

December 9, 2019

Dr. Mark Schmitt
Institutional Official and
Interim Vice President for Research
SUNY Upstate Medical University

The enclosed report summarizes the results of the semiannual program review and facility inspection conducted by the Institutional Animal Care and Use Committee (IACUC), in accordance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), Section IV.B.1.-3., the *Guide for the Care and Use of Laboratory Animals (Guide)*, and the Animal Welfare Act (AWA) regulations, as applicable. Submission of semiannual reports to the Institutional Official is a condition of this University's Animal Welfare Assurance with the NIH Office of Laboratory Animal Welfare (OLAW).

Program Review

The program review is divided into three parts. Review was conducted at a regular IACUC meeting, as follows:

July 8, 2019 Part A – Institutional Policies and Responsibilities

IACUC Policies: Protocol Review & Facility Assessment

August 12, 2019 Part B – Veterinary Care

IACUC Policies: Anesthesia, Antibody Production/Neoplasia, Euthanasia, Misc., Restraint & Restriction, and Surgery

September 9, 2019 Part C – Personnel Training and Occupational Health & Safety

IACUC Policies: Personnel

Facilities Inspection

On October 21, 2019, members of the IACUC performed a Facilities Inspection. The following animal care & use areas were inspected:



The inspections were conducted using the *Guide*. Reasonable correction dates have been set for minor deficiencies noted during the current inspection.

Inspection & Post-approval Monitoring of Individual Labs/Core Facilities

A list of inspections to individual investigator's lab and core facilities conducted during the period May 2019 – October 2019 is included in this report. During these inspections, animal use areas were inspected and animal care and use protocols were reviewed using the *Guide*. Reasonable correction dates have been set for minor deficiencies noted during these site visits.

Please contact me if you have any questions regarding this report.

Respectfully submitted,



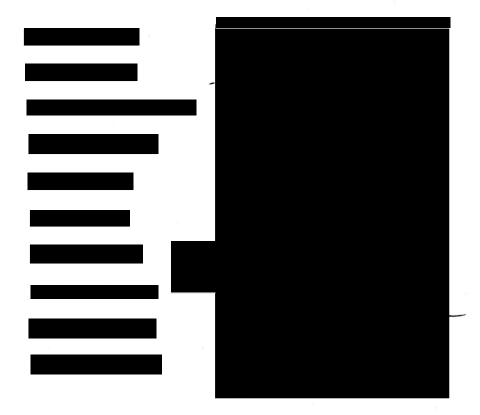
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The undersigned IACUC members approve this report for submission to the Institutional Official:



Enclosure

SUNY Upstate Medical University

Institutional Animal Care and Use Committee

Semiannual Report to the Institutional Official

October 2019

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I. Semiannual Program Review Part A - Institutional Policies and Responsibilities

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 <u>IV.A.1.a.-i.</u>) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

[must] = indicates actions that the Committee for the Update of the Guide considers imperative and mandatory duty or requirement for providing human animal care and use (Guide, p 8)

1. Animal Care and Use Program	Α	M	S	С	NA
 Responsibility for animal well-being is assumed by all members of the program 	Х				
(Guide, <u>p 1</u>) [must]					
 IO has authority to allocate needed resources (Guide, p 13) 	X				
 Resources necessary to manage program of veterinary care are provided (Guide, p 14) [must] 	Х				
 Sufficient resources are available to manage the program, including training of personnel in accord with regulations and the Guide (Guide, pp. 11, 15) 	Х				
 Program needs are regularly communicated to IO by AV and/or IACUC (Guide, p 13) 	Х				
 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] 					Х
 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) 	Х				
2. Investigating & Reporting Animal Welfare Concerns	Α	M	S	С	NA
 Methods for investigating and reporting animal welfare concerns are established (Guide, p 23) [must] 	Х				
 Reported concerns and corrective actions are documented (Guide, p 24) 	Х				
 Mechanisms for reporting concerns are posted in facility and at applicable website with instructions (Guide, p 24) 	Х				
 Includes multiple contacts (Guide, p 24) 	X				
 Includes anonymity, whistle blower policy, nondiscrimination and reprisal protection (Guide, p 24) 	Χ				
3. Disaster Planning and Emergency Preparedness	Α	M	S	С	NA
 Disaster plans for each facility to include satellite locations are in place (Guide, p 35, p 75) [must] 	Х				
 Plans include provisions for euthanasia (Guide, p 35) [must] 	Х				
 Plans include triage plans to meet institutional and investigators' needs (Guide, p 35) 	Х				
 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) 	Х				
 Plans include essential personnel and their training (Guide, p 35) 	X				
 Animal facility plans are approved by the institution and incorporated into overall response plan (<i>Guide</i>, p 35) 	Х				
 Law enforcement and emergency personnel are provided a copy and integration with overall plan is in place (Guide, p 35) 	Х				
4. IACUC	Α	M	S	С	NA

					1
Meets as necessary to fulfill responsibilities (Guide, p 25) [must]	X				
 IACUC Members named in protocols or with conflicts recuse themselves from protocol decisions (Guide, p 26) [must] 	^				
 Continuing IACUC oversight after initial protocol approval is in place (Guide, p 33) 	X				
IACUC evaluates the effectiveness of training programs (<i>Guide</i> , p 15)	Х				
. IACUC Protocol Review - Special Considerations	Α	М	S	С	N.A
	_ ^				147
 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) 	Х				
 For pilot studies, a system to communicate with the IACUC is in place (Guide, p 28) 	Х				
 For genetically modified animals, enhanced monitoring and reporting is in place (Guide, p 28) 	Х				
 Restraint devices, when necessary, are justified in the animal use protocols (Guide, p 29) [must] 	Х				
Alternatives to physical restraint are considered (Guide, p 29)	Х				
 Period of restraint is the minimum to meet scientific objectives (Guide, p 29) 	Х				
Training of animals to adapt to restraint is provided (<i>Guide</i> , <u>p 29</u>)	Х				
Animals that fail to adapt are removed from study (Guide, p 29)	Х				
 Appropriate observation intervals of restrained animals are provided (Guide, p 29) 	X				
 Veterinary care is provided if lesions or illness result from restraint (Guide, p 30) [must] 	Х				
 Explanations of purpose and duration of restraint are provided to study personnel (Guide, p 30) 	Х				
 Multiple surgical procedures on a single animal are justified and outcomes evaluated (Guide, p 30) 	Х				
 Major versus minor surgical procedures are evaluated on a case-by-case basis (Guide, p 30) 	Х				
 Multiple survival procedure justifications in non-regulated species conform to regulated species standards (<i>Guide</i>, p 30) 	Х				
 Animals on food/fluid restriction are monitored to ensure nutritional needs are met (Guide, p 31) 	Х				
 Body weights for food/fluid restricted animals are recorded at least weekly (Guide, p 31) 	Х				
 Daily written records are maintained for food/fluid restricted animals (Guide, p 31) 	Х				
 Pharmaceutical grade chemicals are used, when available, for animal-related procedures (Guide, p 31) 	Х				
 Non-pharmaceutical grade chemicals are described, justified, and approved by IACUC (Guide, p 31) 	Х				
 Investigators conducting field studies know zoonotic diseases, safety issues, laws and regulations applicable in study area (Guide, p 32) 					Х
 Disposition plans are considered for species removed from the wild (Guide, p 32) 					Х
 Toe-clipping only used when no alternative, performed aseptically and with pain relief (Guide, p 75) 	Х				
IACUC Membership and Functions	Α	М	S	С	N
 IACUC is comprised of at least 5 members, appointed by CEO (PHS Policy, IV.A.3.) 	Х				

				Χ	for 3 years	
				^	o IACUC meeting minutes and semiannual reports to the IO are maintained	
					Records (PHS Policy, <u>IV.E.</u>)	•
				V	Federal funding agency	
				Χ	 Promptly reports suspensions of activities by the IACUC to USDA and any 	
				Χ	correction of significant deficiencies	
				^	 Reports are filed within 15 days for failures to adhere to timetable for 	
				Χ	exceptions to the regulations and standards	
					o Reporting mechanism to USDA is in place for IACUC-approved	
				Χ	exceptions/exemptions	
					o Annual report to USDA contains required information including all	
					Reports to U.S. Department of Agriculture (USDA) or Federal funding agencyix	•
				Χ	 Institute must promptly advise OLAW of any suspension of an animal activity by the IACUC (NOT-OD-05-034) 	
				Χ	Policy noncompliance (NOT-OD-05-034)	
				^	sweiv yinonim SH9 of serious/ongoing Guide deviations or PHS or PHS	
				X	semiannual program reviews and facility inspections and includes any	
					 Annual report to OLAW documents program changes, dates of the 	
					Reports to OLAW (PHS Policy, IV.F.)	•
			Χ		o Includes a plan and schedule for correction for each deficiency identified	
				Χ	 Distinguishes significant from minor deficiencies 	
				V	the reasons for each departure ^{vii}	
				Χ	o Describes IACUC-approved departures from the Guide or PHS Policy and	
				Χ	o Includes minority IACUC views	
				Χ	program and facility deficiencies)	
					Compiles program review and facility inspection(s) results (includes all	
				Χ	o Submitted to IO every 6 months	
					Semiannual report to the IO (PHS Policy, <u>IV.B.</u>)	•
ΑN	O	S	M	A	ACUC Records and Reporting Requirements ^{vi}	AI .7
X					are made to USDA/APHIS ^v (Guide, <u>p.32</u>) [must]	
^					Requests for exemptions from major survival surgical procedure restrictions	•
					investigations, agricultural animals) (Guide, p 27-32)	
				Χ	restraint, multiple survival surgery, food and fluid regulation, field	
					Policies are in place for special procedures (e.g., genetically modified animals,	•
				Χ	approved activities (PHS Policy, <u>IV.B.</u>)	
				^	Procedures are in place for review and approval of significant changes to	•
				Χ	Procedures are in place for review, approval, and suspension of animal activities in (PHS Policy, IV.B.)	•
				Χ	(PHS Policy, <u>IV.B.)</u>	
				^	Reviews and investigates concerns about animal care and use at institutioniii	•
				Χ	Methods for reporting and investigating animal welfare concerns are in place (Guide, p 23) [must]	•
				Χ	روعاد والمارك الكاكر والمارك المعانية المعانية المارك المارك المارك. والمارك الماركي. الماركي الماركية الماركي	•
				Χ	Conducts semiannual inspections of institutional animal facilities (PHS Policy, IV.B.)	•
				Χ	IACUC conducts semiannual evaluations of institutional animal care and use program (PHS Policy, <u>IV.B.</u>)	•
				Χ	IACUC authority and resources for oversight and evaluation of institution's program are provided (Guide, p 14)	•
				Χ	Members include a veterinarian, a scientist, a nonscientist, and a nonaffiliated non-lab animal user (Guide, $\frac{D}{D}$) ⁱⁱ	•

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 Records of IACUC reviews are maintained 	for 3 years after the completion	V		
of the study.		^		

I. Semiannual Program Review Part B - Veterinary Care

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 <u>IV.A.1.a.-i.</u>) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

[must] = indicates actions that the Committee for the Update of the Guide considers imperative and mandatory duty or requirement for providing human animal care and use (Guide, p.8)

1.	Veterinary Care	Α	M	S	С	NA
	 An arrangement for veterinarian(s) with training or experience in lab animal medicine is in place including backup veterinary care^{xi} 	Х				
	 Veterinary access to all animals is provided (Guide, p 14) [must] 	X				
	 Direct or delegated authority is given to the veterinarian to oversee all aspects of animal care and use (Guide, p 14) [must] 	Х				
	 Veterinarian provides consultation when pain and distress exceeds anticipated level in protocol (Guide, p 5) [must] 	Х				
	 Veterinarian provides consultation when interventional control is not possible (Guide, p 5) [must] 	Х				
	 If part-time/consulting veterinarian, visits meet programmatic needs (Guide, p 14) 					Х
	 Regular communication occurs between veterinarian and IACUC (Guide, p 14) 	Х				
	 Veterinarian(s) have experience and training in species used (Guide, p 15) [must] 	Х				
	 Veterinarian(s) have experience in facility administration/management (Guide, p 15) 	Х				
2.	Clinical Care and Management	Α	M	S	С	NA
	 Veterinary program offers high quality of care and ethical standards (Guide, p 105) [must] 	Х				
	 Veterinarian provides guidance to all personnel to ensure appropriate husbandry, handling, treatment, anesthesia, analgesia, and euthanasia (Guide, p 106) 	Х				
	 Veterinarian provides oversight to surgery and perioperative care (Guide, p 106) 	Х				
	 Veterinary care program is appropriate for program requirements (Guide, pp. 113-114) 	Х				
	 Veterinarian(s) is familiar with species and use of animals and has access to medical and experimental treatment records (Guide, p 114) 	Х				
	 Procedures to triage and prioritize incident reports are in place (Guide, p 114) 	Χ				
	Procedures are in place to address:					
	 Problems with experiments to determine course of treatment in consultation with investigator (Guide, p 114) 	Х				
	 Recurrent or significant health problems with the IACUC and documentation of treatments and outcomes (Guide, p 114) 	Х				
	 Veterinary review and oversight of medical and animal use records (Guide, p 115) 	Х				
	 Procedures established for timely reporting of animal injury, illness, or disease (Guide, p 114) [must] 	Х				
	 Procedures established for veterinary assessment, treatment, or euthanasia (Guide, p 114) [must] 	Х				

3. Animal Procurement and Transportation/Preventive Medicine Procedures for lawful animal procurement are in place (<i>Guide</i> , p_106) [must] Sufficient facilities and expertise are confirmed prior to procurement (<i>Guide</i> , p_105) Procurement is linked to IACUC review and approval (<i>Guide</i> , p_106) Procurement is linked to IACUC review and approval (<i>Guide</i> , p_106) Propulation status of wildlife species is considered prior to procurement (<i>Guide</i> , p_109) Appropriate records are maintained on animal acquisition (<i>Guide</i> , p_106) Appropriate records are maintained on animal acquisition (<i>Guide</i> , p_106) Appropriate records are maintained on animal acquisition (<i>Guide</i> , p_106) Breeding colonies are based on need and managed to minimize numbers (<i>Guide</i> , p_107) Procedures for compliance with animal transportation regulations, including international requirements, are in place (<i>Guide</i> , p_107) [must] Transportation is planned to ensure safety, security and minimize risk (<i>Guide</i> , p_107) Movement of animals is planned to minimize transit time and deliveries are planned to ensure receiving personnel are available (<i>Guide</i> , p_107-108) Appropriate loading and unloading facilities are available (<i>Guide</i> , p_107-108) Appropriate loading and unloading facilities are available (<i>Guide</i> , p_109) Policies in place on separation by species, source, and health status (<i>Guide</i> , p_108, 111-112) Procedures in place for quarantine to include zoonoses prevention (<i>Guide</i> , p_110) Quarantined animals from different shipments are handled separately or physically separated (<i>Guide</i> , p_110) Procedures in place for stabilization/acclimation (<i>Guide</i> , p_110-111) Procedures in place for stabilization/acclimation (<i>Guide</i> , p_110-111) Procedures in place for stabilization/acclimation (<i>Guide</i> , p_110-111) Procedures in place for stabilization/acclimation (<i>Guide</i> , p_110-111) Procedures in place for stabilization/acclimation (<i>Guide</i> , p_110-111) Procedures in place for surveillance, diagnosis, treatment and control of disease to i	•	Veterinarian is authorized to treat, relieve pain, and/or euthanize (Guide, p 114 [must]	Х				
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 Aseptic technique is followed for survival surgical procedures (Guide, pp. 118-119) 	•	For nonsurvival surgery, the site is clipped, gloves are worn and instruments	Х				
· · · · ·	•	Aseptic technique is followed for survival surgical procedures	X				
Effective procedures for sterilizing instruments and monitoring expiration dates on sterile packs are in place (<i>Guide</i> , p 119) X	•	Effective procedures for sterilizing instruments and monitoring expiration	Х				

•	Procedures for monitoring surgical anesthesia and analgesia are in place (<i>Guide</i> , p 119)	X				
•	For aquatic species, skin surfaces are kept moist during surgical procedures (<i>Guide</i> , p 119)	Х				
•	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)	Х				
5. P	ain, Distress, Anesthesia and Analgesia	Α	M	S	С	NA
•	Guidelines for assessment and categorization of pain, distress and animal wellbeing are provided during training (<i>Guide</i> , p 121)	Х				
•	Selection of analgesics and anesthetics is based on professional veterinary judgment (<i>Guide</i> , p 121)	Х				
•	Painful procedures are monitored to ensure appropriate analgesic management (<i>Guide</i> , p 122)	Х				
•	Nonpharmacologic control of pain is considered as an element of post-procedural care (<i>Guide</i> , p 122)	X				
•	Procedures are in place to assure antinoception before surgery begins (<i>Guide</i> , p 122) [must]	X				
•	Guidelines for selection and use of analgesics and anesthetics are in place and regularly reviewed and updated (<i>Guide</i> , p 122)	X				
•	Special precautions for the use of paralytics are in place to ensure anesthesia ^{xii} (<i>Guide</i> , p 123)	Х				
6. E	uthanasia	Α	M	S	С	NA
•	Methods are consistent with AVMA Guidelines on Euthanasia unless approved by the IACUC (<i>Guide</i> , p. 123)	X				
•	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)	Х				
•	Training is provided on appropriate methods for each species and considers psychological stress to personnel (<i>Guide</i> , p 124)	Х				
•	Procedures and training are in place to ensure death is confirmed (<i>Guide</i> , <u>p</u> <u>124</u>) [must]	X				
7. D	rug Storage and Control	Α	M	S	С	NA
•	Program complies with federal regulations for human and veterinary drugs (<i>Guide</i> , <u>p 115</u>) [must]	X				
•	Drug records and storage procedures are reviewed during facility inspections (<i>Guide</i> , p 115)	X				
•	Procedures are in place to ensure analgesics and anesthetics are used within expiration date (<i>Guide</i> , <u>p 122</u>) [must]	X				
•	Anesthetics and analgesics are acquired, stored, and their use and disposal are recorded legally and safely (<i>Guide</i> , p 122)	X				

I. Semiannual Program Review Part C – Personnel Training and Occupational Health & Safety

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 <u>IV.A.1.a.-i.</u>) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

[must] = indicates actions that the Committee for the Update of the Guide considers imperative and mandatory duty or requirement for providing human animal care and use (Guide, p.8)

1.	IAC	CUC Training	Α	M	S	С	NA
	•	All IACUC members should receive:					
		 Formal orientation to institution's program (Guide, p 17) 	X				
		 Training on legislation, regulations, guidelines, and policies (Guide, p 17) 	X				
		 Training on how to inspect facilities and labs where animal use or housing occurs (<i>Guide</i>, p 17) 	Х				
		 Training on how to review protocols as well as evaluate the program (Guide, p 17) 	Х				
		 Ongoing training/education (Guide, p 17) 	X				
2.	Pe	sonnel Qualifications and Training	Α	M	S	С	NA
	•	All personnel are adequately educated, trained, and/or qualified in basic principles of laboratory animal science. Personnel included [must]:					
		 Veterinary/other professional staff (Guide, p 15-16) 	X				
		o IACUC members (<i>Guide</i> , p 17)	X				
		o Animal care personnel (<i>Guide</i> , p 16)	Х				
		 Research investigators, instructors, technicians, trainees, and students (Guide, pp. 16-17) 	Х				
	•	Continuing education for program and research staff provided to ensure high quality care and reinforce training (<i>Guide</i> , pp. 16-17)	Х				
	•	Training is available prior to starting animal activity (<i>Guide</i> , <u>p 17</u>)	X				
	•	Training is documented (<i>Guide</i> , p 15)	X				
	•	Training program content includes: (Guide, p 17)					
		Methods for reporting concerns (<i>Guide</i> , p 17)	Х				
		o Humane practices of animal care (e.g., housing, husbandry, handling) xiii	Χ				
		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) ^{xiv}	Х				
		 Research/testing methods that minimize numbers necessary to obtain valid results (PHS Policy, IV.A.1.g.) 	Х				
		 Research/testing methods that minimize animal pain or distress (PHS Policy, IV.A.1.g.) 	Х				
		 Use of hazardous agents, including access to OSHA chemical hazard notices where applicable (<i>Guide</i>, p 20) 	Х				
		 Animal care and use legislation (Guide, p 17) 	Χ				
		o IACUC function (<i>Guide</i> , p 17)	Χ				
		o Ethics of animal use and Three R's (Guide, p 17)	Χ				
3.	Oc	cupational Health and Safety of Personnel		M	S	С	NA
	•	Program is in place and is consistent with federal, state, and local regulations (Guide, p 17) [must]	Х				
	•	Program covers <i>all</i> personnel who work in laboratory animal facilities (<i>Guide</i> , p 18)	Х				

•	Changing, washing, and showering facilities are available as appropriate (<i>Guide</i> , p 19)	X				
•	Hazardous facilities are separated from other areas and identified as limited access (<i>Guide</i> , p 19)	Х				
•	Personnel training is provided based on risk (e.g., zoonoses, hazards, personal hygiene, special precautions, animal allergies) (<i>Guide</i> , p 20)	Х				
•	Personal hygiene procedures are in place (e.g., work clothing, eating/drinking/smoking policies) (<i>Guide</i> , p 20)	Х				
•	Procedures for use, storage, and disposal of hazardous biologic, chemical, and physical agents are in place (<i>Guide</i> , p 21)	Х				
•	Personal Protective Equipment for the work area is appropriate and available (<i>Guide</i> , p 21)	Х				
•	Program for medical evaluation and preventive medicine for personnel includes:					
	 Pre-employment evaluation including health history (Guide, p 22) 	X				
	o Immunizations as appropriate (e.g., rabies, tetanus) and tests as appropriate (<i>Guide</i> , p 22)	Х				
	 Zoonosis surveillance as appropriate (e.g., Q-fever, tularemia, Hantavirus, plague) (Guide, p 23) 	Х				
	 Procedures for reporting and treating injuries, including accidents, bites, allergies, etc. (<i>Guide</i>, <u>p 23</u>) 	X				
	 Promotes early diagnosis of allergies including preexisting conditions (Guide, p 22) 	X				
	 Considers confidentiality and other legal factors as required by federal, state and local regulations (Guide, p 22) [must] 	X				
	 If serum samples are collected, the purpose is consistent with federal and state laws (Guide, p 22) [must] 					Х
•	Waste anesthetic gases are scavenged (Guide, p 21)	X				
•	Hearing protection is provided in high noise areas (Guide, p 22)	X				
•	Respiratory protection is available when performing airborne particulate work (<i>Guide</i> , p 22)	Х				
•	Special precautions for personnel who work with nonhuman primates, their tissues or body fluids include:					
	o Tuberculosis screening provided for all exposed personnel (<i>Guide</i> , <u>p 23</u>)	Х				
	 Training and implementation of procedures for bites, scratches, or injuries associated with macaques (<i>Guide</i>, p 23) 	Х				
	 PPE is provided including gloves, arm protection, face masks, face shields, or goggles (Guide, p 21) 	Х				
	 Injuries associated with macaques are carefully evaluated and treatment implemented (Guide, p 23) 	Х				
•	Occupational safety and health of field studies is reviewed by OSH committee or office (<i>Guide</i> , <u>p 32</u>)					Х
Per	sonnel Security	Α	M	S	С	NA
•	Preventive measures in place include pre-employment screening, and physical and IT security (<i>Guide</i> , <u>p 23</u>)	Х				
. Per	 Training and implementation of procedures for bites, scratches, or injuries associated with macaques (<i>Guide</i>, p 23) PPE is provided including gloves, arm protection, face masks, face shields, or goggles (<i>Guide</i>, p 21) Injuries associated with macaques are carefully evaluated and treatment implemented (<i>Guide</i>, p 23) Occupational safety and health of field studies is reviewed by OSH committee or office (<i>Guide</i>, p 32) sonnel Security Preventive measures in place include pre-employment screening, and 	X X X	M	S	С	

II. Semiannual Facility Inspection

Guidance for Inspectors: What constitutes a thorough IACUC inspection?

Terrestrial Animal Housing and Support Areas

Location:

- o animal areas separate from personnel areas (Guide, p 134)
- o separation of species (Guide, p 111)
- o separation by disease status (Guide, p 111)
- o security and access control (Guide, p 151)

Construction:

- o corridors (Guide, p 136)
- o animal room doors (*Guide*, p 137)
- o exterior windows (Guide, p 137)
- o floors (Guide, p 137)
- o drainage (Guide, p 138)
- o walls and ceilings (Guide, p 138)
- o heating ventilation and air conditioning (Guide, p 139)
- o power and lighting (Guide, p 141)
- o noise control (Guide, p 142)
- o vibration control (*Guide*, p 142)
- environmental monitoring (Guide, p 143)

Room/Cage:

- o temperature and humidity (Guide, p 43)
- o ventilation and air quality (Guide, p 45)
- o illumination (Guide, p 47)
- o noise and vibration (Guide, p 49)

Primary Enclosure:

- o space meets physiologic, behavioral xv, and social xvi needs (Guide, pp 51, 55-63)
- o secure environment provided (Guide, p 51)
- o durable, nontoxic materials in good repair and no risk of injury (Guide, p 51)
- o flooring is safe and appropriate for species (Guide, p 51)
- o adequate bedding and structures for resting, sleeping, breeding (Guide, p 52)
- objective assessments of housing and management are made (Guide, p 52)
- o procedures for routine husbandry are documented (Guide, p 52)
- o socially housed animals can escape or hide to avoid aggression (Guide, p 55)
- cage height provides adequate clearance (Guide, p 56)
- animals express natural postures, can turn around, access food and water, and rest away from urine and feces (*Guide*, <u>p</u> 56)
- rationale^{xvii} for Guide/USDA space exceptions approved by IACUC and based on performance indices (Guide, p 56)
- o dogs and cats allowed to exercise and provided human interaction (Guide, p 58)
- o nonhuman primates are socially housed except for scientific, veterinary or behavior reasons (Guide, pp 58-59)
- o single housing of nonhuman primates is for shortest duration possible (Guide, p 60)
- o opportunities for release into larger enclosures is considered for single caged nonhuman primates (Guide, p. 60)
- o agricultural animals are housed socially (Guide, p 60)
- food troughs and water devices for agricultural animals allow access for all animals (Guide, p. 60)

• Environmental Enrichment, Behavioral and Social Management:

- structures and resources promote species typical behavior (Guide, pp 52-54)
- o novelty of enrichment is considered (Guide, p 53)
- 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)
- o animal care personnel receive training to identify abnormal animal behaviors (Guide, p 53)
- o stability of pairs or groups is monitored for incompatibility (Guide, p 64)
- o single housing is justified for social species (Guide, p 64)
- o single housing is limited to the minimum period necessary (Guide, p 64)
- o additional enrichment for single housed animals is provided (*Guide*, p 64)
- o single housing is reviewed regularly by IACUC and veterinarian (Guide, p 64)
- habituation to routine procedures is part of enrichment program (Guide, p 64)

Sheltered or Outdoor Housing: (e.g., barns, corrals, pastures, islands)

- weather protection and opportunity for retreat (Guide, p 54)
- o appropriate size (Guide, p 54)
- o ventilation and sanitation of shelter (no waste/moisture build-up) (Guide, p 54)
- o animal acclimation (Guide, p 55)
- social compatibility (Guide, p 55)
- o roundup/restraint procedures (Guide, p 55)
- o appropriate security (Guide, p 55)

• Naturalistic Environments:

- o animals added /removed with consideration of effect on group (Guide, p 55)
- adequate food, fresh water, and shelter ensured (Guide, p 55)

Food:

- feeding schedule and procedures including caloric intake management (Guide, pp 65-67)
- o contamination prevention (Guide, p 65)
- o vendor quality control (Guide, p 66)
- storage in sealed containers (Guide, p 66)
- o expiration date labeling (Guide, p 66)
- o vermin control (Guide, p 66)
- rotation of stocks (Guide, p 66)

Water:

- ad libitum unless justified (Guide, pp 67-68)
- QC procedures (Guide, pp 67-68)

• Bedding and Nesting Materials:

- o species appropriate (Guide, pp 68-69)
- o keeps animals dry (*Guide*, pp 68-69)
- o QC procedures (Guide, pp 68-69)
- o minimizes scientific variables (Guide, pp 68-69)

Sanitation:

- frequency of bedding/substrate change (Guide, p 70)
- o cleaning and disinfection of microenvironment (Guide, pp 70-71)
- o cleaning and disinfection of macroenvironment (Guide, p 72)
- o assessing effectiveness (Guide, p 73)

Waste Disposal:

- o procedures for collection (Guide, pp 73-74)
- o procedures for storage and disposal (Guide, pp 73-74)
- hazardous wastes are rendered safe before removal from facility (Guide, pp 73-74)
- o animal carcasses (Guide, pp 73-74)

Pest Control:

- o regularly scheduled (Guide, p 74)
- o documented program including control of rodent pests and insecticide use (Guide, p 74)

Emergency, Weekend, and Holiday Animal Care:

- o care provided by qualified personnel every day (Guide, p 74)
- provision for accessible contact information (Guide, p 74)
- monitoring of backup systems (Guide, p 143)
- o veterinary care available after hours, weekends, and holidays (Guide, pp 74, 114)
- a disaster plan that takes into account both personnel and animals (Guide, p 75)

Identification:

- o cage/rack cards contain required information (Guide, p.75)
- o genotype information included and standardized nomenclature used when applicable (Guide, p.75)

Recordkeeping:

clinical records accessible and contain appropriate information (Guide, pp 75-76)

records are provided when animals are transferred between institutions (Guide, p 75)

• Breeding Genetics and Nomenclature:

- o appropriate genetic records, management and monitoring procedures (Guide, p 76)
- phenotypes that affect wellbeing are reported to IACUC and effectively managed (Guide, p 77)

Storage:

- o adequate space for equipment, supplies, food, bedding and refuse (Guide, p 141)
- o bedding in vermin-free area and protected from contamination(Guide, p 141)
- o food in vermin-free, temperature and humidity controlled area and protected from contamination (Guide, p 141)
- o refuse storage is separate (*Guide*, p 141)
- o carcass and animal tissue storage is separate, refrigerated below 7°C and cleanable (Guide, p 141)

Personnel:

o adequate space for locker rooms, administration and training (Guide, p 135)

Aquatic Animal Housing and Support Areas

Location:

- o animal areas separate from personnel areas (Guide, p 134)
- separation of species (Guide, p 111)
- o separation by disease status (Guide, p 111)
- security and access control (Guide, p 151)

Construction:

- o corridors (Guide, p 136)
 - animal room doors (Guide, pp 137, 150)
- o exterior windows (Guide, p 137)
- o floors (Guide, pp 137, 150)
- o drainage (Guide, pp 138, 150)
- o walls and ceilings (Guide, pp 138, 150)
- o heating ventilation and air conditioning (Guide, pp 139, 150-151)
- o power and lighting (Guide, pp 141, 150)
- o noise control (Guide, p 142)
- o vibration control (Guide, p 142)
- o environmental monitoring (Guide, p 143)

Water Quality:

- standards for acceptable quality are established (Guide, p 78)
- o chlorine, chloramines, chemical, and reactive bioproducts are removed or neutralized prior to use in aquatic systems (*Guide*, <u>pp78</u>, <u>86</u>)

Life Support System:

- water source is based on appropriate controls and research requirements (Guide, p 79)
- biofilter is of sufficient size to process bioload (Guide, p.80)

Temperature, Humidity and Ventilation/Illumination/Noise and Vibration:

- temperature and humidity (Guide, pp 43, 80-81)
- o ventilation and air quality (*Guide*, pp 45, 81)
- o illumination (Guide, pp 47, 81)
- noise and vibration (Guide, pp 49, 81)

Primary Enclosure:

- o allows for normal physiological and behavioral needs (*Guide*, p 82)
- allows social interaction for social species (Guide, p 82)
- o provides a balanced, stable environment (Guide, p 82)
- provides appropriate water quality and monitoring (Guide, p.82)
- o allows access to food and waste removal (Guide, p 82)
- o restricts escape and entrapment (Guide, p 82)
- o allows undisturbed observation (Guide, p 82)
- o constructed of nontoxic materials (Guide, p 82)
- prevents electrical hazards (Guide, p 82)

space needs of species are evaluated by IACUC during program evaluations and facility inspections (*Guide*, p.83)

Environmental Enrichment, Social Housing, Behavioral and Social Management:

- enrichment elicits appropriate behaviors and is safe (Guide, p 83)
- semi-aquatic reptiles are provided terrestrial areas (Guide, p.83)
- o handling is kept to a minimum and appropriate techniques are in place at facility or protocol level (Guide, p 84)
- o nets are cleaned, disinfected and managed to avoid contamination of systems (Guide, p 84)

Food:

- o storage to prevent contamination, preserve nutrients and prevent pests (Guide, p 84)
- o delivery ensures access to all, minimizing aggression and nutrient loss (Guide, p 84)
- storage times are based on manufacturer recommendations or accepted practice (Guide, p.84)
- o a nutritionally complete diet is provided (Guide, p 84)

Substrate:

o amount, type and presentation of substrate is appropriate for the system and the species (Guide, p.85)

Sanitation, Cleaning and Disinfection

- frequency of tank/cage cleaning and disinfection is determined by water quality, permits adequate viewing and health monitoring (*Guide*, p.86)
- o cleaning and disinfection of macroenvironment (Guide, p.86)

Waste Disposal:

- o procedures for collection (Guide, pp 73-74)
- o hazardous wastes are rendered safe before removal from facility (Guide, pp 73-74)
- o animal carcasses (Guide, pp 73-74)

Pest Control:

- o regularly scheduled (*Guide*, p 74)
- o documented program including control of pests and insecticide use (Guide, p 74)

Emergency, Weekend, and Holiday Animal Care:

- care provided by qualified personnel every day (Guide, pp 74, 87)
- o provision for accessible contact information (Guide, pp 74, 87)
- o emergency response plans in place to address major system failures (Guide, 87)
- o veterinary care available after hours, weekends, and holidays (*Guide*, pp 74, 114)

Identification:

- o cage/tank cards contain required information (Guide, pp 75, 87)
- o genotype information included and standardized nomenclature used when applicable (Guide, pp 75, 87)

Recordkeeping:

- water quality parameters and frequency of testing recorded (Guide, p 88)
- o records kept on feeding, nonexpired food supplies, live cultures (Guide, p 88)

Storage:

- o adequate space for equipment, supplies, food, substrate and refuse (Guide, p 141)
- substrate protected from contamination (Guide, p 141)
- o food in vermin-free, temperature and humidity controlled area and protected from contamination (Guide, p 141)
- o refuse storage is separate (Guide, p 141)
- carcass and animal tissue storage is separate, refrigerated below 7°C and cleanable (Guide, p 141)

Personnel:

o adequate space for locker rooms, administration and training (Guide, p 135)

Cagewash

Construction and Operation:

- o dedicated central area for sanitizing cages and equipment is provided (Guide, p 143)
- o cage-washing equipment meets need (Guide, p 143)
- o doors, windows, floors, drainage, walls, ceilings (Guide, pp 136-138)
- o convenient to animal areas/waste disposal (Guide, p 143)

- ease of access (including door size) facilitates use (Guide, p 143)
- sufficient space for staging and maneuvering (Guide, p 143)
- safety precautions/clothing/equipment used for waste disposal/prewash/acid wash (Guide, p 143)
- traffic flow clean to dirty with no contamination of clean equipment by dirty equipment and appropriate air pressurization (Guide, p 143)
- o insulation and/or sound attenuation present as needed (Guide, p 143)
- utilities are appropriate (Guide, p 143)
- o ventilation meets heat and humidity load (Guide, p 143)
- safety features (e.g., SOPs, warning signs, eyewash stations) are in use (Guide, p 143)
- o functioning safety devices to prevent entrapment in washer/sterilizers (Guide, p 143)
- o cage wash temperatures are monitored and records are available (Guide, p 73)
- o appropriate clean cage storage (Guide, p 141

Special Facilities: Aseptic Surgery

• General Considerations:

- o location minimizes traffic/contamination (Guide, p 144)
- o functional components (surgical support, animal preparation, surgeon scrub, operating room, postoperative recovery) are designed and separated (physically or otherwise) (Guide, p 144)
- o appropriate drug storage, control, expiration date monitoring (Guide, pp 115, 122)
- o safe sharps disposal system (Guide, p 74)
- adequate records of anesthesia and perioperative care (Guide, p 122)
- aseptic procedures in use for all survival surgery (Guide, pp 118-119)

Operating Room:

- effective contamination control procedures (Guide, p 144)
- o effective cleaning procedures/dedicated tools (Guide, p 145)
- o interior surfaces smooth and impervious to moisture (Guide, p 145)
- HVAC system meets Guide requirements (Guide, p 145)
- o lighting safe and appropriate (Guide, p 145)
- o outlets safe and appropriate (Guide, p 145)
- o scavenging of anesthetic gases implemented (Guide, p 145)

Surgical Support:

- o facility for washing, sterilizing, storing instruments and supplies (Guide, p 145)
- o autoclave monitoring procedures are implemented (Guide, pp 119, 145)
- o storage of autoclaved materials maintains sterility (Guide, p 145)
- o cold sterilization procedures are appropriate (Guide, p 119)

Animal Preparation

Contains large sink to facilitate cleaning of animal and operative site (Guide, p 145)

Surgeon Scrub

o outside operating room, non-hand-operated sink (Guide, p 145)

Postoperative Recovery

 allows adequate observation, easily cleaned, supports physiologic functions, minimizes risk of injury (Guide, p 145)

Dressing Area

place for personnel to change (Guide, p 145)

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

General Considerations:

- labs used to house animals only when scientifically required and limited to minimum period necessary (Guide, p 134)
- o drug storage, control, and expiration dates (Guide, pp 115, 122)
- o sharps disposal (Guide, p 74)
- o anesthetic monitoring (Guide, p 120)

- scavenging of anesthetic gases (Guide, p 21)
- o safety features (e.g., SOPs, safety signs, eyewash stations, secure gas cylinders) are in place (Guide, p 19)
- o carcass disposal (Guide, pp 73-74)

• Additional Concerns for Survival Surgery: (rodent and minor procedures only)

- o rodent survival surgery clean and uncluttered, not used for anything else during surgery (Guide, p 144)
- o records of peri-operative care (Guide, p 120)
- o aseptic procedures (Guide, pp 118-119)
- autoclave monitoring procedures (Guide, pp 119, 145)
- o storage of autoclaved materials (Guide, p 145)
- cold sterilization procedures are appropriate (*Guide*, p 119)

• Imaging/Whole Body Irradiation:

- o location of resource limits contamination risk (*Guide*, p 147)
- o appropriate transportation methods are in place (Guide, p 147)
- o gas anesthesia provision, scavenging and monitoring are appropriate (Guide, p 147)
- appropriate sensors and ventilation are provided for cryogen gases (Guide, p 147)
- o imaging console is located away from radiation source (*Guide*, p 147)

Hazardous Agent Containment:

o facility adheres to APHIS, USDA and CDC Select Agent Regulations and other federal, state and local regulations including security measures (*Guide*, p 148)

Behavioral Studies:

- facility minimizes airborne transmission of noise and ground-borne transmission of vibration (Guide, p. 149)
- o floor coverings reduce sound transmission (Guide, p 149)
- o testing equipment allows for surface disinfection (Guide, p 150)
- components that cannot be cleaned are not in ready contact with animals and kept covered when not in use (Guide, p 150)
- o housing areas are contiguous with testing areas when appropriate (*Guide*, p 150)

II.	Semiannual Facility Inspection
	Part A - Animal Facility
	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.ai.) (include in semiannual report to IO & annual report to OLAW)
	NA = not applicable
	Individuals participating in this inspection:

	Animal Housing & Support Areas					
Room #	Describe Use	Α	M	S	С	NA
	Supplies/equipment storage	Х				
	Waste material storage & Mister Unit	Х				
	Refrigerated Waste Holding	Х				
	Surgery (Multiple users) Covered under PAM program for individual labs					
	Dirty cage wash	Х				
	Chemical storage: locked; did not enter					Χ
	Cylinder gas system: locked; did not enter					Χ
	Water supply		Х			
	Necropsy		Х			

_	Animal Housing & Support Areas					
Room #	Describe Use	A	M	S	С	NA
	Equipment storage room	X				
	Bedding storage	X				
	Clean cage wash	Х				
	Food storage		Х			
	Clean cage storage	Х				
	housing		Х			
	pump room	Х				
	Fluorescent screening room Covered under PAM program for in	dividua	labs			
	housing		Х			
	(Multiple users) Covered under PAM program for individual labs					
	warm housing (Multiple users) Covered under PAM program for individual la	bs				
	Clinical lab/technician office	Х				
	Procedure room		Х			
	housing: Did not enter, currently pinworm positive					Х
	housing	X				
	housing		Х			
	housing (Covered under PAM program for individual labs					
	housing	Х				
	housing	Х				
	Procedure room		Х			
	Debasias test veess (resulting upons). Covered upday DAM research in dividual le	h -	^			
	Behavior test room (multiple users) Covered under PAM program for individual la					
	Behavior test room (Covered under PAM program for individual labs	5				
	Behavior test room (Covered under PAM program for individual labs	,				
	Behavior test room (multiple users) Covered under PAM program for individual la					
	RCL vestibule	X				
	RCL housing	X				
	Storage (future use:)	X				
	RCL housing	Х				
	RCL procedure room:		Х			
	Transgenic gown-in – temporary storage of behavioral testing equipment	Х				
	Behavior test room (Multiple users) Covered under PAM program for individual la	abs				
	Behavior test room (Multiple users) Covered under PAM program for individual la	abs				
	Behavior test room (Multiple users) Covered under PAM program for individual la	bs				
	Behavior test room (Multiple users) Covered under PAM program for individual la	abs				
	PI-assigned procedure room (Covered under PAM program for individual)	al labs				
	PI-assigned procedure room (Covered under PAM program for individual)	ual labs				
	Storage	Х				
	housing:	Х				
	housing	Х				
	housing	Х				

	Animal Housing & Support Areas							
Room #	Describe Use	Α	M	S	С	NA		
	PI-assigned procedure room (Multiple users) Covered under PAM program for inc	dividual	labs					
	PI-assigned imaging area (Multiple users) Covered under PAM program for individual labs							
	Procedure area		Χ					
	PI-assigned imaging area (Multiple users) Covered under PAM program for indiv	vidual la	bs					
	Procedure room	Х						
	Equipment Storage	Х						
	PI-assigned procedure room Covered under PAM program for individual	l labs						
	PI-assigned procedure room Covered under PAM program for individual	labs						
	RCL Housing: currently empty	Х						
	Housing: Did not enter, currently pinworm positive					Х		
	Housing	Х						
	Procedure room		Х					
	Procedure room		Χ					
	Storage	Х						
	Housing	Х						
	Empty	Х						

II.	Semiannual Facility Inspection Part B -	Animal Facility
Key	A = acceptableM = minor deficiencyS = significant deficiency (is or may	be a threat to animal health or safety) v IV.A.1.ai.) (include in semiannual report to IO & in annual report to OLAW)
	Individuals participating in this in	nspection:

	SCID Facility Animal Housing & Support Areas					
Room #	Describe Use	Α	M	S	С	NA
	Non-sterile entrance/gowning area	Х				
	Spray lock	X				
	Shared equipment/procedure room	Х				
	Clean procedure room		Χ			
	Biocontainment housing	Х				
	Staging/dirty side of autoclave	Х				
	Clean storage/clean side of autoclave	Х				
	housing	Х				
	housing		Χ			
	BSL procedure room	Х				

		Main Animal Housing & Support Areas					
Room #	Describe Use		Α	M	S	С	NA
	Cage wash		X				
	Out of service		X				
	Clean storage		X				
	Food storage		X				
	Bedding storage		X				
	Out of service		X				
	Bottle fill & clean storage		X				
	Out of service		X				
	Out of service		X				
	Out of service		X				
	Out of service		Х				
	Micro CT procedure room	Covered under PAM program for individual labs					
	Laundry		Х				
	Out of service		X				

	Animal Housing & Support Areas					
Room #	Describe Use	Α	M	S	С	NA
	housing	X				
	Procedure room	X				
	Procedure room	X				
	Quarantine	X				
	housing	X				
	housing		Х			
	housing	X				
	Procedure room		Х			
	Procedure room	X				
	housing	X				
	housing		Χ			

	Animal Housing & Support Areas					
Room #	Describe Use	Α	M	S	С	NA
	Dead Animal Storage	X				
	Sharps Container Storage		Х			
	Trash room		Х			
	Bulk chemical storage	X				
	Autoclave – currently inoperable	Х				
	Euthanasia room	Х				
	Quarantine	X				
	Storage	Х				
	Storage		Х			

	Animal Housing & Support Areas					
Room #	Describe Use	Α	M	S	С	NA
	Storage		Χ			
	Storage	Χ				
	housing	Χ				
	lab		Χ			
	mechanical	Х				

II. Semiannu	al Facility Inspection
Part C -	Animal Facility
Key:	
A = accep	able
M = minor	deficiency
	ant deficiency (is or may be a threat to animal health or safety)
	e in program (PHS Policy IV.A.1.ai.) (include in semiannual report to IO & in annual report to OLAW)
NA = not a	
Individual	s participating in this inspection:

		Surgical & Support Areas					
Room #	Describe Use		Α	M	S	С	NA
	prep room	Covered under PAM program for individual labs					
	lab	Covered under PAM program for individual labs					
	OR 4	Covered under PAM program for individual labs					
	OR 1 - storage		Х				
	OR prep/lobby		X				
	Storage		Х				
	OR SCRUB		Х				
	OR 3		Х				
	OR storage / lau	ndry		Х			

	Animal Housing & Support Areas					
Room #	Describe Use	Α	M	S	С	NA
	Cage wash – clean side		Х			
	Cage wash – dirty side	Χ				
	Equipment storage/supplies	Х				
	Housing	Х				
	Procedure room	Χ				
	animal housing	Х				
	Dead animal cooler	Х				
	Chemical storage	Χ				
	Ante area	Х				
	Food cooler		Х			

	Animal Ho	ousing & Support Areas					
Room #	Describe Use		Α	М	S	С	NA
	Bedding		Х				
	Isolation / Biohazard housing		X				
	Procedure room		Х				
	housing		Х				
	housing		Х				
	Procedure room		Х				
	housing		X				
	Necropsy			Χ			
	Storage – out of service						Χ
	Hallways near	and vivarium entrance	Х				
	loading dock		Х				

II.	Semiannual	I Facility	Inspection
	Part D _ DI	ΛP	

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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 <u>IV.A.1.a.-i.</u>) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

Individuals participating in this inspection:

DLAR					
	Α	M	S	С	NA
DLAR	Χ				

III. Report of Deficiencies and Corrective Action Schedule

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 <u>IV.A.1.a.-i.</u>) (include in semiannual report to IO & in annual report to OLAW)

NA = not applicable

Deficiency Category*	Room/Area	Deficiency	Corrective action	Responsible Party	Correction Deadline	Date Completed
М		Certificates of Radiation Safety registration expired	Contact PI and RS office for current certificates	IACUC	12/21/19	11/22/19
М		Expired saline and PBS found	Confiscated	IACUC	10/21/19	10/21/19
М		Fume hood expired	DLAR will schedule certification	DLAR	12/21/19	11/14/19
М		Rusted perfusion equipment found in fume hood	IACUC will contact PI	IACUC	11/21/19	11/13/19
М		2 open boxes of Kellogg's "Froot Loops" cereal found	Confiscated	IACUC	10/21/19	10/21/19
М		3 boxes of expired povidone- iodine swabs found	Confiscated	IACUC	10/21/19	10/21/19
М		Expired food and expired flove mash" found	Disposed	DLAR	10/21/19	10/21/19
M		 Label on containers of water reads last cleaned on 3/9/17. Large blue tub with no label. Expired pH standards. 	IACUC will contact PI IACUC will contact PI Confiscated	IACUC	11/21/19	11/11/19
М		Algae growth on tanks	Clean tanks	DLAR/	10/22/19	10/22/19
М		Expired Puralube (eye ointment) found	Confiscated	IACUC	10/21/19	10/21/19
М		Room dimly light, 1 side of lights out	Lights not out, just on lower intensity as designed for animal room. No correction required.	N/A		
М		Missing sprinkler cover, rusty sprinkler	Submitted work order for repair	DLAR	12/31/19	
М		Chipped paint found in corner	Removed	DLAR/	10/21/19	10/21/19
М		Paint cracks, chips in wall	Submitted work order for repair	DLAR	12/31/19	
М		Cracked ceiling paint	Submitted work order for repair	DLAR	12/31/19	
М		Remove door for extension cord	Submitted work order for repair	DLAR	12/31/19	
М		Cracked paint on duct and floor paint	Submitted work order for repair	DLAR	12/31/19	
М		Ceiling paint cracked	Submitted work order for repair	DLAR	12/31/19	
М		Ceiling paint peeling	Submitted work order for repair	DLAR	12/31/19	
М		Expired chemicals	Confiscated	DLAR/	10/21/19	10/21/19

М	Laundry check list not completed since Feb	Removed list, not currently relevant	DLAR/	11/21/19	11/11/19
М	1) Active leak in ceiling panel 2) Wooden crates for live animals	 Submitted work order for ceiling leak Removed wooden crates 	DLAR/	12/31/19	
М	Pallets too close to wall	Moved pallets away from wall	DLAR	10/21/19	10/21/19
М	Unlabeled specimen preservative	Removed	DLAR	11/21/19	11/11/19

IV. Minority Comments

No minority opinions were expressed during the program review and facilities inspections.

V. Individual inspections/ Post-approval monitoring

Investigator	Date	Building	Room	IACUC#	Species	Use	Comments
	10/22/2019						Procedures described were consistent with protocol. Space appropriate for intended use.
	10/22/2019						Procedures described were consistent with protocol. Space appropriate for intended use.
	10/22/2019						Procedures described were consistent with protocol. Space appropriate for intended use.
	10/16/2019						Procedures described were consistent with protocol. Space appropriate for intended use.

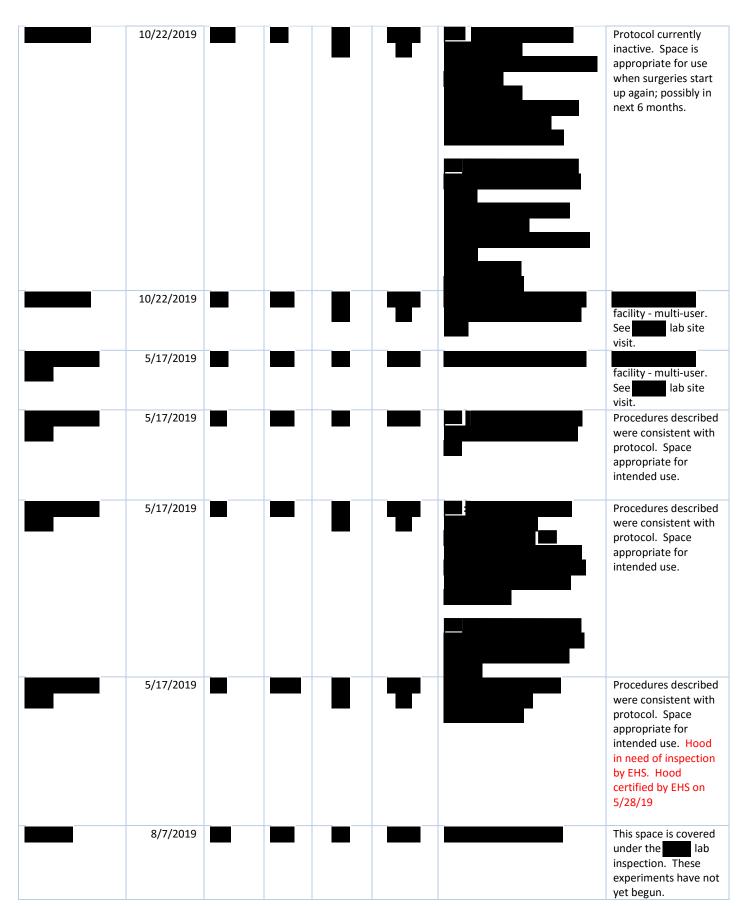


5/13/2019		Procedures described were consistent with protocol. Space appropriate for intended use. Lab hood was congested but not currently working with animals.
5/13/2019		Procedures described were consistent with protocol. Space appropriate for intended use.
5/13/2019	-	Procedures described were consistent with protocol. Space appropriate for intended use.
5/13/2019		Procedures described were consistent with protocol. Space appropriate for intended use.
9/4/2019		Procedures described were consistent with protocol. Space appropriate for intended use.
6/11/2019		Procedures described were consistent with protocol. Space appropriate for intended use.

6/11/2019			Procedures described were consistent with protocol. Space appropriate for intended use.
6/11/2019			Procedures described were consistent with protocol. Space appropriate for intended use.
6/11/2019			Procedures described were consistent with protocol. Space appropriate for intended use.
6/11/2019			Procedures described were consistent with protocol. Space appropriate for intended use.
6/11/2019			Procedures described were consistent with protocol. Space appropriate for intended use.
6/6/2019			No ongoing, none planned for next 6 months.
6/6/2019			No ongoing, none planned for next 6 months.
6/6/2019		-	Has not performed in past six months. No plans to resume in next 6 months.
6/6/2019			Procedures described were consistent with protocol. Space appropriate for intended. Hood in need of inspection.

			Contacted EHS for completion
6/6/2019			No plans to perform these procedures in the next six months. Did not visit.
6/6/2019			Procedures described were consistent with protocol. Space appropriate for intended use.
6/6/2019			No plans to perform these procedures in the next six months. Did not visit.
6/6/2019			No plans to perform these procedures in the next six months. Did not visit.
6/6/2019			No plans to perform these procedures in the next six months. Did not visit.
6/6/2019		,	No plans to perform these procedures in the next six months. Did not visit.
6/6/2019			No plans to perform these procedures in the next six months. Did not visit.
6/6/2019			Procedures described were consistent with protocol. Space appropriate for intended use.
6/6/2019			Procedures described were consistent with protocol. Space appropriate for intended use. Hood in need of inspection. Contacted EHS for completion.
6/6/2019			Project is in its initial stages and these procedures have not yet begun; location(s) to be determined in consultation with

			Attending/Clinical Vet(s).
10/22	2/2019		Procedures described were consistent with protocol. Space appropriate for intended use.
10/22	2/2019		Procedures described were consistent with protocol. See lab site visit.
10/22	2/2019		Behavioral tests are inactive.
10/1:	1/2019		No recent training sessions. Perhaps in next 6 months. Space is appropriate for use. Space appropriate for intended use.
6/26	6/2019		Procedures described were consistent with protocol. See lab site visit.
	6/2019		Procedures described were consistent with protocol. Space appropriate for intended use.
6/26	6/2019		Space is covered under lab site visit.

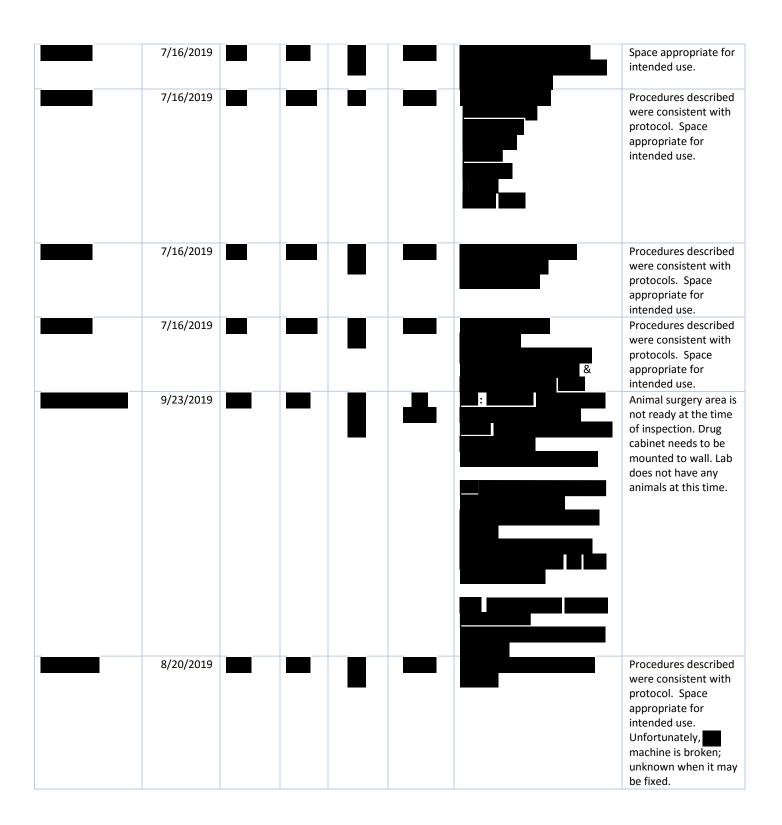


8/7/2019		wer pro app	cedures described re consistent with tocol. Space propriate for ended use.
8/7/2019		reconduction of the conduction	porizer ertification was e in April 2019. I get 2 orizers on edule to be ertified on next nd (Oct 2019) und expired gical gloves and ne; removed by staff.
8/7/2019		Spa The	ce covered under lab inspection. ese experiments erot yet begun.
8/7/2019		No	work is being ne with
8/13/2019		Fun re-c emito g Exp fou con dru adn PI v about IAC pro app wel pro give to a mer emi	ne hood in need of certification. ailed get hood checked. ired and and offiscated. Expired g had not been minstered to was questioned out surgery on
6/26/2019		faci See visi	
6/26/2019		per this sur	surgeries not being formed in nor at time. This gery may be formed in



_			 		
	6/11/2019				Procedures described were consistent with protocol. Space appropriate for intended use.
	6/11/2019				Procedures described were consistent with protocol. Space appropriate for intended use.
	7/10/2019				Have not performed in past six months. This room is new location due to equipment change.
	7/10/2019				Procedures described were consistent with protocols. Space appropriate for intended use.
	10/22/2019				Procedures described were consistent with protocol. Space appropriate for intended use.
	10/22/2019				Procedures described were consistent with protocol. Space appropriate for intended use.





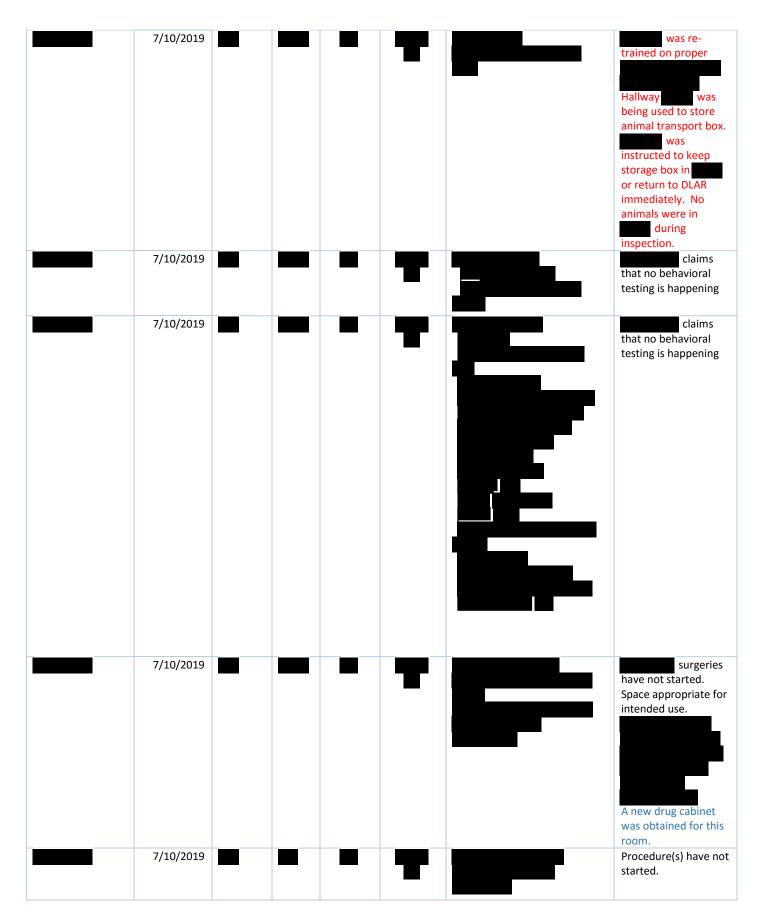
8/20/2019		Procedures described were consistent with protocol. Space appropriate for intended use. Hoods need recertification:
5/17/2019		Procedures described were consistent with protocol. not being conducted in this space at this time.Space appropriate for intended use.
5/17/2019		Procedures described were consistent with protocol. Space appropriate for intended use. Hood in need of inspection by EHS. Hood checked by EHS on 5/28/19
2/4/2019		Procedures described were consistent with protocol. Space appropriate for intended use.
2/4/2019		Procedures described were consistent with protocol. Space appropriate for intended use.
9/26/2019		Procedures described were consistent with protocol. See lab site visit.
9/26/2019		Procedures described were consistent with protocol. Space appropriate for intended use.
9/26/2019		Procedures described were consistent with protocol. Space appropriate for intended use. Drug cabinet was unlocked at time of inspection; was corrected

0/00/00/0		
9/26/2019		Procedures described were consistent with protocol. Space appropriate for intended use.
9/26/2019		Procedures described were consistent with protocol. Space appropriate for intended use.
9/26/2019		Procedures described were consistent with protocol. Space appropriate for intended use.
7/9/2019		Space appropriate for intended use.
10/1/2019		Procedures described were consistent with protocol. Space appropriate for intended use. infestations have only been happening in DLAR facility.
5/15/2019		Procedures described were consistent with protocol. Space appropriate for intended use.
5/15/2019		Procedures described were consistent with protocol. Space appropriate for intended use.

5/15/2019		, k	Procedures described were consistent with protocol. Space appropriate for ntended use.
5/15/2019		, s	Procedures described were consistent with protocol. Space appropriate for intended use.
5/15/2019		, s	Procedures described were consistent with protocol. Space appropriate for intended use.
10/11/2019		r I a t t s I F	have started yet. PI will need to acquire a ockable drug cabinet and get it mounted to the wall. PI will speak tharing ocked drug cabinet if PI's cabinet is not mounted in time for irst surgery.
10/11/2019		k	Not in use at this time by PI. Room is covered under inspection 10/22/2019
7/8/2019			Procedures described were consistent with protocol. Space appropriate for ntended use.
7/8/2019			Currently not being performed at this ime.

7/16/2019		All ok. has not started yet.
7/16/2019		All ok.
7/16/2019		Procedures described were consistent with protocol. Space appropriate for intended use.
9/11/2019		No use of controlled substances during the past six months; no plans for next six months.
9/11/2019		Procedures described were consistent with protocol. Space appropriate for intended use.
9/11/2019		performed within the past six months. Space covered under lab.
9/11/2019		Procedures described were consistent with protocol. Space appropriate for intended use.





7/10/2019		Procedure(s) have not started.
7/10/2019		Procedure(s) have not started.
5/21/2019		Procedures described were consistent with protocol. Performed under supervision of Space appropriate for intended use.
5/21/2019		Procedures described were consistent with protocol. Space appropriate for intended use.
5/21/2019		Procedures described were consistent with protocol. Space appropriate for intended use.

5/21/2019		Procedures described were consistent with protocol. Space appropriate for intended use.
5/21/2019		Procedures described were consistent with protocol. Space appropriate for intended use.
9/11/2019		Procedures described were consistent with protocol. Space appropriate for intended use.
9/11/2019		Procedures described were consistent with protocol. Space appropriate for intended use.
9/11/2019		Procedures described were consistent with protocol. Space appropriate for intended use.
9/11/2019		Procedures described were consistent with protocol. Space appropriate for intended use.
9/11/2019		Procedures described were consistent with protocol. Space appropriate for intended use.

Endnotes

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.

- 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;"
 - 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..."

ii Part 2 Subpart C - Research Facilities

- 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 2.31(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."
- xiii 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."
- xiv 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].
- xv Part 3 Subpart A 3.8 "...research facilities must develop, document, and follow an appropriate plan to provide dogs with the opportunity for exercise. In addition the plan must be approved by the attending veterinarian. The plan must provide written standard procedures..."
- xvi Part 3 Subpart D 3.81 "...research facilities must develop, document, and follow an appropriate plan for environment enhancement adequate to promote the psychological well-being of nonhuman primates."
- xvii Part 3 Subpart A 3.6(c)(1) "Each dog housed in a primary enclosure must be provided with a minimum amount of floor space, calculated as follows: (length of dog in inches + 6)² /144 = required floor space in square feet)."
 - Part 3 Subpart D 3.80 (b) "Primary enclosures [for nonhuman primates] must meet the minimum space requirements provided in this subpart."
 - In situations where the USDA regulations and the *Guide* differ with respect to space requirements, the larger of the two must be followed.