



Ames Research Center
Moffett Field, CA 94035-1000

Memorandum to: (b) (6), (b) (7)(C),
(b) (7)(F) Institutional Official

From: Institutional Animal Care and Use Committee

Subject: Semiannual Report of the Program Review and Facility Inspection

Date: 11 September 2019

This report summarizes the IACUC's results of its most recent program review and facility inspection, as required by the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals ([Policy](#)), Section [IV.B.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 institution's Animal Welfare Assurance with the NIH Office of Laboratory Animal Welfare (OLAW).

Since the last review, the following changes have occurred in the institution's program for animal care and use (PHS Policy [IV.A.1.a.-i.](#)): [optional]

The program's previous Institutional Official, (b) (6), (b) (7)(C), (b) (7)(F) retired. The Center Director, Dr. Eugene Tu appointed (b) (6), (b) (7)(C), (b) (7)(F) as the new Institutional Official.

A new non-affiliated member was appointed to the committee by the IO on August 22, 2019. The former non-affiliated member was re-appointed to the committee as a non-scientific member by the IO on August 22, 2019 and will also now function as the IACUC Administrator.

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

Departures from the PHS Policy, the *Guide*, and the AWA.

Select A or B:

- ☐ A. There were no departures during this reporting period.
- ☒ B. The following departures have been reviewed and approved by the IACUC: [include reason for each departure]

Hindlimb Unloading (HLU) studies using mice are performed by NASA investigators to study the effect of unloading and disuse (similar to weightlessness) on bone and muscle. The procedure entails: 1) prolonged restraint of animals; 2) single housing of a social species, and; 3) non-standard housing including cages without bedding, minimal nesting material, food placed on the floor of the cage, and a cage with dimensions of 7.6" X 11" X 12. The IACUC has an approved guideline for the use of the Hindlimb Unloading technique and each use of the technique is justified in protocols approved by the IACUC.

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

Animal Care and Use Program Review Date(s): 11 September 2019

Select A or B:

- ☒ A. There were no deficiencies in the program during this reporting period.



- [] B. The following deficiencies have been identified: *[describe each deficiency, identify each deficiency as either minor or significant, and provide a reasonable and specific plan and schedule for the correction of each deficiency, deficiencies may be recorded on a separate table and attached, the last page of OLAW's Sample Semiannual Program Review and Facility Inspection Checklist provides a sample table]*

III. Deficiencies in the Institution's Animal Facility

Animal Facility Inspection Date(s): 11 September 2019

Select A or B:

- [] A. There were no deficiencies in the animal facility during this reporting period.
- [X] B. The following deficiencies have been identified: *[describe each deficiency, identify each deficiency as either minor or significant, and provide a reasonable and specific plan and schedule for the correction of each deficiency, deficiencies may be recorded on a separate table and attached, the last page of OLAW's Sample Semiannual Program Review and Facility Inspection Checklist provides a sample table]*

There were no significant deficiencies found. The following minor deficiencies were identified and assigned to the facility manager for correction by the next semi-annual review.

- Update Animal Welfare Reporting signs with new IO name and contact information in E Wing.
- Post the Whistleblower Act signs in E Wing.
- Repair peeling paint on electrical conduit near E-10.
- Repair peeling paint and scratches on several doors in E Wing.
- Secondary containers are needed for jugs of cleaner found in the sink in E-3
- Repair dripping sink faucet found in E-2.
- Repair peeling paint found in autoclave room.
- Safety cabinet in C-6 is due for retesting.
- Biosafety hood in D-13 expired on 6/19/19, service or label as "not in use."
- Remove cardboard boxes found on the floor in D-4.

The following items were identified to be addressed with the PI's.

- Dirty cages found in Building 236, Room 227. Cages should be returned to the dirty side of the facility ASAP (e.g., at the end of each day or at the start of the next day).
- Rats scheduled for euthanasia were found with no food (but with water) in E-4. Animals should be provided food and water *ad libitum* unless scientifically justified in an approved protocol.

IV. Minority Views

Select A or B:

- [X] A. No minority views were submitted or expressed.
- [] B. The following minority views were expressed: *[insert minority views here or attach]*



V. Status of AAALAC Accreditation [*identify accredited facilities, if applicable*]

The Institution's Program for Laboratory Animal Care and Use is accredited by AAALAC, International. Full accreditation was last granted July, 2019.

VI. Signatures [*signatures of a majority of the IACUC members required by AWAR (§2.31,c,3), if applicable*]

***See attached form.**

Names of IACUC Members	Signatures

Respectfully Submitted,

(b) (6), (b) (7)(C), (b) (7)(F)

(b) (6), (b) (7)(C), (b) (7)(F)

(b) (6), (b) (7)(C), (b) (7)(F) Chair

(b) (6), (b) (7)(C), (b) (7)(F) DVM, Attending Veterinarian

(b) (6), (b) (7)(C), (b) (7)(F)

LEFT FOR
CALL IN/PROGRAM REVIEW &
INSPECTION

(b) (6), (b) (7)(C), (b) (7)(F) Science Member

(b) (6), (b) (7)(C), (b) (7)(F) Science Member

(b) (6), (b) (7)(C), (b) (7)(F)

(b) (6), (b) (7)(C), (b) (7)(F) J.D., L.L.M, Non-science Member

(b) (6), (b) (7)(C), (b) (7)(F)

(b) (6), (b) (7)(C), (b) (7)(F) Administrator,

(b) (6), (b) (7)(C), (b) (7)(F)

(b) (6), (b) (7)(C), (b) (7)(F) Non-affiliated Member

I. Semiannual Program Review and Facility Inspection Report

Date: 11 September 2019

Members in Attendance: Chair, Attending Veterinarian, 2 Scientist Members, Non-Scientist Member, Non-Affiliated Member

Deficiency Category*	✓	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
M		E Wing	Animal Welfare Reporting signs have outdated IO listed. Update Animal Welfare Reporting signs with new IO name and contact information.	Vivarium Manager	Correct by 11 March 2020	
M		E Wing	Whistleblower Act signs were not posted. Post Whistleblower Act signs in E Wing.	Vivarium Manager	Correct by 11 March 2020	
M		E-10	Peeling paint was found on the electrical conduit. Repair peeling paint.	Vivarium Manager	Correct by 11 March 2020	
M		E Wing	Peeling paint and scratches found on several doors in E-Wing. Repair paint on doors.	Vivarium Manager	Correct by 11 March 2020	
M		E-3	Jugs of cleaner were found without secondary containers. Provide secondary containers for jugs of cleaner.	Vivarium Manager	Correct by 11 March 2020	
M		E-2	Dripping sink faucet was found. Repair sink faucet.	Vivarium Manager	Correct by 11 March 2020	

M	Autoclave Room	Peeling paint found in autoclave room. Repaint damaged area.	Vivarium Manager	Correct by 11 March 2020	
M	C-6	Safety cabinet is due for retesting. Have safety cabinet serviced/tested.	Vivarium Manager	Correct by 11 March 2020	
M	D-13	Biosafety hood expired on 19 June 2019. Service this hood or label it "not in use."	Vivarium Manager	Correct by 11 March 2020	
M	D-4	Cardboard boxes found on the floor. Remove cardboard boxes from floor.	Vivarium Manager	Correct by 11 March 2020	
M	(b) (7)(F)	Dirty cages found. Cages should be returned to the dirty side of the facility ASAP (e.g., at the end of each day or the start of the next day). Review deficiency with PI, return dirty cages to the dirty side of the facility.	Vivarium Manager	Correct by 11 March 2020	
M	E-4	Rats scheduled for euthanasia were found with no food (but with water). Animals should be provided with food and water ad libitum unless scientifically justified in an approved protocol. Review deficiency with PI.	Vivarium Manager	Correct by 11 March 2020	

* 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

September 11, 2019

1. Animal Care and Use Program ^{NEW}

	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 onsite (<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 ^{NEW}

	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 ^{NEW}

	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 NEW

	A*	M	S	C	NA
• All IACUC members should receive:					
o Formal orientation to institution's program (Guide, p 17)	X				
o Training on legislation, regulations, guidelines, and policies (Guide, p 17)	X				
o 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.)					
o Submitted to IO every 6 months	X				
o Compiles program review and facility inspection(s) results (includes all program and facility deficiencies)	X				
o Includes minority IACUC views	X				

o Describes IACUC-approved departures from the <i>Guide</i> or PHS Policy and the reasons for each departure ^{vii}	X				
o Distinguishes significant from minor deficiencies	X				
o Includes a plan and schedule for correction for each deficiency identified ^{viii}	X				
• Reports to OLAW (PHS Policy, 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}					

o Research/testing methods that minimize numbers necessary to obtain valid results (PHS Policy, IV.A.1.q.)	X				
o Research/testing methods that minimize animal pain or distress (PHS Policy, IV.A.1.q.)	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 <i>all</i> 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 NEW

	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 NEW

	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

NOTES:

Veterinary Care

1. Clinical Care and Management NEW

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

2. Animal Procurement and Transportation/Preventive Medicine

	A*	M	S	C	NA
• Procedures for lawful animal procurement are in place (<i>Guide, p 106</i>) [must]	X				
• Sufficient facilities and expertise are confirmed prior to procurement (<i>Guide, p 106</i>)	X				
• Procurement is linked to IACUC review and approval (<i>Guide, p 106</i>)	X				
• Random source dogs and cats are inspected for identification (<i>Guide, p 106</i>)					X
• Population status of wildlife species is considered prior to procurement (<i>Guide, p 106</i>)	X				
• Appropriate records are maintained on animal acquisition (<i>Guide, p 106</i>)	X				
• Animal vendors are evaluated to meet program needs and quality (<i>Guide, p 106</i>)	X				
• Breeding colonies are based on need and managed to minimize numbers (<i>Guide, p 107</i>)	X				
• Procedures for compliance with animal transportation regulations, including international requirements, are in place (<i>Guide, p 107</i>) [must]	X				
• Transportation is planned to ensure safety, security and minimize risk (<i>Guide, p 107</i>)	X				
• Movement of animals is planned to minimize transit time and deliveries are planned to ensure receiving personnel are available (<i>Guide, pp 107-108</i>)	X				
• Appropriate loading and unloading facilities are available (<i>Guide, p 109</i>)	X				
• Environment at receiving site is appropriate (<i>Guide, p 109</i>)	X				
• Policies in place on separation by species, source, and health status (<i>Guide, pp 109, 111-112</i>)	X				
• Procedures in place for quarantine to include zoonoses prevention (<i>Guide, p 110</i>)	X				
• Quarantined animals from different shipments are handled separately or physically separated (<i>Guide, p 110</i>)	X				
• Procedures in place for stabilization/acclimation (<i>Guide, pp 110-111</i>)	X				
• Policies in place for isolation of sick animals (<i>Guide, p 112</i>)	X				
• Program is in place for surveillance, diagnosis, treatment and control of disease to include daily observation (<i>Guide, p 112</i>)	X				
• Diagnostic resources are available for preventive health program (<i>Guide, p 112</i>)	X				

3. Surgery

	A*	M	S	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>) [must]	X				
• Pre-surgical plans are developed and include veterinary input (e.g., location, supplies,	X				

anesthetic and analgesic use, peri-operative care, recordkeeping) (<i>Guide</i> , p 116)					
• Aseptic surgery is conducted in dedicated facilities or spaces, unless exception justified and IACUC approved (<i>Guide</i> , p 116)	X				
• Surgical procedures including laparoscopic procedures are categorized as major or minor (<i>Guide</i> , pp 117-118)	X				
• For nonsurvival surgery, the site is clipped, gloves are worn and instruments and area are clean (<i>Guide</i> , p 118)	X				
• Aseptic technique is followed for survival surgical procedures (<i>Guide</i> , pp 118-119)	X				
• Effective procedures for sterilizing instruments and monitoring expiration dates on sterile packs are in place (<i>Guide</i> , p 119)	X				
• 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)					X
• Post-operative monitoring and care are provided by trained personnel and documented (e.g., thermoregulation, physiologic function, analgesia, infection, removal of skin closures) (<i>Guide</i> , pp 119-120)	X				

4. 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</i> , p 121)	X				
• Selection of analgesics and anesthetics is based on professional veterinary judgment (<i>Guide</i> , p 121)	X				
• Painful procedures are monitored to ensure appropriate analgesic management (<i>Guide</i> , p 122)	X				
• Nonpharmacologic control of pain is considered as an element of postprocedural care (<i>Guide</i> , p 122)	X				
• Procedures are in place to assure antinociception 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 ^{xiv} (<i>Guide</i> , p 123)					X

5. Euthanasia

	A*	M	S	C	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)	X				
• Training is provided on appropriate methods for each species and considers psychological stress to personnel (<i>Guide</i> , p 124)	X				
• Procedures and training are in place to ensure death is confirmed (<i>Guide</i> , p 124) [must]	X				

6. Drug Storage and Control ^{NEW}

	A*	M	S	C	NA
• Program complies with federal regulations for human and veterinary drugs (<i>Guide</i> , p 115) [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> , 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

NOTES:

II. 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.

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.”