

GEORGIA STATE UNIVERSITY INSTITUTIONAL
ANIMAL CARE AND USE COMMITTEE
P.O. Box 3999
Atlanta, GA 30302-3999

Mail: In Person:
58 Edgewood Ave. NE, Suite
310 Email: iacuc@gsu.edu
Web: <http://ursa.research.gsu.edu/iacuc/>



Memorandum

To: Timothy L. Denning, Ph.D.
Vice President for Research and Economic Development,
Institutional Official for Animal Care and Use

From: Institutional Animal Care and Use Committee

Subject: Report of the IACUC's Evaluations - Animal Care and Use Program
Review and Facilities Inspection

Date: November 01, 2021

This represents the semiannual report of the Institutional Animal Care and Use Committee (IACUC), as required by the PHS Policy on Humane Care and Use of Laboratory and as a condition of this institution's Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW), and USDA Animal Welfare Regulations, 9 CFR Chapter I, subchapter A, as applicable.

Evaluation of the Animal Care and Use Program

1. The IACUC conducted its semiannual evaluation of the institution's animal care and use program on October 22, 2021, using the 8th Edition of the *Guide for the Care and Use of Laboratory Animals (Guide)*, and, as applicable, 9 CFR Chapter I, 2.31

The Committee used the NRC Guide for the Care and Use of Laboratory Animals and other pertinent resources, e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare) as a basis for the review. To facilitate the evaluation, the Committee used a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website. The evaluation included, but was not necessarily limited to, a review of the following: a) IACUC Membership and Functions; b) IACUC Records and Reporting Requirements; c) Husbandry and Veterinary Care (all aspects); d) Personnel Qualifications (Experience and Training); e) Occupational Health and Safety; and f) disaster planning. In addition, the evaluation included a review of the Institution's PHS Assurance. No member was involuntarily excluded from participating in any portion of the review.

2. Accreditation.

The Institution's Program for Laboratory Animal Care and Use is accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC-Int'l).

3. IACUC Approved Departures from the NRC "Guide", PHS Policy and the AWA.

The reason for these exemptions to Regulations are listed below:

USDA

"IACUC Functions: Review ... programs ... and inspect ... using the [USDA regs] as a basis for evaluation. [IACUC] reports must contain a description of ... facility's adherence to the [USDA regs] and must identify specifically any departures [from them] and must state the reasons for each departure."

PHS Policy p. 7

"Functions of the IACUC review ... programs ... inspect using the Guide as a basis for evaluation." "[IACUC] reports must contain a description of the nature and extent of the Institution's adherence to the Guide and this Policy and must identify specifically any departures from the provisions of the Guide and this Policy and must state the reasons for each depart."

9 CFR AWA Part 3 (Subpart B) §3.28(b)(3)(i)

"The interior height of any primary enclosure used to confine hamsters shall be at least 6 inches."

Roborovskii dwarf hamsters (*P. roborovskii*) have been housed in 5-inch-high cages because it is documented that 6-inch-high cages are detrimental to the growth of a similar sized hamster species (*P. sungorus*) [Gilman WC, et.al "Effect of the New USDA Cage Height Standard on Body Weights of Weanling and Djungarian Dwarf Hamsters (*Phodopus sungorus*). Contemporary Topics in Lab Animal Science, 32(1): 17-19, 1993.]

9 CFR AWA Part 3 (Subpart B) §3.31(a) (1)

"[Hamster] enclosures shall be sanitized at least once every 2 weeks..."

- a. Nursing Syrian hamster cages may go for more than 14 days between cage changes due to pre-parturition cage change and post-parturition cage change interval.
- b. Cage accessories (wire bar top, food hopper, solid cage top, filter top) are changed out for all rodent species quarterly congruent with the findings in the article entitled "Investigation of Appropriate Sanitization Frequency for Rodent Caging Accessories: Evidence Supporting Less-frequent Cleaning" as found in JAALAS, 45(6), 40-43, 2006; as well as in-house ATP testing performed between March 2019 and April 2019.

9 CFR AWA Part 3 (Subpart B) §3.33

"Animals housed in the same primary enclosure shall be maintained in compatible groups, ..."

- a. It is essential to be able to manipulate social housing conditions to study the effects of social experience on brain and behavior, so some Syrian Hamsters are singly housed. That would include experimental animals that were ordered and only ever singly housed, the Resident Aggressor (RA) colony, breeders (that may or may not have a litter with them), and any group housed animals that were eventually singly housed to become experimental animals, RAs, or breeders. Syrian Hamsters are solitary and territorial animals in the wild.

- b. Social hierarchy paradigm: One hamster will be placed into each of the 4 compartments for an acclimatization period of up to 3 days with food and water readily available. After habituation, the dividers will be removed to allow the hamsters to interact freely and establish a hierarchy. Initial hierarchy establishment will be monitored by a live observer and hamsters will be allowed to freely interact for up to 7 days but will not spend a more than a total of 8 days in the apparatus. Hamster rank within the hierarchy will be determined using the percentage of agonistic encounters won, average distance covered over the interaction days and other behavioral measures. To assess long-term hierarchy maintenance, animals may be reintroduced to the apparatus for the above-mentioned period.

NRC "Guide to the Care and Use of Laboratory Animals", 8th Edition, pg.70

"Cleaning and Disinfection of the Microenvironment. In general, enclosures and accessories, such as tops, should be sanitized at least once every 2 weeks.

Cage accessories (wire bar top, food hopper, solid cage top, filter top) are changed out for all rodent species quarterly congruent with the findings in the article entitled "Investigation of Appropriate Sanitization Frequency for Rodent Caging Accessories: Evidence Supporting Less-frequent Cleaning" as found in JAALAS, 45(6), 40-43, 2006; as well as in-house ATP testing performed between March 2019 and April 2019.

NRC "Guide to the Care and Use of Laboratory Animals", 8th Edition, pg.44

Recommended Dry—bulb macroenvironmental temperatures for common lab animals." Dry-bulb room temperature settings for rodents are typically set below the animals' LCT to avoid heat stress and should reflect different species-specific LCT values.

Housing mice in thermo-neutral (~85°F) or cold (40°C) housing with IACUC approval.

NRC "Guide to the Care and Use of Laboratory Animals", 8th Edition, pg.111

"Physical separation of animals by species is recommended to prevent interspecies disease transmission and to eliminate the potential for anxiety and physiologic and behavioral changes due to interspecies conflict.

Housing mice and Robo hamsters in ABSL3 (same room, separated in different IVCs.)

NRC "Guide to the Care and Use of Laboratory Animals", 8th Edition, pg.66

"Most natural-ingredient, dry laboratory animal diets stored properly can be used up to 6 months after manufacture. Non-stabilized vitamin C in manufactured feeds generally has a shelf life of only 3 months, but commonly used stabilized forms can extend the shelf life of feed. Refrigeration preserves nutritional quality and lengthens shelf life, but food storage time should be reduced to the lowest practical period and the manufacturers' recommendations considered. Purified and chemically defined diets are often less stable than natural-ingredient diets and their shelf life is usually less than 6 months (Fullerton et al. 1982); they should be stored at 4°C (39°F) or lower."

LabDiet® has proven product stability for the following items:

LabDiet® Standard Products	9 months
LabDiet® & IsoPro® Irradiated Diets	12 months
<u>Vitamin C Sensitive Standard Species Diets</u>	
LabDiet® Non-Human Primate (Stabilized Vitamin C)	9 months
LabDiet® Guinea Pig Products (Stabilized Vitamin C)	9 months

4. Program Deficiencies.

No deficiencies were identified. All aspects of the program are consistent with the *PHS Policy*, the *Guide*, and applicable Animal Welfare Regulations.

Inspection of the Animal Facilities

1. The IACUC inspected the following areas on: 9/28/2021- PSC HCC 644 TB Housing; 10/05/2021- PSC/RSC Animal Housing and Zebrafish housing; 10/08/2021 - PSC ABSL2, ABSL3 (HHC) housing SARS-CoV2, WNV; 10/12/2021 - NSC Animal Facility and Research Labs; 10/13/2021- PSC/RSC Research labs and 10/21/2021 - LRC Animal Housing and Animal Transportation Vans; using the *Guide*, and, as applicable, 9 CFR Chapter I, 2.31.

Members of the Committee, or ad hoc Inspectors, visited all the institution's facilities where live animals are housed or used, i.e., holding areas, animal care support areas, storage areas, and procedure areas. The Committee, or ad hoc members, used the NRC Guide and other pertinent resources, e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare) as a basis for the inspection. To facilitate the evaluation, the Committee, or ad hoc members, used a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website. No member was involuntarily excluded from participating in any portion of the inspection.

2. Facility Deficiencies.

Attached is a list of deficiencies. As required, the Committee categorized them as significant or minor (a significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel) and developed a reasonable and specific plan and schedule for correcting each deficiency. All other aspects of the program are consistent with the PHS Policy, the Guide, and applicable Animal Welfare Regulations.

Minority Views

There were no minority view(s) expressed.

I. Semiannual Program Review and Facility Inspection Report

Date: 9/28/21- PSC HCC 644 TB housing; 10/5/2021- PSC/RSC Animal Housing; 10/8/2021- HCC space; 10/12/2021- NSC housing and labs; 10/13/2021- PSC/RSC labs; 10/21/2021- LRC

Members in Attendance: [REDACTED]

Deficiency Category*	✓	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
M		[REDACTED]	Pest control issue. Trash bin overflowing outside load doc. Maggots found 5 feet inside PSC building coming from waffle house trash bin. Reported to 3-0700 facilities.	GSU facilities	Report future incidents to facility Steve Whitfield	10/6/2021
M		[REDACTED]	Expired peroxiguard. Dispose.	DAR	Disposed during inspection	10/5/2021
M		[REDACTED]	Expired peroxiguard. Dispose.	DAR	Disposed during inspection	10/5/2021
M		[REDACTED]	Right rear light not working. Place work order. Three other lights work.	DAR	Work order placed	
M		[REDACTED]	Sharps container without proper lid (top removed allowing needle retrieval). Replace with correct lid.	DAR	By 10/8/2021	10/8/2021
M		[REDACTED]	Expired supplies (bacitracin, puralube, surgilube). Dispose and monitor supplies routinely. Dirty, shredded towel found in drawer. Dispose if using with animals because of shredded string. Clean towel if using for non-animal work.	[REDACTED]	By 10/15/2021 By 10/15/2021	10/15/2021 10/15/2021
M		[REDACTED]	Metal carts need to be cleaned and debris removed including old pellets.	[REDACTED]	By 10/18/2021	10/15/2021

M		Isopentane bottle found under the sink. Confirm proper storage of chemical/ chematix inventory.		Follow-up with safety office	
		Room needs to be clean. Rat feces found on the floor and old debris (bedding, hair) found around surgical/recovery sites. Clean spaces after each use.		By 10/12/2021	10/8/2021
		Lots of expired material found room (6 bottles sodium chloride, lidocaine, surgical blades). Go through all drawers and storage and dispose of expired supplies.		By 10/12/2021	10/8/2021
		18 used water bottles found in procedure room. Return animal equipment to DAR after use.		By 10/12/2021	10/11/2021
		Two containers of food found in procedure room, without proper storage (in hopper and bucket). Food disposed. Store food properly to prevent vermin/pest control issues and keep food fresh.		By 10/12/2021	10/11/2021
M		Paint flaking on wall around outlet. Repaint.	DAR	By 10/18/2021	10/15/2021
M		Old supplies in top drawer without PI identification. Uristix expired. Disposed.	Unk	Disposed at inspection	10/5/2021
M		Cage card bin broken; Fix	DAR	By 10/18/2021	10/15/2021
M		Exposed needle on cart; dispose. Review sharps safety with lab members.		Disposed at inspection	10/5/2021
M		Expired food; disposed	DAR	Disposed at inspection	10/12/2021

M		Leaking sink reported on 10/1; not fixed as of 10/5 but work order in.	DAR	Work order placed	10/15/2021
M		DEA license expired in binder. Confirm PI has current license.		By 10/15/2021	10/13/2021
		Controlled substance log not organized. Organize by agent, receiving lots, current and previous logs, and stock versus dispensing amounts.		By 10/15/2021	10/13/2021
		Expired euthasol not labeled in controlled drug storage. Label expired and separate from agents not expired.		Labeled at inspection	10/13/2021
		Back-up guillotine #2 not sharpened; Sharpen before use and document date.		At next procedure	
M		Individual administered doses of controlled substance (testosterone) not recorded in drug logbook. Document each dose administered.		At next procedure	
M		Isoflurane induction chamber dirty. Clean after each use.		By 10/18/21	10/15/2021
		Open blade on benchtop. Disposed.		Disposed during inspection	10/13/2021
M		Individual doses of controlled substances not recorded in drug logs. Record each administered dose from the stock vile.		At next procedure	

M		No decapitation shears log. Need log to document when shears are used and sharpened.		At next procedure	
M		Isoflurane machine not in service. Label "DO NOT USE". Owner of machine unknown.	unk	By 10/18/2021	10/15/2021
M		Metacam expired. Dispose One eyewash station not checked weekly. Check weekly.		Disposed By 10/18/2021	10/15/2021 10/15/2021
M		Expired sodium chloride. Dispose.		Disposed after inspection	10/13/2021
M		New isoflurane loaner machine without date of calibration. Add date machine received. Arrange for calibration.		By 10/18/2021	
M		Nair gel without "open date". List date.		Date added	10/15/2021
M		Expired materials (betadine solution swabs, needles, cotton applicator). Disposed during inspection.		Disposed during inspection	10/13/2021
		Xylazine expired. Labeled Expired in controlled drug storage.		Labeled during inspection	10/13/2021
M		Animal sign out log not completed. Complete log when animals are removed from the room.		At next procedure	
M		Equipment power cords daisy chained to extension cords. Arrange power cords properly and remove double extension chain.		By 10/18/2021	
M		Expired antisedan. Discarded during the inspection.		Discarded during inspection	10/12/2021
M		Expired single use eyewash bottles. Disposed at inspection.	DAR	Disposed during inspection	10/13/2021

M		Three reagent bottles found not labeled with contents. Label.		By 10/18/2021	

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

I. Semiannual Program Review Checklist ⁱ

Institutional Policies and Responsibilities

Date: October 22, 2021

1. Animal Care and Use Program	A*	M	S	C	NA
• Responsibility for animal well-being is assumed by all members of the program (<i>Guide, p 1</i>) [must]	X				
• IO has authority to allocate needed resources (<i>Guide, p 13</i>)	X				
• Resources necessary to manage program of veterinary care are provided (<i>Guide, p 14</i>) [must]	X				
• Sufficient resources are available to manage the program, including training of personnel in accord with regulations and the <i>Guide</i> (<i>Guide, pp 11, 15</i>)	X				
• Program needs are regularly communicated to IO by AV and/or IACUC (<i>Guide, p 13</i>)	X				
• Responsibilities for daily animal care and facility management are assigned to specific individual(s) when a full-time veterinarian is not available on site (<i>Guide, p 14</i>) [must]	X				
• Inter-institutional collaborations are described in formal written agreements (<i>Guide, p 15</i>)	X				
• Written agreements address responsibilities, animal ownership, and IACUC oversight (<i>Guide, p 15</i>)	X				
2. Disaster Planning and Emergency Preparedness	A*	M	S	C	NA
• Disaster plans for each facility to include satellite locations are in place (<i>Guide, p 35, p 75</i>) [must]	X				
• Plans include provisions for euthanasia (<i>Guide, p 35</i>) [must]	X				
• Plans include triage plans to meet institutional and investigators' needs (<i>Guide, p 35</i>)	X				
• Plans define actions to prevent animal injury or death due to HVAC or other failures (<i>Guide, p 35</i>)	X				
• Plans describe preservation of critical or irreplaceable animals (<i>Guide, p 35</i>)	X				
• Plans include essential personnel and their training (<i>Guide, p 35</i>)	X				
• Animal facility plans are approved by the institution and incorporated into overall response plan (<i>Guide, p 35</i>)	X				
• Law enforcement and emergency personnel are provided a copy and integration with overall plan is in place (<i>Guide, p 35</i>)	X				
3. IACUC	A*	M	S	C	NA
• Meets as necessary to fulfill responsibilities (<i>Guide, p 25</i>) [must]	X				
• IACUC Members named in protocols or with conflicts recuse themselves from protocol decisions (<i>Guide, p 26</i>) [must]	X				
• Continuing IACUC oversight after initial protocol approval is in place (<i>Guide, p 33</i>)	X				
• IACUC evaluates the effectiveness of training programs (<i>Guide, p 15</i>)	X				
4. IACUC Protocol Review - Special Considerations	A*	M	S	C	NA
• Humane endpoints are established for studies that involve tumor models, infectious diseases, vaccine challenge, pain modeling, trauma, production of monoclonal antibodies, assessment of toxicologic effects, organ or system failure, and models of cardiovascular shock (<i>Guide, p 27</i>)	X				
• For pilot studies, a system to communicate with the IACUC is in place (<i>Guide, p 28</i>)	X				
• For genetically modified animals, enhanced monitoring and reporting is in place (<i>Guide, p 28</i>)	X				
• Restraint devices are justified in the animal use protocols (<i>Guide, p 29</i>) [must]	X				
• Alternatives to physical restraint are considered (<i>Guide, p 29</i>)	X				
• Period of restraint is the minimum to meet scientific objectives (<i>Guide, p 29</i>)	X				
• Training of animals to adapt to restraint is provided (<i>Guide, p 29</i>)	X				
• Animals that fail to adapt are removed from study (<i>Guide, p 29</i>)	X				
• Appropriate observation intervals of restrained animals are provided (<i>Guide, p 29</i>)	X				
• Veterinary care is provided if lesions or illness result from restraint (<i>Guide, p 30</i>) [must]	X				
• Explanations of purpose and duration of restraint are provided to study personnel	X				

(Guide, p 30)					
• Multiple surgical procedures on a single animal are justified and outcomes evaluated (Guide, p 30)	X				
• Major versus minor surgical procedures are evaluated on a case-by-case basis (Guide, p 30)	X				
• Multiple survival procedure justifications in non-regulated species conform to regulated species standards (Guide, p 30)	X				
• Animals on food/fluid restriction are monitored to ensure nutritional needs are met (Guide, p 31)	X				
• Body weights for food/fluid restricted animals are recorded at least weekly (Guide, p 31)	X				
• Daily written records are maintained for food/fluid restricted animals (Guide, p 31)	X				
• Pharmaceutical grade chemicals are used, when available, for animal-related procedures (Guide, p 31)	X				
• Non-pharmaceutical grade chemicals are described, justified, and approved by IACUC (Guide, p 31)	X				
• Investigators conducting field studies know zoonotic diseases, safety issues, laws and regulations applicable in study area (Guide, p 32)	X				
• Disposition plans are considered for species removed from the wild (Guide, p 32)	X				
• Toe-clipping only used when no alternative, performed aseptically and with pain relief (Guide, p 75)	X				

5. IACUC Membership and Functions

	A*	M	S	C	NA
• IACUC is comprised of at least 5 members, appointed by CEO (PHS Policy, IV.A.3.)	X				
• Members include a veterinarian, a scientist, a nonscientist, and a nonaffiliated non-lab animal user (Guide, p 24) ⁱⁱ	X				
• IACUC authority and resources for oversight and evaluation of institution's program are provided (Guide, p 14)	X				
• IACUC conducts semiannual evaluations of institutional animal care and use program (PHS Policy, IV.B.)	X				
• Conducts semiannual inspections of institutional animal facilities (PHS Policy, IV.B.)	X				
• IACUC organizationally reports to the Institutional Official (PHS Policy, IV.A.1.b.)	X				
• Methods for reporting and investigating animal welfare concerns are in place (Guide, p 23) [must]	X				
• Reviews and investigates concerns about animal care and use at institution ⁱⁱⁱ (PHS Policy, IV.B.)	X				
• Procedures are in place for review, approval, and suspension of animal activities ^{iv} (PHS Policy, IV.B.)	X				
• Procedures are in place for review and approval of significant changes to approved activities (PHS Policy, IV.B.)	X				
• Policies are in place for special procedures (e.g., genetically modified animals, restraint, multiple survival surgery, food and fluid regulation, field investigations, agricultural animals) (Guide, p 27-32)	X				
• Requests for exemptions from major survival surgical procedure restrictions are made to USDA/APHIS ^v (Guide, p 30) [must]	X				

6. IACUC Training

	A*	M	S	C	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 (Guide, p 17)	X				
◦ Training on how to review protocols as well as evaluate the program (Guide, p 17)	X				
◦ Ongoing training/education (Guide, p 17)	X				

7. IACUC Records and Reporting Requirements^{vi}

	A*	M	S	C	NA
• Semiannual report to the IO (PHS Policy, IV.B.)					
◦ Submitted to IO every 6 months	X				
◦ Compiles program review and facility inspection(s) results (includes all program and facility deficiencies)	X				
◦ Includes minority IACUC views	X				

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

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

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

9. Personnel Qualifications and Training

	A*	M	S	C	NA
• All personnel are adequately educated, trained, and/or qualified in basic principles of laboratory animal science. Personnel included: [must]					
o Veterinary/other professional staff (<i>Guide</i> , p 15-16)	X				
o IACUC members (<i>Guide</i> , p 17)	X				
o Animal care personnel (<i>Guide</i> , p 16)	X				
o Research investigators, instructors, technicians, trainees, and students (<i>Guide</i> , pp 16-17)	X				
• Continuing education for program and research staff provided to ensure high quality care and reinforce training (<i>Guide</i> , pp 16-17)	X				
• Training is available prior to starting animal activity (<i>Guide</i> , p 17)	X				
• Training is documented (<i>Guide</i> , p 15)	X				
• Training program content includes: (<i>Guide</i>, p 17)					
o Methods for reporting concerns (<i>Guide</i> , p 17)	X				
o Humane practices of animal care (e.g., housing, husbandry, handling) ^{xii}	X				
o Humane practices of animal use (e.g., research procedures, use of anesthesia, pre- and post-operative care, aseptic surgical techniques and euthanasia (<i>Guide</i> , p 17) ^{xiii}	X				

o Research/testing methods that minimize numbers necessary to obtain valid results (PHS Policy, IV.A.1.g.)	X				
o Research/testing methods that minimize animal pain or distress (PHS Policy, IV.A.1.g.)	X				
o Use of hazardous agents, including access to OSHA chemical hazard notices where applicable (Guide, p 20)	X				
o Animal care and use legislation (Guide, p 17)	X				
o IACUC function (Guide, p 17)	X				
o Ethics of animal use and Three R's (Guide, p 17)	X				

10. Occupational Health and Safety of Personnel

	A*	M	S	C	NA
• Program is in place and is consistent with federal, state, and local regulations (Guide, p 17) [must]	X				
• Program covers all personnel who work in laboratory animal facilities (Guide, p 18)	X				
• Changing, washing, and showering facilities are available as appropriate (Guide, p 19)	X				
• Hazardous facilities are separated from other areas and identified as limited access (Guide, p 19)	X				
• Personnel training is provided based on risk (e.g., zoonoses, hazards, personal hygiene, special precautions, animal allergies) (Guide, p 20)	X				
• Personal hygiene procedures are in place (e.g., work clothing, eating/drinking/smoking policies) (Guide, p 20)	X				
• Procedures for use, storage, and disposal of hazardous biologic, chemical, and physical agents are in place (Guide, p 21)	X				
• Personal Protective Equipment for the work area is appropriate and available (Guide, p 21)	X				
• Program for medical evaluation and preventive medicine for personnel includes:					
o Pre-employment evaluation including health history (Guide, p 22)	X				
o Immunizations as appropriate (e.g., rabies, tetanus) and tests as appropriate (Guide, p 22)	X				
o Zoonosis surveillance as appropriate (e.g., Q-fever, tularemia, Hantavirus, plague) (Guide, p 23)	X				
o Procedures for reporting and treating injuries, including accidents, bites, allergies, etc. (Guide, p 23)	X				
o Promotes early diagnosis of allergies including preexisting conditions (Guide, p 22)	X				
o Considers confidentiality and other legal factors as required by federal, state and local regulations (Guide, p 22) [must]	X				
o If serum samples are collected, the purpose is consistent with federal and state laws (Guide, p 22) [must]	X				
• 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 (Guide, p 22)	X				
• 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)	X				
o Training and implementation of procedures for bites, scratches, or injuries associated with macaques (Guide, p 23)	X				
o PPE is provided including gloves, arm protection, face masks, face shields, or goggles (Guide, p 21)	X				
o Injuries associated with macaques are carefully evaluated and treatment implemented (Guide, p 23)	X				
• Occupational safety and health of field studies is reviewed by OSH committee or office (Guide, p 32)	X				

11. Personnel Security

	A*	M	S	C	NA
• Preventive measures in place include pre-employment screening, and physical and IT security (Guide, p 23)	X				

12. Investigating & Reporting Animal Welfare Concerns

	A*	M	S	C	NA
• Methods for investigating and reporting animal welfare concerns are established	X				

(Guide, p 23) [must]					
• 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)	X				
o Includes multiple contacts (Guide, p 24)	X				
o Includes anonymity, whistle blower policy, nondiscrimination and reprisal protection (Guide, p 24)	X				

* A = acceptable

M = minor deficiency

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

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

NA = not applicable

Veterinary Care Date:

October 22, 2021

1. Clinical Care and Management

	A*	M	S	C	NA
• Veterinary program offers high quality of care and ethical standards (Guide, p 105) [must]	X				
• Veterinarian provides guidance to all personnel to ensure appropriate husbandry, 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 (Guide, p 115)	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 114) [must]	X				
• Veterinarian is authorized to treat, relieve pain, and/or euthanize (Guide, p 114) [must]	X				

2. Animal Procurement and Transportation/Preventive Medicine

	A*	M	S	C	NA
• 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)					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)	X				
• 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 ensure receiving personnel are available (Guide, pp 107- 108)	X				
• Appropriate loading and unloading facilities are available (Guide, p 109)	X				
• Environment at receiving site is appropriate (Guide, p 109)	X				
• Policies in place on separation by species, source, and health status (Guide, pp 109, 111-112)	X				
• Procedures in place for quarantine to include zoonosis prevention (Guide, p 110)	X				
• Quarantined animals from different shipments are handled separately or physically	X				

separated (<i>Guide, p 110</i>)					
• Procedures in place for stabilization/acclimation (<i>Guide, pp 110-111</i>)	X				
• Policies in place for isolation of sick animals (<i>Guide, p 112</i>)	X				
• Program is in place for surveillance, diagnosis, treatment and control of disease to include daily observation (<i>Guide, p 112</i>)	X				
• Diagnostic resources are available for preventive health program (<i>Guide, p 112</i>)	X				

3. Surgery

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

4. Pain, Distress, Anesthesia and Analgesia

	A*	M	S	C	NA
• Guidelines for assessment and categorization of pain, distress and animal wellbeing are provided during training (<i>Guide, p 121</i>)	X				
• Selection of analgesics and anesthetics is based on professional veterinary judgment (<i>Guide, p 121</i>)	X				
• Painful procedures are monitored to ensure appropriate analgesic management (<i>Guide, p 122</i>)	X				
• Nonpharmacologic control of pain is considered as an element of postprocedural care (<i>Guide, p 122</i>)	X				
• Procedures are in place to assure antinoception before surgery begins (<i>Guide, p 122</i>)	X				
• Guidelines for selection and use of analgesics and anesthetics are in place and regularly reviewed and updated (<i>Guide, p 122</i>)	X				
• Special precautions for the use of paralytics are in place to ensure anesthesia ^{xiv} (<i>Guide, p 123</i>)	X				

5. Euthanasia

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

6. Drug Storage and Control

	A*	M	S	C	NA
• Program complies with federal regulations for human and veterinary drugs (<i>Guide, p 115</i>)	X				
• Drug records and storage procedures are reviewed during facility inspections (<i>Guide, p 115</i>)	X				

• Procedures are in place to ensure analgesics and anesthetics are used within expiration date (<i>Guide</i> , p 122) [must]	X				
• Anesthetics and analgesics are acquired, stored, and their use and disposal are recorded legally and safely (<i>Guide</i> , p 122)	X				

* A = acceptable

M = minor deficiency

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

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

NA = not applicable

II.

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

ii Part 2 Subpart C - Research Facilities

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

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

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

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

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

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

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

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

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..."

^{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."

October 2021 Inspection and Program Review

Minority Views

If there are minority IACUC views regarding the semiannual report, the Institutional Official must be informed and copies of the minority views attached to the report. If there are no minority views, the report should include a statement to that effect.

Signatures

At least a majority of the members of the IACUC must sign the report:

Date

0/22/2021

0/22/2021

10/22/2021

10/22/2021

10/22/2021

10/22/2021

10/22/2021

10/22/2021

10/22/2021

10/22/2021

10/22/2021

10/22/2021

10/22/2021

10/22/2021