SEMIANNUAL REPORT

ANIMAL CARE AND USE PROGRAM REVIEW AND FACILITY INSPECTION OF THE

Rocky Mountain Laboratories

October 2019

Section A - Site Visits & Program Review

1) Inspections of the RML 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	Туре	Date	ACUC Members	
Redacted by agreement	AF, Surgery	10/01/2019	Redacted by agreement	
	AF	10/01/2019		
	AF, Surgery	10/01/2019		
	AF	10/01/2019		
	AF, Surgery	10/01/2019		

- 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) The following document(s) were used as the basis for review of the animal care and use program:

	Document/Resource:
	Guide for the Care & Use of Laboratory Animals, 8th Edition (Guide)
	AAALAC Program Description
	OACU "Animal Program Semiannual Assessment Checklist" (1 page summary)
√*	OACU/OLAW "Semiannual Program Review & Facility Inspection Checklist" (24 pages)
	Other documents/resources (please specify)
* Mod	ified version (Program review only)

4) The program review was conducted in the following manner:

	Program Review Process
	Full committee member review for ALL of the review, i.e. the
	documents/resources listed in A3) are included in the meeting packet and
	reviewed at a fully convened meeting
	Full committee and subcommittee review, i.e. the documents/resources listed in
	A3) are assigned to various members who review their parts/sections and then
	they discuss their reviews with the full committee for a final review/approval
	Designated member review, i.e. the documents/resources listed in A3) are
√	assigned to various members who review their parts/sections and then report
	back to the full committee the results of their designated review
	Other, please describe:

Section B – Regulatory Compliance:

Except as noted in Sections 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:

N/A

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

Role (ACUC Chair, ACUC AV, IC APD, or IC Animal Program Manager)	Name	Action (joined or departed)
N/A		

3) Animal Facility/Area Changes:

Facility Type (AF/SF)	Location	Action (opened, closed, under renovation, etc.)
1	Redacted by agreement	Several repairs underway to correct structural and mechanical issues associated with an aging building

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:

Guide Departures	Guide Departure Citation (page #)	Justification (scientific, veterinary, or animal welfare)
Dwarf hamsters are housed in caging of	Space allocation – (p. 55 – 63)	Veterinary/Animal Welfare
5" in height	Table 3.2 (p.57)	

2. Exceptions to the AWAR:

Species	# Animals Affected (this Period)	9CFR title/section	Description and Rationale
Non-human Primates	79	2.31 d). iv). A). Institutional Animal Care and Use Committee (Column E Procedures)	79 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 at least twice 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	35	2.31 d). iv). A). Institutional Animal Care and Use Committee (Column E Procedures)	35 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	45	2.31 d). iv). A). Institutional Animal Care and Use Committee (Column E Procedures)	45 hamsters infected with ABSL-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.
Swine	9	2.31 d). iv). A). Institutional Animal Care and Use Committee (Column E Procedures)	9 swine infected with ABSL-4 agents have been used in approved research efforts for the generation of models of human disease and vaccine development. All animals are monitored at least twice 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.
Rabbits	15	2.31 d). iv). A). Institutional Animal Care and Use	15 rabbits infected with Staphylococcus aureus have been used in approved research efforts for the generation of models of human disease and vaccine development. All

		Committee (Column E Procedures)	animals are monitored at least twice 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 bacterial and immune parameters being measured. Therefore, these animals are listed as "column E" for these studies.
Non-human primates	91	3.81 Environmental Enrichment to Promote Psychological Well Being (Singly Housed NHP).	91 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	7	3.81 Environmental Enrichment to Promote Psychological Well Being (Singly Housed NHP).	7 non-human primates displaying aggressive behavior, for medical and/or clinical treatment 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 program review, and facilities and laboratory inspections were achieved within the time intervals projected on the previous semiannual report.

<u>Section F – Current Deficiencies & Plans:</u>

Deficiencies found *over the past 6 months* during RML 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	Sign for Reporting an animal welfare concern is not current version		Redacted by agreement	Replace with correct sign	RMVB	10/02/2019	С
2	(b)(5)						
3							
4							
5	"date received" for fresh food not filled in	М	Redacted by agreement	Complete label	RMVB	10/04/2019	С
6	Bug present	М		Removed at time of inspection	RMVB	Removed at time of inspection	С
8	(b)(5)						
9	Ethanol bottle exp date not legible	М	Redacted by agreement	Place new label	RMVB	10/04/2019	С
10	(b)(5)						
11	Wadded up laboratory diaper in scrub sink, dead wasp in sink,	М	Armco, East side	Clean prior to use	RMVB	Not currently in use	

foamy mac lacking exp			
date			
Dirty towels on floor			
Generally dirty and dusty			

¹M=minor: S=significant

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: [X] None

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 RML.

Section I – Minority Report

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

²C=corrected; P=pending

RML ACUC Member Signatures:

	Redacted by agreement
,	
Olivia Otal III III ali	
Olivia Steele-Mortimer, Chair, ACUC Redacted by agreement	
Redacted by agreement	
Dana Rast St. V. i i	
Dana Scott, Attending Veterinarian	
Redacted by agreement	
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Semiannual Report Attachment 3 Supplemental Information Fall 2019

<u>Instructions:</u> Submit the following information with your Fall 2019 Semiannual Report as a separate file called IC SI F19.

NOTE: *Guide* Exceptions (IC REP Fall 2019, section D): a reminder that a new column was added in the spring 2019 cycle asking for the *Guide* citation for Exceptions (*Guide* chapter, section, and page number).

1. Number of approved Animal Study Proposals (ASPs) as of 31 Oct 2019:

Provide the total number of active/approved ASPs as of the 31 October 2019 cutoff date.

2. 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.

- 1. Multiple Species Housed. In Redacted by 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 Mesocricetus auratus are housed in the same room as Rattus norvegicus. In addition, multiple species of rodents are co-housed in the animal holding rooms of the maximum containment laboratory Redacted by arrowment animals are housed in individually-ventilated caging. (Reference: Guide, p. 111)
- Extended Cage Change Frequency. The RML ACUC has approved facility-wide extended cage change for mice. Mice in microisolator cages are changed once every 14 days. The Veterinary branch conducted a study on the impact of a 14-day cage change (parameters included ammonia levels, condition of bedding, and behavior & appearance of the animals) and no impact was found. (Reference: Guide, p. 70)
- 3. Cage Size not in accordance with Guide recommendation. The Guide standard for mouse cage height is 5 inches, and cage height for hamsters is 6 inches. RML has colonies of several different hamster species, including 4 species of what can be described as dwarf hamsters. These species are Djhungarian (*Phodopus campbelli*), Siberian (*Phodopus sungorus*), Chinese (*Cricetulus griseus*) and Armenian (*Cricetulus migratorius*) hamsters. These 4 species of hamsters are approximately the size of a laboratory mouse (*Mus musculus*). 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. They are able to reach food and water comfortably in a standard (5" high) mouse cage. (Reference: Guide, p. 55 58)

April 30, 2020

Date:		

Institutional Animal Care & Use Committee Roster

				New
Member Name	Degree/Credentials	Position Title	PHS Policy Membership Role	Member
Olivia Steele-Mortimer	PhD	Principal Investigator	Chair	
Dana Scott	DVM, DACVP	Branch Chief	Attending Veterinarian	
Redacted by agreement				
				片片

ACUC Chair Mailing Address & Phone #: Redacted by agreement

Attending Vet 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, 2019

Spring Program Review Date(s):	4/8/20			
Fall Program Review Date(s):				

Bldg/Area/Rm	Facility Insp. Date(s) Spring / Fall		AF/SF; Gross Sq. Ft.						Species Housed Average						ventory		
Redacted by agreement	3/24/2020		22 000	¹ Mice	² Peromyscus	³ Hamsters	1	6,022	2	122	3	162					
			23,000	⁴ Guinea pigs	⁵ Rhesus NHP	6	4	63	5	7	6						
	3/25/2020		0.000	¹ Mice	² Mastomys	³ Guinea pigs	1	471	2	2	3	14					
			8,900	4	5	6	4		5		6						
	3/24/2020			¹ Mice	² Hamsters	³ Rats	1	863	2	3	3	4					
			1,600	4	5	6	4		5		6						
	3/25/2020		0.000	¹ Mice	² Mastomys	³ Guinea pigs	1	109	2	7	3	7					
			3,000	⁴ Swine	⁵ Cynos (NHP)	⁶ Rhesus (NHP)	4	1	5	8	6	5					
	"			¹ AGMS (NHP)	2	3	1	8	2		3						
				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

Spring Semiannual Report Submission Date: October 31, 2019

CONTINUATION PAGE

Bldg/Area/Rm	Facility Ins	sp. Date(s) g / Fall	AF/SF; Gross Sq. Ft.	Species Housed Average Daily Inventory					
Redacted by agreement	3/25/2020		1,600	1 Cynos (NHP)	² Rhesus (NHP)	3 AGMs (NHP)	1 3	² 9	3 8 6
	3/24/2020		1,600	1 Mastomys	5	6	1 143	5	6
				4	5	6	4	5	6
				4	5	6	4	5	6
				4	5	6	4	5	3 6

I. Semiannual Program Review Checklist

Institutional Policies and Responsibilities

Date: October 2, 2019

	imal Care and Use Program	A*	М	S	С	N.
a.	Responsibility for animal well-being is assumed by all members of the program (Guide, p 1)	\checkmark				
b.	IO has authority to allocate needed resources (Guide, p 13)	√				
c.	Resources necessary to manage program of veterinary care are provided (<i>Guide</i> , \underline{p} $\underline{14}$)	√				
d.	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)	√				
e.	Program needs are regularly communicated to IO by AV and/or IACUC (<i>Guide</i> , p 13)	√				
f.	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)	√				
g.	Inter-institutional collaborations are described in formal written agreements ($Guide, p$ 15)	\checkmark				
h.	Written agreements address responsibilities, animal ownership, and IACUC oversight ($Guide$, p 15)	√				
Dis	saster Planning and Emergency Preparedness	\mathbf{A}^*	М	s	С	N/
<u>75</u>		√				
b.	Plans include provisions for euthanasia (<i>Guide</i> , <u>p 35</u>)	\checkmark				
c.	3 · · · · · · · · · · · · · · · · · · ·	√				
d.	failures (<i>Guide</i> , p 35)	√				
_	Plans describe preservation of critical or irreplaceable animals (<i>Guide</i> , <u>p 35</u>)	√_				
f.	Plans include essential personnel and their training (<i>Guide</i> , <u>p 35</u>)	√				
g.	Animal facility plans are approved by the institution and incorporated into overall response plan ($Guide$, p 35)	√				
h.	Law enforcement and emergency personnel are provided a copy and integration with overall plan is in place (<i>Guide</i> , <u>p 35</u>)	√				
IA	cuc	\mathbf{A}^*	М	S	С	NA
a.	Meets as necessary to fulfill responsibilities (Guide, p 25)	√				
	IACUC Members named in protocols or with conflicts recuse themselves from protocol decisions (<i>Guide</i> , <u>p 26</u>)	√				
	Continuing IACUC oversight after initial protocol approval is in place (Guide, p 33)	\checkmark				
d.	IACUC evaluates the effectiveness of training programs (<i>Guide</i> , <u>p 15</u>)	√				
IA	CUC Protocol Review - Special Considerations	\mathbf{A}^*	М	S	С	NA
a.	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)	√				
b.	For pilot studies, a system to communicate with the IACUC is in place (Guide, p 28)	√				
c.		√				
d.	Restraint devices are justified in the animal use protocols (Guide, p 29)	√				
e.	· / — /	√				
f.	Period of restraint is the minimum to meet scientific objectives (Guide, p 29)					√
g.	Training of animals to adapt to restraint is provided (Guide, p 29)					√
h.	, ——,					√
i.	Appropriate observation intervals of restrained animals are provided (Guide, p 29)					√
j.	Veterinary care is provided if lesions or illness result from restraint (<i>Guide</i> , \underline{p} 30)					√

	k.	Explanations of purpose and duration of restraint are provided to study personnel ($Guide$, p 30)					√
	I.	Multiple surgical procedures on a single animal are justified and outcomes evaluated (Guide, p 30)					√
	m.	Major versus minor surgical procedures are evaluated on a case-by-case basis (<i>Guide</i> , p 30)	√				
	n.	Multiple survival procedure justifications in non-regulated species conform to regulated species standards (<i>Guide</i> , p 30)					√
	ο.	Animals on food/fluid restriction are monitored to ensure nutritional needs are met (<i>Guide</i> , p 31)					√
	p.	Body weights for food/fluid restricted animals are recorded at least weekly (<i>Guide</i> , \underline{p} 31)					√
	q.	Daily written records are maintained for food/fluid restricted animals (Guide, p 31)					√
	r.	Pharmaceutical grade chemicals are used, when available, for animal-related procedures (<i>Guide</i> , p 31)	√				
	s.	Non-pharmaceutical grade chemicals are described, justified, and approved by IACUC (Guide, p 31)	√				
	t.	Investigators conducting field studies know zoonotic diseases, safety issues, laws and regulations applicable in study area (<i>Guide</i> , <u>p 32</u>)	√				
	u.	Disposition plans are considered for species removed from the wild (Guide, p 32)					√
	٧.	Toe-clipping only used when no alternative, performed aseptically and with pain relief ($Guide$, p 75)	√				
_	т л л	CUC Membership and Functions	\mathbf{A}^*	М	S	_	NA
٥.		IACUC is comprised of at least 5 members, appointed by CEO (PHS Policy, IV.A.3.)		141			ITA
			√				
	D.	Members include a veterinarian, a scientist, a nonscientist, and a nonaffiliated non-lab	√				
	_	animal user (<i>Guide</i> , <u>p 24</u>) IACUC authority and resources for oversight and evaluation of institution's program					
	С.	are provided ($Guide$, p 14)	√				
	А	IACUC conducts semiannual evaluations of institutional animal care and use program					
	u.	(PHS Policy, <u>IV.B.</u>)					
	e.	Conducts semiannual inspections of institutional animal facilities (PHS Policy, <u>IV.B.</u>)	√				
	f.	IACUC organizationally reports to the Institutional Official (PHS Policy, IV.A.1.b.)	√				
	g.	Methods for reporting and investigating animal welfare concerns are in place (<i>Guide</i> , <u>p.</u>					
		<u>23</u>)	V				
	h.	Reviews and investigates concerns about animal care and use at institution (PHS	√				
		Policy, <u>IV.B.</u>)	v				
	i.	Procedures are in place for review, approval, and suspension of animal activities (PHS Policy, <u>IV.B.</u>)	√				
	j.	Procedures are in place for review and approval of significant changes to approved activities (PHS Policy, <u>IV.B.</u>)	√				
	k.	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</i> , p 27-32)	√				
	I.	Requests for exemptions from major survival surgical procedure restrictions are made to USDA/APHIS (<i>Guide</i> , <u>p 30</u>)					√
6	TA	CUC Training	\mathbf{A}^*	М	s	С	NA
υ.		All IACUC members should receive:	~	1-1	3	_	117
	a.	a. Formal orientation to institution's program (<i>Guide</i> , <u>p 17</u>)	√				
		b. Training on legislation, regulations, guidelines, and policies (<i>Guide</i> , p 17)	v √				
		c. Training on how to inspect facilities and labs where animal use or housing					
		occurs (Guide, p 17)	√				
		d. Training on how to review protocols as well as evaluate the program (<i>Guide</i> , <u>p</u>	√				
		17) Ongoing training/education (Guide p. 17)					
		e. Ongoing training/education (<i>Guide</i> , <u>p 17</u>)	√				
7.	ΙΔ	CUC Records and Reporting Requirements	\mathbf{A}^*	м	S	С	NA
-	a.					_	
		a. Submitted to IO every 6 months	√				
		b. Compiles program review and facility inspection(s) results (includes all program					
		· - · · · · · · · · · · · · · · · · · ·					-

		and facility deficiencies)	√,				
		c. Includes minority IACUC views	√				
		 Describes IACUC-approved departures from the Guide or PHS Policy and the reasons for each departure 	√				
		e. Distinguishes significant from minor deficiencies	√_				
	b.	f. Includes a plan and schedule for correction for each deficiency identified Reports to OLAW (PHS Policy, <u>IV.F.</u>)	√				
		 Annual report to OLAW documents program changes, dates of the semiannual program reviews and facility inspections and includes any minority views 	√				
		 b. Promptly advises OLAW of serious/ongoing <i>Guide</i> deviations or PHS Policy noncompliance (NOT-OD-05-034) 	√				
		 Institute must promptly advise OLAW of any suspension of an animal activity by the IACUC (NOT-OD-05-034) 	√				
	c.	Reports to U.S. Department of Agriculture (USDA) or Federal funding agency					
		 a. Annual report to USDA contains required information including all exceptions/exemptions 	\checkmark				
		 Reporting mechanism to USDA is in place for IACUC-approved exceptions to the regulations and standards 	√				
		 Reports are filed within 15 days for failures to adhere to timetable for correction of significant deficiencies 	√				
		 d. Promptly reports suspensions of activities by the IACUC to USDA and any Federal funding agency 	\checkmark				
	d.	Records (PHS Policy, <u>IV.E.</u>)					
		 IACUC meeting minutes and semiannual reports to the IO are maintained for 3 years 	√				
		b. Records of IACUC reviews of animal activities include all required information	√				
		 Records of IACUC reviews are maintained for 3 years after the completion of the study 	√				
Q	Vo	terinary Care (See also next section - Veterinary Care)	\mathbf{A}^*	М	s	С	NA
σ.		An arrangement for veterinarian(s) with training or experience in lab animal medicine		1-1	3		IVA
		is in place including backup veterinary care	√				
		Veterinary access to all animals is provided (<i>Guide</i> , <u>p 14</u>) Direct or delegated authority is given to the veterinarian to oversee all aspects of	√				
		animal care and use (Guide, p 14)	√				
		Veterinarian provides consultation when pain and distress exceeds anticipated level in protocol ($Guide$, p 5)	√				
		Veterinarian provides consultation when interventional control is not possible (<i>Guide</i> , p. 5)	√				
	f.	If part time /consulting veterinarian, visits meet programmatic needs (<i>Guide</i> , <u>p 14</u>)	,				√
	g.	Regular communication occurs between veterinarian and IACUC (<i>Guide</i> , <u>p 14</u>) Veterinarian(s) have experience and training in species used (<i>Guide</i> , <u>p 15</u>)	√				
	h. i.	Veterinarian(s) have experience and training in species used ($Guide$, $p = 15$) Veterinarian(s) have experience in facility administration/management ($Guide$, $p = 15$)	√ √				
		veterinarian(s) have experience in racinty daministration, management (Garae, <u>p.15)</u>	v				
9.	Pe	rsonnel Qualifications and Training	\mathbf{A}^*	М	S	C	NA
	a.	All personnel are adequately educated, trained, and/or qualified in basic principles of lal science. Personnel included:	bora	tory	anim	al	
		a. Veterinary/other professional staff (Guide, p 15-16)	\checkmark				
		b. IACUC members (<i>Guide</i> , <u>p 17</u>)	\checkmark				
		c. Animal care personnel (Guide, p 16)	√				
		 Research investigators, instructors, technicians, trainees, and students (Guide, pp 16-17) 	√				
	b.	Continuing education for program and research staff provided to ensure high quality care and reinforce training (<i>Guide</i> , pp 16-17)	√				
	c.	Training is available prior to starting animal activity (<i>Guide</i> , p 17)	√				
		Training is documented (<i>Guide</i> , p 15)	V				
	d.		v				
		Training program content includes: (Guide, p 17)	v				
			√ √				

	 Humane practices of animal use (e.g., research procedures, use of anesthesia, pre- and post-operative care, aseptic surgical techniques and euthanasia 	√				
	 Research/testing methods that minimize numbers necessary to obtain valid results (PHS Policy, <u>IV.A.1.g.</u>) 	√				
	 Research/testing methods that minimize animal pain or distress (PHS Policy, IV.A.1.g.) 	√				
	f. Use of hazardous agents, including access to OSHA chemical hazard notices where applicable (Guide, p 20)	√				
	g. Animal care and use legislation (Guide, p 17)	√				
	h. IACUC function (<i>Guide</i> , <u>p 17</u>)	\checkmark				
	i. Ethics of animal use and Three R's (<i>Guide</i> , <u>p 17</u>)	√				
10.	Occupational Health and Safety of Personnel	\mathbf{A}^*	М	s	С	NA
a.	p 17)	√				
b.	Program covers all personnel who work in laboratory animal facilities (Guide, p 18)	\checkmark				
c.	Changing, washing, and showering facilities are available as appropriate (Guide, $p19$)	\checkmark				
d.	Hazardous facilities are separated from other areas and identified as limited access $(Guide, p 19)$	√				
e.	Personnel training is provided based on risk (e.g., zoonoses, hazards, personal hygiene, special precautions, animal allergies) (<i>Guide</i> , p 20)	√				
f.	Personal hygiene procedures are in place (e.g., work clothing, eating/drinking/smoking policies) (<i>Guide</i> , p 20)	√				
g.	Procedures for use, storage, and disposal of hazardous biologic, chemical, and physical agents are in place (<i>Guide</i> , p 21)	√				
h.	Personal Protective Equipment for the work area is appropriate and available ($Guide, \underline{p}$ 21)	√				
i.	Program for medical evaluation and preventive medicine for personnel includes:					
	a. Pre-employment evaluation including health history (Guide, p 22)	√				
	 Immunizations as appropriate (e.g., rabies, tetanus) and tests as appropriate (Guide, p 22) 	√				
	 Zoonosis surveillance as appropriate (e.g., Q-fever, tularemia, Hantavirus, plague) (Guide, p 23) 	√				
	 d. Procedures for reporting and treating injuries, including accidents, bites, allergies, etc. (Guide, p 23) 	√				
j.	Promotes early diagnosis of allergies including preexisting conditions (Guide, p22)	\checkmark				
	 Considers confidentiality and other legal factors as required by federal, state and local regulations (Guide, p 22) 	√				
	 If serum samples are collected, the purpose is consistent with federal and state laws (Guide, p 22) 	√				
k.	3 · · · · · · · · · · · · · · · · · · ·	\checkmark				
l.	Hearing protection is provided in high noise areas (Guide, p 22)					
m.	 Respiratory protection is available when performing airborne particulate work (Guide, p 22) 	√				
n.	Special precautions for personnel who work with nonhuman primates, their tissues or b	ody	fluid	s inc	lude	:
	a. Tuberculosis screening provided for all exposed personnel (Guide, p 23)	√				
	 b. Training and implementation of procedures for bites, scratches, or injuries associated with macaques (<i>Guide</i>, p 23) 	√				
0.	PPE is provided including gloves, arm protection, face masks, face shields, or goggles ($Guide$, $p \ge 1$)	√				
	 a. Injuries associated with macaques are carefully evaluated and treatment implemented (Guide, p 23) 	√				
p.		√				

11.	Personnel Security	\mathbf{A}^*	М	s	С	NA
a.	Preventive measures in place include pre-employment screening, and physical and IT security ($Guide$, p 23)	√				
12.	Investigating & Reporting Animal Welfare Concerns	\mathbf{A}^*	М	s	С	NA
a.	Methods for investigating and reporting animal welfare concerns are established (Guide, p 23)	√				
b.	Reported concerns and corrective actions are documented (Guide, p 24)	√				
c.	Mechanisms for reporting concerns are posted in facility and at applicable website with instructions ($Guide$, p 24)	√				
	a. Includes multiple contacts (<i>Guide</i> , <u>p 24</u>)	\checkmark				
	 Includes anonymity, whistle blower policy, nondiscrimination and reprisal protection (Guide, p 24) 	√				

^{*} **A** = acceptable

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C = change in program (PHS Policy <u>IV.A.1.a.-i.</u>) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

NOTES: Performed by Dr. Steele-Mortimer, Dr. Scott and Redacted by agreement

Veterinary Care Date: October 2, 2019

1. C	linical Care and Management	\mathbf{A}^*	М	S	С	NA
а	. Veterinary program offers high quality of care and ethical standards (<i>Guide</i> , \underline{p} 105)	√				
	. Veterinarian provides guidance to all personnel to ensure appropriate husbandry, handling, treatment, anesthesia, analgesia, and euthanasia	√				
	. Veterinarian provides oversight to surgery and perioperative care (<i>Guide</i> , p 106)	√_				
d	. Veterinary care program is appropriate for program requirements (<i>Guide</i> , <u>pp 113-</u> 114)	√				
	. Veterinarian(s) is familiar with species and use of animals and has access to medical and experimental treatment records (<i>Guide</i> , p 114)	√				
f.	· · · · · · · · · · · · · · · · · · ·	√				
g	. Procedures are in place to address:	,				
	 a. Problems with experiments to determine course of treatment in consultation with investigator (Guide, p 114) 	√				
	b. Recurrent or significant health problems with the IACUC and	√				
	documentation of treatments and outcomes (Guide, p 114)					
	c. Veterinary review and oversight of medical and animal use records -	√				
h	. Procedures established for timely reporting of animal injury, illness, or disease (<i>Guide</i> , p 114)	√				
i.	, , , , , , , , , , , , , , , , , , , ,	V				
j.		√				
2. A	nimal Procurement and Transportation/Preventive Medicine	A *	М	s	С	NA
	. Procedures for lawful animal procurement are in place (Guide, p 106)	√				
b	. Sufficient facilities and expertise are confirmed prior to procurement (Guide, p 106)	√				
С	. Procurement is linked to IACUC review and approval (Guide, p 106)	√				
d	, — — — — — — — — — — — — — — — — — — —					√
е	. Population status of wildlife species is considered prior to procurement ($Guide$, $p106$)	\checkmark				
f.	· · · · · · · · · · · · · · · · · · ·	√				
	. Animal vendors are evaluated to meet program needs and quality (<i>Guide</i> , <u>p 106</u>)	√				
h	. Breeding colonies are based on need and managed to minimize numbers (<i>Guide</i> , p 107)	√				
i.	international requirements are in place (Guide, p 107)	√				
j.	, , , , , , , , , , , , , , , , , , , ,	√				
k	. Movement of animals is planned to minimize transit time and deliveries are planned to ensure receiving personnel are available (<i>Guide</i> , pp 107-108)	√				
I.		√				
n	n. Environment at receiving site is appropriate (<i>Guide</i> , <u>p 109</u>)	√				
	. Policies in place on separation by species, source, and health status (<i>Guide</i> , <u>pp</u> 109, 111-112)	√				
	. Procedures in place for quarantine to include zoonoses prevention (<i>Guide</i> , <u>p 110</u>)	√				
р	. Quarantined animals from different shipments are handled separately or physically separated (<i>Guide</i> , p 110)	√				
q	. Procedures in place for stabilization/acclimation (Guide, pp 110-111)	√				
r.	Policies in place for isolation of sick animals (Guide, p 112)	√				
S	Program is in place for surveillance, diagnosis, treatment and control of disease to include daily observation (<i>Guide</i> , p 112)	√				
t.		√				
3. S	Surgery	\mathbf{A}^*	М	S	С	NA
	. Surgical outcomes are assessed, and corrective changes instituted (Guide, p 115)	√				
	. Researchers have appropriate training to ensure good technique (<i>Guide</i> , <u>p 115</u>)	√				

	c.	Pre-surgical plans are developed and include veterinary input (e.g., location, supplies, anesthetic and analgesic use, peri-operative care, recordkeeping) (<i>Guide</i> , p 116)	√				
	d.	Aseptic surgery is conducted in dedicated facilities or spaces, unless exception justified and IACUC approved (<i>Guide</i> , p 116)	√				
	e.	Surgical procedures including laparoscopic procedures are categorized as major or minor (<i>Guide</i> , pp 117-118)	√				
	f.	For non-survival surgery, the site is clipped, gloves are worn and instruments and area are clean ($Guide$, p 118)	\checkmark				
	g.	Aseptic technique is followed for survival surgical procedures (<i>Guide</i> , pp 118-119)	\checkmark				
	h.	Effective procedures for sterilizing instruments and monitoring expiration dates on sterile packs are in place (<i>Guide</i> , p 119)	\checkmark				
	i.	Procedures for monitoring surgical anesthesia and analgesia are in place (Guide, \underline{p} 119)	\checkmark				
	j.	For aquatic species, skin surfaces are kept moist during surgical procedures ($Guide, p$ 119)					√
	k.	Post-operative monitoring and care are provided by trained personnel and documented (e.g., thermoregulation, physiologic function, analgesia, infection, removal of skin closures) ($Guide$, pp 119-120)	√				
4.	Pai	in, Distress, Anesthesia and Analgesia	\mathbf{A}^*	М	S	С	NA
		Guidelines for assessment and categorization of pain, distress and animal wellbeing are provided during training ($Guide$, p 121)	√				
		Selection of analgesics and anesthetics is based on professional veterinary judgment ($Guide$, p 121)	√				
		Painful procedures are monitored to ensure appropriate analgesic management (Guide, p 122)	√				
		Nonpharmacologic control of pain is considered as an element of postprocedural care (<i>Guide</i> , <u>p 122</u>)	√				
	e.	Procedures are in place to assure anti-noception before surgery begins (<i>Guide</i> , <u>p 122</u>)	√				
	f.	Guidelines for selection and use of analgesics and anesthetics are in place and regularly reviewed and updated ($Guide$, p 122)	\checkmark				
	g.	Special precautions for the use of paralytics are in place to ensure anesthesia ($Guide$, p 123)					√
5.	Eu	thanasia	\mathbf{A}^*	М	S	С	NA
	a.	IACUC (Guide, p 123)	\checkmark				
	b.	Standardized methods are developed and approved by the veterinarian and IACUC that avoid distress and consider animal age and species (<i>Guide</i> , pp 123-124)	√				
	c.	Training is provided on appropriate methods for each species and considers psychological stress to personnel ($Guide$, p 124)	√				
	d.	Procedures and training are in place to ensure death is confirmed (<i>Guide</i> , <u>p 124</u>)	√				
6.	Dru	ug Storage and Control	\mathbf{A}^*	М	S	С	NA
	a.	Program complies with federal regulations for human and veterinary drugs ($Guide, \underline{p}$. 115)	√				
	b.	Drug records and storage procedures are reviewed during facility inspections ($Guide$, p 115)	√				
		Procedures are in place to ensure analgesics and anesthetics are used within expiration date ($Guide$, p 122)	√				
	d.	Anesthetics and analgesics are acquired, stored, and their use and disposal are recorded legally and safely ($Guide$, p 122)	√				
*	Λ –	accentable					

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