected from contamination (<i>Guide, p 141</i>)	x				
o refuse storage is separate (<i>Guide, p 141</i>)	x				
o carcass and animal tissue storage is separate, refrigerated below 7°C and cleanable (<i>Guide, p 141</i>)	x				
• Personnel:					
o adequate space for locker rooms, administration and training (<i>Guide, p 135</i>)	x				

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NOTES:

Cagewash**Date: May 20, 2021****Location: ARC****A* M S C NA**

• Construction and Operation:					
o dedicated central area for sanitizing cages and equipment is provided (<i>Guide, p 143</i>)	X				
o cage-washing equipment meets need (<i>Guide, p 143</i>)	X				
o doors, windows, floors, drainage, walls, ceilings (<i>Guide, pp 136-138</i>)	X				
o convenient to animal areas/waste disposal (<i>Guide, p 143</i>)	X				
o ease of access (including door size) facilitates use (<i>Guide, p 143</i>)	X				
o sufficient space for staging and maneuvering (<i>Guide, p 143</i>)	X				
o safety precautions/clothing/equipment used for waste disposal/prewash/acid wash ((<i>Guide, p 143</i>)	X				
o traffic flow clean to dirty with no contamination of clean equipment by dirty equipment and appropriate air pressurization (<i>Guide, p 143</i>)	X				
o insulation and/or sound attenuation present as needed (<i>Guide, p 143</i>)	X				
o utilities are appropriate (<i>Guide, p 143</i>)	X				
o ventilation meets heat and humidity load (<i>Guide, p 143</i>)	X				
o safety features (e.g., SOPs, warning signs, eyewash stations) are in use (<i>Guide, p 143</i>)	X				
o functioning safety devices to prevent entrapment in washer/sterilizers (<i>Guide, p 143</i>)	X				
o cage wash temperatures are monitored and records are available (<i>Guide, p 73</i>)	X				
o appropriate clean cage storage (<i>Guide, p 141</i>)	X				

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