[University of California, Los Angeles]

Roger M. Wakimoto, Vice Chancellor for Research

Subject: Semiannual Report of the Program Review and Facility Inspection Date: July 23, 2019 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.13., 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.ai.): [optional] The following ARC Policies were updated or revised during the reporting period: • Tracking and Reporting Animal Numbers (revised 1/2019) 1. 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: [X] A. There were no departures during this reporting period. [] B. The following departures have been reviewed and approved by the IACUC: Deficiencies in the Institution's Animal Care and Use Program Animal Care and Use Program Review Date(s): July 22, 2019 Select A or B: [X] A. There were no deficiencies in the program during this reporting period. [] B. The following deficiencies have been Identified:	From:	Institutional Animal Care and Use Committee
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Memorandum to:

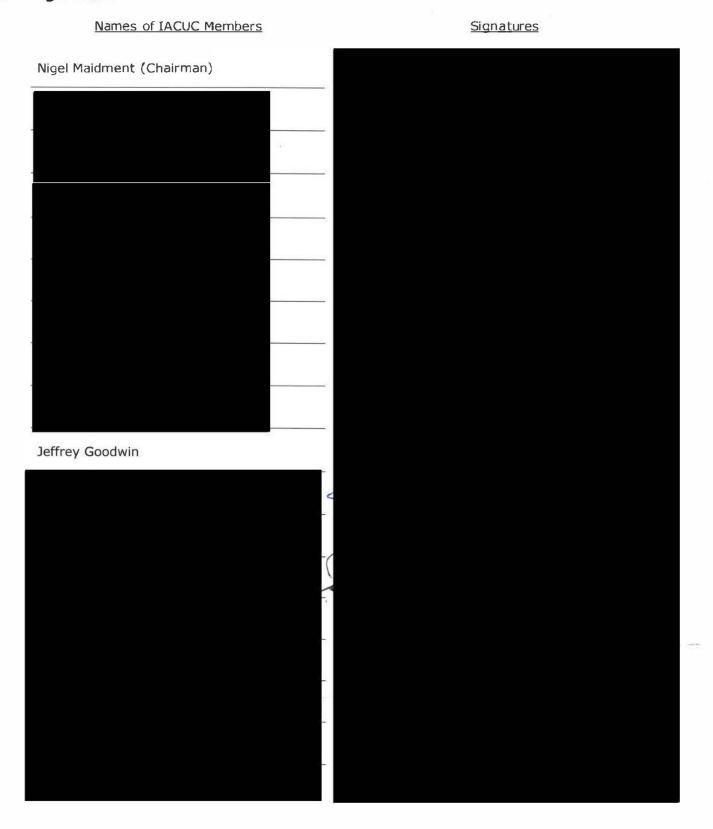
III. Deficiencies in the Institution's Animal Facility

IV.

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Animal Facility Inspection Date(s): Inspections are performed on a rolling basis, as documented monthly reports to the ARC and IO. Select A or B: [] A. There were no deficiencies in the animal facility during this reporting period. [X] B. The following deficiencies have been identified: [describe each deficiency, identify each deficiency as either minor or significant, and provide a reasonable and specific plan and schedule for the correction of each deficiency, deficiencies may be recorded a separate table and attached, the last page of OLAW's Sample Semiannual Program Review and Facility Inspection Checklist provides a sample table]	l on
Facility deficiencies are described in the inspection reports submitted to the IO each month. The ARC administrative staff follows up with PIs in instances where additional information is requested following ARC review. A reasonable and specific plan and schedule for correcting ea deficiency is provided in each inspection report.	
Minority Views Select A or B: [X] A. No minority views were submitted or expressed. [] B. The following minority views were expressed: [insert minority views here or attach]	
Status of AAALAC Accreditation [identify accredited facilities, if applicable] Fully accredited.	

VI. Signatures



Semiannual Program Review and Facility Inspection Checklist: <u>January – June 2019</u>

Both the USDA Animal Welfare Act Regulations [§2.31(c)(1) and §2.31(c)(3)] and the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy IV.B.1 and IV.B.3) require that the Institutional Animal Care and Use Committee (at UCLA, the ARC) conduct evaluations of the institutional animal care and use program, and inspections of the animal facilities, at least once every six months and forward the Committee's evaluation report and recommendations to the Institutional Official. The ARC uses Sections I of the OLAW Checklist to conduct the program review. Facility inspections are performed on a rolling basis; as such, inspection reports are reviewed by the ARC each month and final reports forwarded to the IO upon resolution of deficiencies.

Abbreviations:

APHIS - Animal and Plant Health Inspection Service

ARC - Animal Research Committee

AV - Attending Veterinarian

CEO - Chief Executive Officer (at UCLA: Chancellor Gene Block)

DLAM - Division of Laboratory Animal Care

EH&S - Environment, Health & Safety

HVAC - Heating, Ventilation and Air Conditioning

IACUC - Institutional Animal Care and Use Committee

IO - Institutional Official (at UCLA: Vice Chancellor for Research Roger M. Wakimoto)

PAM – Post-approval Monitoring

Checklist Key:

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 Institutional Official, or IO, and in annual report to OLAW)

NA = not applicable

Highlighting Key:

Red = "must" statement in the Guide

<mark>Yellow</mark> = comments added to checklist to clarify or expand upon processes used at UCLA

Green = plan/schedule for correction from last PE; requires discussion

I. Semiannual Program Review Checklist i

Institutional Policies and Responsibilities

1. Animal Care and Use Program	A	M	S	C	NA
• Responsibility for animal well-being is assumed by all members of the program (Guide,					
<u>p 1) </u>	Χ				
 IO has authority to allocate needed resources (Guide, p 13) 	X				
 Resources necessary to manage program of veterinary care are provided (Guide, p 14) 	Х				
Sufficient resources are available to manage the program, including training of					
personnel in accord with regulations and the Guide (Guide, pp 11, 15)	X				
 Program needs are regularly communicated to IO by AV and/or IACUC (Guide, 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 (Guide, p 14) [must]	X				
 Inter-institutional collaborations are described in formal written agreements (Guide, p 15) 	Х				
 Written agreements address responsibilities, animal ownership, and IACUC oversight (Guide, p 15) 	X				
2. Disaster Planning and Emergency Preparedness	A	М	S	С	NA
 Disaster plans for each facility to include satellite locations are in place (Guide, p 35, p 					
75) [must]	X				
Plans include provisions for euthanasia (Guide, p 35) [must]	X				
 Plans include triage plans to meet institutional and investigators' needs (Guíde, p 35) 	X				
 Plans define actions to prevent animal injury or death due to HVAC or other failures (Guide, p 35) 	Х				
 Plans describe preservation of critical or irreplaceable animals (Guide, p 35) 	X				
 Plans include essential personnel and their training (Guide, p 35) 	Х				
 Animal facility plans are approved by the institution and incorporated into overall response plan (Guide, p 35) 	Х				
 Law enforcement and emergency personnel are provided a copy and integration with overall plan is in place (Guide, p 35) 	Х				
3. IACUC	Α	М	S	С	NA
 Meets as necessary to fulfill responsibilities (Guide, p 25) must 	Х				
IACUC Members named in protocols or with actual or perceived conflicts recuse					
themselves from protocol discussion and decisions (Guide, p 26) [must]	X				
 Continuing IACUC oversight after initial protocol approval is in place (Guide, p 33) 	Χ				
 IACUC evaluates the effectiveness of training programs (Guide, p 15) 	X				
TACIC Protocol Povious Considerations		M	_	_	BIA
4. IACUC Protocol Review - Special Considerations	A	M	S	С	NA
 Humane endpoints are established for studies that involve tumor models, infectious diseases, vaccine challenge, pain modeling, controlled trauma studies, production of monoclonal antibodies, assessment of toxicologic effects, organ or system failure, and 					
models of cardiovascular shock, as well as other models of human and animal disease. (Guide, p 27)	X				
 (Guide, p 27) For pilot studies, a mechanism to communicate preliminary results of pilot studies with the IACUC is in place (Guide, p 28) For genetically modified animals, enhanced monitoring and reporting is in place 	х				
 (Guide, p 27) For pilot studies, a mechanism to communicate preliminary results of pilot studies with the IACUC is in place (Guide, p 28) For genetically modified animals, enhanced monitoring and reporting is in place (Guide, p 28), if needed 	X X				
 (Guide, p 27) For pilot studies, a mechanism to communicate preliminary results of pilot studies with the IACUC is in place (Guide, p 28) For genetically modified animals, enhanced monitoring and reporting is in place (Guide, p 28), if needed Restraint devices are justified in the animal use protocols (Guide, p 29) [must] 	х				
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	•	Semiannual report to the IO (PHS Policy, <u>IV.B.</u>)					
7	TΔ	CUC Records and Reporting Requirements ^{vi}	A	М	S	С	NA
		o Ongoing training/education (<i>Guide</i> , <u>p 17</u>)	Χ				
		o Training on how to review protocols as well as evaluate the program (<i>Guide</i> , <u>p</u> <u>17</u>)	Χ				
		(Guide, p <u>17</u>)	X				
		o Training on how to inspect facilities and labs where animal use or housing occurs		7			
		o Training on legislation, regulations, guidelines, and policies (Guide, p 17)	X	-			
	•	 Formal orientation to institution's program (Guide, p 17) 	X				
J.	•	All IACUC members should receive:	A	141	3		ITA
6	TA	CUC Training	A	М	S	С	NA
	•	Requests for exemptions from major survival surgical procedure restrictions are made to USDA/APHIS* (<i>Guide</i> , <u>p</u> 30) [must]	X				
_	-	agricultural animals) (Guide, p 27-32) Requests for exemptions from major survival surgical procedure restrictions are made.	X	-			
		restraint, multiple survival surgery, food and fluid regulation, field investigations,	• /				
	•	Policies are in place for special procedures (e.g., genetically modified animals,					
	_	activities (PHS Policy, IV.B.)	Χ				
	•	Procedures are in place for review and approval of significant changes to approved	^				
	•	Procedures are in place for review, approval, and suspension of animal activities ^{iv} (PHS Policy, <u>IV.B.</u>)	X				
		Procedures are in place for review, approval, and suspension of animal activities!	X				
	•	Reviews and investigates concerns about animal care and use at institutioniii (PHS					
		23) [must]	Χ				
	•	Methods for reporting and investigating animal welfare concerns are in place (Guide, p	^				
-	•	Conducts semiannual inspections of institutional animal facilities (PHS Policy, <u>IV.B.</u>) IACUC organizationally reports to the Institutional Official (PHS Policy, <u>IV.A.1.b.</u>)	X	-			
		(PHS Policy, IV.B.)	X				-
	•	IACUC conducts semiannual evaluations of institutional animal care and use program					
		are provided (Guide, p 14)	X				
	•	IACUC authority and resources for oversight and evaluation of institution's program	^				
	•	Members include a veterinarian, a scientist, a nonscientist, and a nonaffiliated non-lab animal user (<i>Guide</i> , <u>p_24</u>) ⁱⁱ	X				
-		Chancellor for Research, as IO, via UCLA Delegation 255.03.	X	-			
		July 23, 2012: The CEO (i.e., UCLA Chancellor) has delegated authority to the Vice					
٠.	•	IACUC is comprised of at least 5 members, appointed by CEO (PHS Policy, IV.A.3.)			<u> </u>		
5.	IΔ	CUC Membership and Functions	A	М	S	С	NA
	,,,	(Guide, <u>p 75</u>)	X				
	•	Toe-clipping only used when no alternative, performed aseptically and with pain relief					
	-	(Guide, p 32)	X				
_	•	The disposition plans for species removed from the wild are considered and reviewed	٨				-
	•	Investigators conducting field studies know zoonotic diseases, safety issues, laws and regulations applicable in study area (<i>Guide</i> , <u>p 32</u>)	X				
		by the IACUC (Guide, p 31)	X				-
	•	Non- pharmaceutical grade chemicals are identified, their use justified, and approved					
		procedures (Guide, p_31)	Χ				
	÷	Pharmaceutical grade chemicals are used, when available, for animal-related	^				
	•	Daily written records are maintained for food/fluid restricted animals (<i>Guide</i> , <u>p 31</u>)	X				
	•	Body weights for food/fluid restricted animals are recorded at least weekly (<i>Guide</i> , <u>p</u> <u>31</u>)	X				
		(Guide, p 31)	X	-			
	•	Animals on food/fluid restriction are monitored to ensure nutritional needs are met					
	•	species standards (Guide, p. 30)	Х				
	•	<u>p 30</u>) Multiple survival procedure justifications in non-regulated species conform to regulated	X				
	•	Major versus minor surgical procedures are evaluated on a case-by-case basis (Guide,	1.				
		(Guide, p 30)	Χ				
	•	Multiple surgical procedures on a single animal are justified and outcomes evaluated					
	•	Explanations for the purpose and duration of restraint are provided to personnel conducting the study by the PI or senior laboratory staff (<i>Guide</i> , p 30)	X				

						1	
		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	Χ				
		 Describes IACUC-approved departures from the Guide or PHS Policy and the 					
		reasons for each departure ^{vii}	X				
_		Distinguishes significant from minor deficiencies	X				
		o Includes a <u>pl</u> an and schedule for correction for each deficiency identified viii	X				
	•	Reports to OLAW (PHS Policy, IV.F.)					
		 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 Guide 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					
		 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				
		o Reports are filed within 15 days for failures to adhere to timetable for correction of					
		significant deficiencies	Х				
		 Promptly reports suspensions of activities by the IACUC to USDA and any Federal 					
		funding agency	X				
	•	Records (PHS Policy, IV.E.)					
		o 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 	Χ				
		o Records of IACUC reviews are maintained for 3 years after the completion of the					
		study	X				
		study	^				
			^				
8.		terinary Care (See also next section - Veterinary Care)	A	М	s	С	NA
8.	•	terinary Care (See also next section - Veterinary Care) An arrangement for veterinarian(s) with training or experience in lab animal medicine	A	М	S	С	NA
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Special precautions for personnel who work with nonhuman primates, their tissues or body fluids include: Tuberculosis screening provided for all exposed personnel (Guide, p 23) Training and implementation of procedures for bites, scratches, or injuries associated with macaques (Guide, p 23) PPE is provided including gloves, arm protection, face masks, face shields, or goggles (Guide, p 21) Injuries associated with macaques are carefully evaluated and treatment implemented (Guide, p 23) Occupational safety and health of field studies is reviewed by OSH committee or office (Guide, p 32) Personnel Security	X X X X	M	S	c	NA
Special precautions for personnel who work with nonhuman primates, their tissues or body fluids include: Tuberculosis screening provided for all exposed personnel (Guide, p 23) Training and implementation of procedures for bites, scratches, or injuries associated with macaques (Guide, p 23) PPE is provided including gloves, arm protection, face masks, face shields, or goggles (Guide, p 21) Injuries associated with macaques are carefully evaluated and treatment implemented (Guide, p 23) Occupational safety and health of field studies is reviewed by OSH committee or office	X X X				
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Special precautions for personnel who work with nonhuman primates, their tissues or body fluids include: o Tuberculosis screening provided for all exposed personnel (Guide, p 23) Training and implementation of procedures for bites, scratches, or injuries associated with macaques (Guide, p 23)	X				
Special precautions for personnel who work with nonhuman primates, their tissues or body fluids include: Tuberculosis screening provided for all exposed personnel (Guide, p 23) Training and implementation of procedures for bites, scratches, or injuries	X				,
Special precautions for personnel who work with nonhuman primates, their tissues or body fluids include: Tuberculosis screening provided for all exposed personnel (Guide, p 23)					
Special precautions for personnel who work with nonhuman primates, their tissues or	X				
	X				
	V				
Respiratory protection is available when performing airborne particulate work (<i>Guide</i> ,					
Hearing protection is provided in high noise areas (Guide, p_22)	Χ				
Waste anesthetic gases are scavenged (Guide, p 21)	X				
laws (Guide, p_22) <mark>[must]</mark>	X				
o If serum samples are collected, the purpose is consistent with federal and state	٨				
o Considers confidentiality and other legal factors as required by federal, state and local regulations (<i>Guide</i> , <u>p_22</u>) [must]	X				
o Promotes early diagnosis of allergies including preexisting conditions (<i>Guide</i> , <u>p 22</u>)	X				
etc. (<i>Guide</i> , <u>p 23</u>)	X				
o Procedures for reporting and treating injuries, including accidents, bites, allergies,					
(Guide, p 23)	X				
(Guide, p 22) o Zoonosis surveillance as appropriate (e.g., Q-fever, tularemia, Hantavirus, plague)	X				
Immunizations as appropriate (e.g., rabies, tetanus) and tests as appropriate	V				
o Pre-employment evaluation including health history (Guide, p_22)	Χ				
Program for medical evaluation and preventive medicine for personnel includes:					
21)	X				
Personal Protective Equipment for the work area is appropriate and available (Guide, p	^	-	-		-
Procedures for use, storage, and disposal of hazardous biologic, chemical, and physical agents are in place (<i>Guide</i> , <u>p 21</u>)	X				
policies) (Guide, p 20)	X				
Personal hygiene procedures are in place (e.g., work clothing, eating/drinking/smoking					
hygiene, special precautions, animal allergies) (Guide, p 20)	X				
Personnel training is provided based on risk (e.g., zoonoses, hazards, personal					
Hazardous facilities are separated from other areas and identified as limited access (Guide, p 19)	X				
Changing, washing, and showering facilities are available as appropriate (Guide, p 19)	X				
Program covers all personnel who work in laboratory animal facilities (Guide, p_18)	X				
<u>p 17)</u> [must]	X				
Program is in place and is consistent with federal, state, and local regulations (Guide,	••	_ · ·			
Occupational Health and Safety of Personnel	A	М	S	С	NA
o Ethics of animal use and Three R's (Guide, p 17)	X				
o IACUC function (Guide, p 17)	X				
o Animal care and use legislation (Guide, p 17)	X				
applicable (Guide, p 20)	Χ				
IV.A.1.q.)Use of hazardous agents, including access to OSHA chemical hazard notices where	X				
Research/testing methods that minimize animal pain or distress (PHS Policy,	• /				
(PHS Policy, IV.A.1.q.)	X				
Research/testing methods that minimize numbers necessary to obtain valid results	^				
	V				
Humane practices of animal use (e.g., research procedures, use of anesthesia,					
0	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}	pre- and post-operative care, aseptic surgical techniques and euthanasia (Guide, p	pre- and post-operative care, aseptic surgical techniques and euthanasia (<i>Guide</i> , p	pre- and post-operative care, aseptic surgical techniques and euthanasia (<i>Guide</i> , p	pre- and post-operative care, aseptic surgical techniques and euthanasia (<i>Guide</i> , p

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security (Guide, p 23)

X

12.	Investigating & Reporting Animal Welfare Concerns	A	M	S	С	NA
•	Methods for investigating and reporting animal welfare concerns are established					
	(Guide, p 23) must	X				
•	Reported concerns and corrective actions are documented (Guide, p 24)	X				
•	Mechanisms for reporting concerns are posted in facility and at applicable website with					
	instructions (Guide, p 24)	Χ				
	o Includes multiple contacts (Guide, p 24)	Χ				
_	o Includes anonymity, whistle blower policy, nondiscrimination and reprisal					
	protection (Guide, p 24)	Χ				

Veterinary Care

. Clinical Care and Management	A	M	S	С	N/
 Veterinary program offers high quality of care and ethical standards (Guide, p. 105) 		5 7	6 1		
[must]	X				
 Veterinarian provides guidance to all personnel to ensure appropriate husbandry, 	l				
handling, treatment, anesthesia, analgesia, and euthanasia (Guide, p 106)	X	_			
 Veterinarian provides oversight to surgery and perioperative care (Guide, p 106) 	X				
 Veterinary care program is appropriate for program requirements (Guide, pp 113-114) 	X				
 Veterinarian(s) is familiar with species and use of animals and has access to medical 					
and experimental treatment records (Guide, p 114)	X				
 Procedures to triage and prioritize incident reports are in place (Guide, p 114) 	X				
Procedures are in place to address:	,				
o Problems with experiments to determine course of treatment in consultation with					
investigator (Guide, p 114)	X				
o Recurrent or significant health problems with the IACUC and documentation of					
treatments and outcomes (Guide, p 114)	X				
o Veterinary review and oversight of medical and animal use records (<i>Guide</i> , <u>p 115</u>)	X				
 Procedures established for timely reporting of animal injury, illness, or disease (Guide, 					
p 114) must	X				
	^				
Procedures established for veterinary assessment, treatment, or euthanasia (Guide, p. 111)	\ \				
114) [must]	X				
 Veterinarian is authorized to treat, relieve pain, and/or euthanize (Guide, p 114) 					
must	X	S.			
. Animal Procurement and Transportation/Preventive Medicine	A	M	S	C	N
Procedures for lawful animal procurement are in place (Guide, p 106) [must]	X				
 Sufficient facilities and expertise are confirmed prior to procurement (Guide, p 106) 	X				
 Procurement is linked to IACUC review and approval (Guide, p_106) 	X	-			_
Random source dogs and cats are inspected for identification (Guide, p 106) Random source dogs and cats are inspected for identification (Guide, p 106) Random source dogs and cats are inspected for identification (Guide, p 106)					V
July 25, 2016: Dogs and cats are not obtained from Class B dealers.	37	-			X
Population status of wildlife species is considered prior to procurement (Guide, p_106)	X		-		-
Appropriate records are maintained on animal acquisition (Guide, p 106)	X	-			
 Animal vendors are evaluated to meet program needs and quality (Guide, p 106) 	Х	-			-
Breeding colonies are based on need and managed to minimize numbers (Guide, p					
107)	X				
Procedures for compliance with animal transportation regulations, including					
international requirements, are in place (Guide, p 107) [must]	X				
 Transportation is planned to ensure safety, security and minimize risk (Guide, p 107) 	X				
 Movement of animals is planned to minimize transit time and deliveries are planned to 					
	X				
ensure receiving personnel are available (Guide, pp 107- 108)					
 ensure receiving personnel are available (Guide, pp 107- 108) Appropriate loading and unloading facilities are available (Guide, p 109) 	X				
 Appropriate loading and unloading facilities are available (Guide, p 109) Environment at receiving site is appropriate (Guide, p 109) 	X	3			
 Appropriate loading and unloading facilities are available (Guide, p 109) Environment at receiving site is appropriate (Guide, p 109) 					
 Appropriate loading and unloading facilities are available (Guide, p 109) Environment at receiving site is appropriate (Guide, p 109) Policies in place on separation by species, source, and health status (Guide, pp 109, 					
 Appropriate loading and unloading facilities are available (Guide, p 109) Environment at receiving site is appropriate (Guide, p 109) Policies in place on separation by species, source, and health status (Guide, pp 109, 111-112) 	X	-			
 Appropriate loading and unloading facilities are available (Guide, p 109) Environment at receiving site is appropriate (Guide, p 109) Policies in place on separation by species, source, and health status (Guide, pp 109, 111-112) Procedures in place for quarantine to include zoonoses prevention (Guide, p 110) 	X				
 Appropriate loading and unloading facilities are available (Guide, p 109) Environment at receiving site is appropriate (Guide, p 109) Policies in place on separation by species, source, and health status (Guide, pp 109, 111-112) Procedures in place for quarantine to include zoonoses prevention (Guide, p 110) Quarantined animals from different shipments are handled separately or physically 	X X X				
 Appropriate loading and unloading facilities are available (Guide, p 109) Environment at receiving site is appropriate (Guide, p 109) Policies in place on separation by species, source, and health status (Guide, pp 109, 111-112) Procedures in place for quarantine to include zoonoses prevention (Guide, p 110) Quarantined animals from different shipments are handled separately or physically separated (Guide, p 110) 	X X X				
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		anesthetic and analgesic use, peri-operative care, recordkeeping) (Guide, p_116)					
	•	Aseptic surgery is conducted in dedicated facilities or spaces, unless exception justified					
	-	and IACUC approved (Guide, p 116)	X				
	•	Surgical procedures including laparoscopic procedures are categorized as major or					
-		minor (Guide, pp 117-118)	X				
	•	For nonsurvival surgery, the site is clipped, gloves are worn and instruments and area					
		are clean (Guide, p 118)	X				
	•	Aseptic technique is followed for survival surgical procedures (Guide, pp 118-119)	X				
	•	Effective procedures for sterilizing instruments and monitoring expiration dates on					
		sterile packs are in place (Guide, <u>p</u> <u>119</u>)	X				
	•	Procedures for monitoring surgical anesthesia and analgesia are in place (Guide, p					
		<u>119</u>)	X				
	•	For aquatic species, skin surfaces are kept moist during surgical procedures (Guide, p					
		<u>119</u>)	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</i> , pp. 119-120)	X				4:
	_				_		
4.	Pa	in, Distress, Anesthesia and Analgesia	Α	M	S	С	NA
	•	Guidelines for assessment and categorization of pain, distress and animal wellbeing					
		are provided during training (Guide, p 121)	X				
	•	Selection of analgesics and anesthetics is based on professional veterinary judgment					
_	-	(Guide, p 121)	X				
	•	Painful procedures are monitored to ensure appropriate analgesic management					
		(Guide, <u>p 122)</u>	X				
	•	Nonpharmacologic control of pain is considered as an element of postprocedural care					
_	-	(Guide, p 122)	X				
	•	Procedures are in place to assure antinoception before surgery begins (Guide, p 122)					
_	95_	[must]	Χ				
	•	Guidelines for selection and use of analgesics and anesthetics are in place and					
_		regularly reviewed and updated (Guide, p_122)	X				
	•	Special precautions for the use of paralytics are in place to ensure anesthesiaxiv					
		(Guide, p 123)	X				
5	Fu	thanasia	A	M	S	C	NA
<u> </u>	•	Methods are consistent with AVMA Guidelines on Euthanasia unless approved by the					117
	•	IACUC (Guide, p 123)	Χ				
-	•	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)	X				
	•	Training is provided on appropriate methods for each species and considers					
		psychological stress to personnel (Guide, p 124)	X				
	•	Procedures and training are in place to ensure death is confirmed (<i>Guide</i> , p. 124)					
		must	X				
_		(music	^				-
6.	Dr	ug Storage and Control	A	M	S	C	NA
	•	Program complies with federal regulations for human and veterinary drugs(Guide, p					
		115) [must]	X				
	•	Drug records and storage procedures are reviewed during facility inspections (Guide, p					
		<u>115</u>)	X				
	•	Procedures are in place to ensure analgesics and anesthetics are used within					
		expiration date (Guide, p 122) must	Χ				
	•	Anesthetics and analgesics are acquired, stored, and their use and disposal are					
		recorded legally and safely (Guide, p 122)	X				

II. Semiannual Facility Inspection Checklist

ARC inspections are performed on a rolling basis and reports for each month of laboratory and vivarium inspections are provided to the Institutional Official (IO) on an ongoing basis.

III. Semiannual Program Review and Facility Inspection Report

A report detailing deficiencies identified during the prior months set of inspections, as well as plan/schedule for correction of those deficiencies, is reviewed/approved by the ARC at a convened meeting the month following those inspections (e.g., the report pertaining to inspections performed in January is reviewed at an ARC meeting in February). Reports are forwarded to the IO upon resolution of deficiencies.

Deficiencies identified during the program review are highlighted and described in Section I, then summarized in the Report to IO.

IV. Endnotes

¹ 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.

- 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]
- x 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;"

ⁱⁱ Part 2 Subpart C - Research Facilities

- 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].
- xiv 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."