

SEMIANNUAL REPORT

ANIMAL CARE AND USE PROGRAM REVIEW AND FACILITY INSPECTION OF THE National Heart, Lung & Blood Institute (NHLBI) Fall 2019

Section A – Site Visits & Program Review

- 1) Inspections of the **NHLBI** animal facilities (AF), satellite holding facilities (SF), USDA-defined study areas for regulated species (SA) and areas where any surgical manipulations (Surg) are performed (as applicable) were conducted as indicated below:

Location	Type	Date	ACUC Members	
Redacted by agreement	Surg	9/25/19	Redacted by agreement	Hawkins, Redacted by agreement
	Surg	9/25/19	Redacted by agreement	Hawkins, Redacted by agreement
	Surg	9/25/19	Redacted by agreement	Hawkins, Redacted by agreement
	Surg	9/23/19	Hawkins, Redacted by agreement	Redacted by agreement
	AF	9/19/19	Redacted by agreement	Hawkins Redacted by agreement
	AF	9/19/19	Redacted by agreement	Hawkins Redacted by agreement
	Surg	9/23/19	Hawkins, Redacted by agreement	Redacted by agreement
	SF	9/23/19	Hawkins, Redacted by agreement	Redacted by agreement
	Surg	9/23/19	Hawkins, Redacted by agreement	Redacted by agreement
	Surg	9/25/19	Redacted by agreement	Hawkins, Redacted by agreement
	SF	9/25/19	Redacted by agreement	Hawkins, Redacted by agreement
	Surg	9/24/19	Redacted by agreement	Hawkins, Redacted by agreement

- 2) Visits by at least one member of the ACUC to all remaining areas where animal activities were performed were conducted. These visits occurred during the previous six months and findings and corrective actions are described in this or the previous semiannual report.
- 3) The following document(s) was/were used as the basis for review of the animal care and use program:

	Document/Resource:
	Guide for the Care & Use of Laboratory Animals, 8 th Edition (Guide)
	AAALAC Program Description
	OACU "Animal Program Semiannual Assessment Checklist" (1 page summary)
X	OACU/OLAW Semiannual Program Review & Facility Inspection Checklist (24 pages)

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

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

Section B – Regulatory Compliance:

Except as noted in Sections E, F, and G below, the facilities and program are in full compliance with the Public Health Service Policy, the Animal Welfare Act Regulations and the Guide, which were used as the basis for this evaluation.

Section C – Program Changes:

The following administrative and procedural changes have occurred since the program was last evaluated:

1) Administrative/Procedural Changes: None**2) Key Personnel Changes - ACUC Chair, ACUC Attending Vet, APD, or Program Manager:**

Role (ACUC Chair, ACUC AV, IC APD, or IC Animal Program Manager)	Name	Action (joined or departed)
None		

3) Animal Facility/Area Changes: None

Facility Type (AF/SF)	Location	Action (opened, closed, under renovation, etc.)
None		

Section D – Guide Departures & USDA Exceptions:

Departures from the standards of the *Guide* and exceptions to the USDA *Animal Welfare Act Regulations*, which have been approved by the Animal Care and Use Committee, include the following:

1. Departures from the Guide:

Guide Departures	Justification (scientific, veterinary, or animal welfare)
Single housed mice on grid floors	Rodents are placed on wire grid floors of metabolic cages (singly housed) to obtain uncontaminated fecal and urine samples. Or, mice are placed on a perforated plastic floor without bedding to remove urine and feces from a sealed metabolic cage.
Housing temperature outside of <i>Guide</i> parameters, single housed.	Mice are placed in a cold environment at 4° C from 1 to 8 hours to determine the effects in genetically engineered mouse models. The animals will be singly housed so they won't huddle to retain heat. Or, mice will be kept at 42.5°C to monitor ability to adapt to warm conditions.
Altered oxygen levels	Mice are housed in sealed chambers with increased or decreased oxygen levels to study long term health effects in various lines of genetically altered mice.
No surgical prep prior to skin biopsy	Prior to skin biopsies of mice, the skin will not be prepped since the prepping agents and scrubbing action can interfere with subsequent analyses requiring live cells, such as flow cytometry.
Extended rodent cage change frequency	In order to provide humane care of animals in the face of severe staffing and/or supply shortages in an emergency situation, the cage change frequency for rodents in the NHLBI Tower facility may be extended by up to four weeks depending on cage condition and veterinary recommendation.
No acclimation period -- mice	Timed pregnant mice are delivered directly to the lab for embryonic tissue collection because it is essential that it be done at the proper time point. Or, to inoculate neonates with viral particles in case dams are not available as scheduled

Housing on softwood (pine & cedar) bedding	In order to characterize the effects of microbiota environment on hematopoiesis and bone marrow failure diseases, mice will be housed on softwood (pine & cedar) bedding in a facility with endemic mouse pathogens. This follows a well-established published model developed by a collaborator.
Food & Fluid Regulation	Rodents are provided a controlled amount of gel-based diet to match the metabolic food and fluid requirements of the animal.
Food Regulation	Mice may be fed for 1 hour each day to ensure motivation for behavioral testing for food rewards.
No Bedding	Mice are kept in enclosed metabolic cages and bedding interferes with airflow and sensors.
Altered Light Cycle	Mice are kept in constant darkness to understand the effects on circadian rhythm in genetically altered mice.

2. Exceptions to the AWAR:

Species	9CFR title/section	Description and rationale
Pigs & Sheep	<u>2.31 Institutional Animal Care and Use Committee (Major Operative Procedure)</u>	Multiple cardiac catheterization procedures are performed to study the repair of various induced heart defects including Patent Ductus Arteriosus, damaged valves, infarction, cardiac rhythm disorders, vascular aneurysm, testing new catheter-based devices and treatment of tumors of the heart and other organs. Generally these procedures do not have significant adverse effects for animals undergoing survival procedures, but those that do are counted as having multiple major survival procedures.
Non-human primates	<u>2.31 Institutional Animal Care and Use Committee (Major Operative Procedure)</u>	The goal is to create a myocardial infarct model, via a thoracotomy or cardiac catheterization, followed by a second thoracotomy 12 to 16 weeks later. The second surgery will inject a new type of stem cell into the infarcted area to induce healing. Sham saline control surgeries will also be done.
Non-human primates	<u>2.31 Institutional Animal Care and Use Committee (Major Operative Procedure)</u>	In order to track the homing of NK cells post-infusion, up to 3 liver biopsies will be performed. The first will be 24 hours post-infusion, the second at 48 hours and a possible third biopsy may be done at 4 to 7 days post-infusion. A laparoscopic technique will be used, but if that is not successful a laparotomy will be performed.

Section E – Previous Deficiencies & Plans:

The committee validated that the plans and schedules for deficiencies noted during the previous NHLBI program review, and facilities and laboratory inspections were achieved within the time intervals projected on the previous semiannual report.

Section F – Current Deficiencies & Plans:

Deficiencies found *over the past 6 months* during NHLBI program review, facility inspections, and laboratory inspections, are as follows:

	Deficiency	¹ M/S	Location	Correction Plan	Responsible Party	Scheduled Completion Date	² Status: C/P
1	Surgical skin prep was not done as described in the protocol.	S	Redacted by agreement	Technician was suspended from animal work and has left the NIH.	Lab Staff	9/19/19	C
2	Bite-Scratch kit signs need posting	M		Post signs on fridge and room door	Lab Staff	9/20/19	C
3	Expired drug	M		Discarded during visit	Lab Staff	9/20/19	C
4	Obstructed front grid	M		Corrected during visit	Lab Staff	9/20/19	C

	on BSC						
5	Unlabeled fluid bottle	M	Redacted by agreement	Discarded during visit	Lab Staff	9/23/19	C
6	Guillotine blade needs sharpening	M		Sharpen blade	Lab Staff	9/23/19	C
7	Eyewash not flushed	M		Flush eyewash station	Lab Staff	9/23/19	C
8	MPW box overfilled	M		Box closed for pickup	Lab Staff	9/23/19	C
9	Eyewash not flushed	M		Flushed eyewash station	Lab Staff	9/24/19	C
10	Expired syringes	M		Discard syringes	Lab Staff	9/25/19	C
11	Cannisters of alcohol and betadine gauze need to be replaced	M		Replace pre-soaked gauze squares	Lab Staff	9/25/19	C
12	Punctured sterile water vial with no date	M		Discarded during visit	Lab Staff	9/24/19	C
13	Expired drug	M		Discard drug	Lab Staff	9/25/19	C
14	Unlabeled conical vials containing fluid	M		Items labeled	Lab Staff	9/24/19	C
15	Unlabeled spray bottle containing fluid	M		Items labeled	Lab Staff	9/24/19	C
16	Punctured sterile water vial with no date	M		Discarded during visit	Lab Staff	9/24/19	C
17	Safety shower needs flushing	M		Flush shower	Lab Staff	9/26/19	C
18	Space heater plugged into power strip	M		Training provided, unplugged heater	Lab Staff	9/25/19	C
19	Expired drug & fluids	M	Redacted by agreement	Discarded during visit	Lab Staff	9/25/19	C
20	Expired drug	M		Discarded during visit	AP Staff	9/25/19	C
21	Eyewash not flushed	M		Flushed eyewash station	AP Staff	9/25/19	C

¹M=minor; S=significant²C=corrected; P=pending**Section G – Reportable Events:**

PHS Policy (i.e. OLAW) reportable events that occurred in the last 6 months or that are still awaiting final disposition are as follows:

INCIDENT: The Principal Investigator (PI) reported to the Animal Program Director (APD), that one of the lab technicians had performed a bone marrow biopsy on a non-human primate without the proper skin preparation (clipping and prepping the skin) as described in the protocol. Upon investigation of the incident with the facility and lab staff, it was determined that the protocol procedures had not been followed.

ACTIONS: The Animal Care and Use Committee (ACUC) Chair was notified, at which point a subcommittee consisting of the APD and an ACUC member were appointed to further investigate the incident.

After discussion at a convened meeting, the ACUC concluded that this was a reportable incident of protocol noncompliance. It was determined that the technician involved was both skilled and highly experienced with the procedure and was aware of the requirements of the protocol. With the concurrence of the PI, the ACUC determined that this technician should not be allowed to conduct procedures on animals. Since this incident occurred, the technician has left the laboratory group and is no longer employed at NIH.

Section H – Shared & Central Facilities:

This semiannual report also encompasses review and oversight of animals and animal activities

which were present or occurred in shared or central facilities. Deficiencies were noted and transmitted directly to the facility, and if necessary, to the responsible Animal Care and Use Committee. These reviews were conducted as indicated below:

Building	Date	ACUC Members		
Redacted by agreement	9/19/19	Redacted by agreement	Hawkins,	Redacted by agreement
	9/24/19	Redacted by agreement	Hawkins,	Redacted by agreement
	9/24/19	Redacted by agreement	Hawkins,	
	9/23/19	Hawkins,	Redacted by agreement	
	9/24/19	Redacted by agreement	Hawkins,	Redacted by agreement
	9/20/19	Redacted by agreement	Hawkins,	Redacted by agreement
	9/20/19		Hawkins,	
	9/20/19		Hawkins,	

Section I – Minority Report

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

Redacted by agreement

Chair, ACUC, Scientist
Elizabeth "Tish" Murphy, Ph.D.

Redacted by agreement

Attending Veterinarian
James Hawkins, DVM, MS

Redacted by agreement

Redacted by agreement

Assurance#: A-4149-01

Date October 31, 2019

Institutional Animal Care & Use Committee Roster

Member Name	Degree/Credentials	Position Title	PHS Policy Membership Role	New Member
Elizabeth Murphy	PhD	Senior Investigator	Chair	<input type="checkbox"/>
James Hawkins	DVM, MS, DACLAM	Animal Program Director	Attending Veterinarian	<input type="checkbox"/>
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ACUC Chair Mailing Address & Phone #

Redacted by agreement

Attending Vet Phone #:

Redacted by agreement

NATIONAL INSTITUTES OF HEALTH
Facilities and Animal Species Inventory Table
Assurance Number: A-4149-01

IC Name: National Heart, Lung, and Blood Institute

Spring Semiannual Report Submission Date: April 30, 2019

Spring Program Review Date(s):	4/10/19					
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Fall Program Review Date(s):	10/9/19					
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Bldg/Area/Rm	Facility Insp. Date(s) Spring / Fall		AF/SF; Gross Sq. Ft.	Species Housed			Average Daily Inventory		
Redacted by agreement	3/29/19	9/19/19	1070	1 Mice	2	3	1 4,400	2	3
				4	5	6	4	5	6
	3/29/19	9/19/19	424	1 Mice	2 Rats	3	1 200	2 30	3
				4	5	6	4	5	6
	4/1/19	9/25/19	11,826	1 Mice	2	3	1 20	2	3
				4	5	6	4	5	6
	4/26/19	9/23/19	3	1 Fish	2	3	1 20	2	3
				4	5	6	4	5	6
				1	2	3	1	2	3
				4	5	6	4	5	6

Semiannual Report Attachment 3

Supplemental Information

Fall 2019

Performance Standards:

Provide a description of ACUC approved performance standards. For additional information and examples, see the "Guide Departures & Performance Standards" document developed by OACU.

NHLBI-Redacted by agreement Issue: room pressurization – negative. Reference: p. 139, GUIDE. . . areas for surgery or clean equipment storage should be kept under relative positive pressure with clean air. Facility Constraint: This room is part of a suite that opens onto a heavily trafficked corridor and is maintained in a negative pressurization state to reduce laboratory animal allergen exposure to hospital personnel. Additionally, the suite's main entrance room has no air exhaust fixtures in its walls or ceilings, and maintaining the storage room in a DP (-) status helps ensure the main suite entrance room remains DP (-) to its adjacent hospital corridor. Mitigations: Water bottles and clean cages maintained in this area are shrouded and normally used within two days. Water bottles are filled in this area and taken to the animal rooms immediately. Animal feed is ordered directly from the supplier and is typically used within 2 weeks. All bags are marked with the arrival date and checked for mold when opened. The room is maintained at a setpoint of 68°F and the humidity is below 50%. No animal health issues have been identified resulting from operating this room in a negative pressurization state.

ACUC Approved June 12, 2019

Mouse Breeding Groups. The ACUC has approved this policy as an engineering standard option. This scheme should not be used if pups are developmentally delayed and require weaning later than 21 days.

Two pregnant females or females with litters (with or without the male), may be left in a cage together if the total number of animals does not exceed fourteen (2-3 adults, 11-12 pups at 14 days old). The two litters must also be within 3 days of age of each other. Litters with a larger age discrepancy will result in "milk-stripping" and trampling by the older, stronger litter. Pups should be weaned at 21 days of age or as soon as the next litter is delivered, whichever occurs first. It is also essential to follow the procedures of the facility where the mice are housed regarding prompt response to notifications for weaning. Under some unique circumstances, one male may be used to breed with 3 to 4 females. If this method is used, then female mice should be removed when obviously pregnant and no litters are allowed to be born in the cage.

Reference: *Guide* pp. 56-57

NHLBI ACUC Policy for Social Housing of Rodents and Aquatic Species

Co-housing of social rodent and aquatic species is the current standard as required by the most recent version of the *Guide*.

Standards

In NHLBI, social housing should be considered the default method of housing rodent and aquatic species. Exceptions to this standard because of the study design should be justified in the Animal Study Proposal (ASP) and approved by the Animal Care and Use Committee (ACUC). In addition, animals may be single housed at the discretion of the veterinarian, or due to breeding strategies or genotyping methods.

Single housing resulting from incompatibility or other veterinary concerns should be handled on a case-by-case basis using the professional judgment of the qualified veterinary staff. When necessary, single housing of social animals should be limited to the minimum period necessary. In the absence of other animals, additional enrichment may be offered.

Rodents

All rodents should be group housed regardless of age with the following exceptions:

- Study Design - If rodents cannot be housed in single-sex compatible pairs or groups for all of, or a portion of, the study, a written scientific justification for this exception to social housing must be listed in the ASP and subsequently reviewed and approved by the ACUC. Consideration should be given for animals following surgery or other procedures where the animal must be individually housed to protect the incision, sutures, or implant. The Principal Investigator (PI) must describe the group(s) of animals that will not be socially housed and the frequency and duration of non-social housing.

The following exceptions DO NOT require ongoing or repeated prior approval by the IC ACUC:

- Attrition During a Study - Rodents originally group housed may eventually become individually housed as a result of cage mates being removed during the course of an experiment. While consideration should be given to re-housing with other animals, study duration and potential introduction of variables may preclude re-housing socially. If the experimental design precludes the re-housing of an animal to protect the integrity of the research, treatment group, or line (e.g. genetic, scientific, etc.) it should also be noted in the ASP.
- Social Incompatibility – The aggressive nature of individual animals/strains may require single housing.
- Breeding
 - o The territorial behavior of many male rodents, especially mice, requires them to be individually housed to ensure breeding efficiency when females are introduced into the male's cage/territory. Therefore, male rodents may be housed individually when designated for breeding. Once a male rodent has been used for breeding, he should not be returned to group housing as severe fighting will frequently ensue. These animals should be identified as socially incompatible.
 - o Bred females may be singly or group housed during their gestation as determined by the ACUC approved standard operating procedures for the holding facility and caging styles available.

- Veterinary Concerns - The veterinary staff under the authority of the attending veterinarian may exempt an individual animal from participation in social housing for social aggression, animal health or other medical veterinary reasons.
- Single Individuals at Weaning – Single rodents that have no littermates of the same gender (e.g. one female or male in the litter) may be individually housed if other animals of the same genetic background and age are not available for pairing. Pairing recently weaned animals with markedly older animals, especially males, often results in the younger animals being severely barbered or injured. Consideration should be given to re-housing single weaned female rodents together.

Fish

All aquatic species should be group housed regardless of age. The exceptions for study design (requiring description in the ASP), social incompatibility, breeding, veterinary concerns and attrition are the same as for rodents.

The following exception, unique to fish species, does not require description in the ASP:

- Genotyping – Because long-term marking of individual fish is impractical, animals that have been sampled for genotype analysis may be single housed.

References

Guide for the Care and Use of Laboratory Animals, ILAR, NAS, Eighth Edition, 2011

NIH ARAC Guideline for Social Housing of Rodents and Aquatic Species
http://oacu.od.nih.gov/ARAC/documents/Social_Housing.pdf

Approved: 12/9/2015, , 6/12/2019

Oct. 9, 2019

I. Semiannual Program Review Checklist i Institutional Policies and Responsibilities

Date:

1. Animal Care and Use Program ^{NEW} (NIH Policy 3040-2)

- Responsibility for animal well-being is assumed by all members of the program (Guide, p 1) [must]
- IO has authority to allocate needed resources (Guide, p 13)
- Resources necessary to manage program of veterinary care are provided (Guide, p 14) [must]
- Sufficient resources are available to manage the program, including training of personnel in accord with regulations and the Guide (Guide, pp 11, 15)
- Program needs are regularly communicated to IO by AV and/or IACUC (Guide, p 13)
- 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]
- Inter-institutional collaborations are described in formal written agreements (Guide, p 15; **OLAW; NIH ARAC Guideline C4**)
- Written agreements address responsibilities, animal ownership, and IACUC oversight (Guide, p 15; **NIH ARAC Guideline C4**)

A* M S C NA

2. Disaster Planning and Emergency Preparedness ^{NEW} (OLAW; USDA; NIH OACU Disaster Planning)

- Disaster plans for each facility to include satellite locations are in place (Guide, p 35, p 75) [must]
- Plans include provisions for euthanasia (Guide, p 35) [must]
- Plans include triage plans to meet institutional and investigators' needs (Guide, p 35)
- Plans define actions to prevent animal injury or death due to HVAC or other failures (Guide, p 35)
- Plans describe preservation of critical or irreplaceable animals (Guide, p 35)
- Plans include essential personnel and their training (Guide, p 35)
- Animal facility plans are approved by the institution and incorporated into overall response plan (Guide, p 35)
- Law enforcement and emergency personnel are provided a copy and integration with overall plan is in place (Guide, p 35)

A* M S C NA

3. IACUC ^{NEW} (OLAW; NIH Policy 3040-2)

- Meets as necessary to fulfill responsibilities (Guide, p 25) [must]
- IACUC Members named in protocols or with conflicts recuse themselves from protocol decisions (Guide, p 26; **OLAW; NIH ARAC Guideline C7**) [must]
- Continuing IACUC oversight after initial protocol approval is in place (Guide, p 33; **OLAW**)
- IACUC evaluates the effectiveness of training programs (Guide, p 15)
- IACUC Policy in place for use of Designated Member Review subsequent to Full Committee Review and new members informed of the policy. (**OLAW; NIH ARAC Guideline C7**)
- Non-affiliated member(s) regularly participate in Semiannual Program Review & Facility Inspection Process

A* M S C NA

4. IACUC Protocol Review - Special Considerations (USDA#12)

- Humane endpoints are established for studies that involve tumor models, infectious diseases, vaccine challenge, pain

A* M S C NA

modeling, trauma, production of monoclonal antibodies, assessment of toxicologic effects, organ or system failure, and models of cardiovascular shock (<i>Guide</i> , p 27; NIH ARAC Guideline C6)					
• For pilot studies, a system to communicate with the IACUC is in place (<i>Guide</i> , p 28; OLAW)					
• For genetically modified animals, enhanced monitoring and reporting is in place (<i>Guide</i> , p 28)					
• Restraint devices are justified in the animal use protocols (<i>Guide</i> , p 29) [must]					
• Alternatives to physical restraint are considered (<i>Guide</i> , p 29)					
• Period of restraint is the minimum to meet scientific objectives (<i>Guide</i> , p 29)					
• Training of animals to adapt to restraint is provided (<i>Guide</i> , p 29)					
• Animals that fail to adapt are removed from study (<i>Guide</i> , p 29)					
• Appropriate observation intervals of restrained animals are provided (<i>Guide</i> , p 29)					
• Veterinary care is provided if lesions or illness result from restraint (<i>Guide</i> , p 30) [must]					
• Explanations of purpose and duration of restraint are provided to study personnel (<i>Guide</i> , p 30)					
• Multiple surgical procedures on a single animal are justified and outcomes evaluated (<i>Guide</i> , p 30; OLAW; USDA#14)					
• Major versus minor surgical procedures are evaluated on a case-by-case basis (<i>Guide</i> , p 30)					
• Multiple survival procedure justifications in non-regulated species conform to regulated species standards (<i>Guide</i> , p 30)					
• Animals on food/fluid restriction are monitored to ensure nutritional needs are met (<i>Guide</i> , p 31; OLAW; NIH ARAC Guideline B7)					
• Body weights for food/fluid restricted animals are recorded at least weekly (<i>Guide</i> , p 31; NIH ARAC Guideline B7)					
• Daily written records are maintained for food/fluid restricted animals (<i>Guide</i> , p 31; NIH ARAC Guideline B7)					
• Pharmaceutical grade chemicals are used, when available, for animal-related procedures (<i>Guide</i> , p 31; OLAW; NIH ARAC Guideline B13)					
• Non-pharmaceutical grade chemicals are described, justified, and approved by IACUC (<i>Guide</i> , p 31; NIH ARAC Guideline B13)					
• Investigators conducting field studies know zoonotic diseases, safety issues, laws and regulations applicable in study area (<i>Guide</i> , p 32)					
• Disposition plans are considered for species removed from the wild (<i>Guide</i> , p 32)					
• Toe-clipping only used when no alternative, performed aseptically and with pain relief (<i>Guide</i> , p 75; NIH ARAC Guideline B9)					
5. IACUC Membership and Functions (OLAW; NIH Policy 3040-2)	A*	M	S	C	NA
• IACUC is comprised of at least 5 members, appointed by CEO (PHS Policy, IV.A.3.; NIH ARAC Guideline C9)					
• Members include a veterinarian, a scientist, a nonscientist, and a nonaffiliated non-lab animal user (<i>Guide</i> , p 24 ⁱⁱ ; NIH ARAC Guideline C9)					
• IACUC authority and resources for oversight and evaluation of institution's program are provided (<i>Guide</i> , p 14)					
• IACUC conducts semiannual evaluations of institutional animal care and use program (PHS Policy, IV.B.)					
• Conducts semiannual inspections of institutional animal facilities (PHS Policy, IV.B.)					
• Non-affiliate member(s) actively participate in meetings and semiannual program review.					
• IACUC organizationally reports to the Institutional Official (PHS Policy, IV.A.1.b.)					
• Methods for reporting and investigating animal welfare concerns are in place (<i>Guide</i> , p 23; NIH ARAC Guideline C2; NIH Policy Memo) [must]					

<ul style="list-style-type: none"> Reviews and investigates concerns about animal care and use at institutionⁱⁱⁱ (PHS Policy, IV.B.; NIH ARAC Guideline C2; NIH Policy Memo) Procedures are in place for review, approval, and suspension of animal activities^{iv} (PHS Policy, IV.B.; NIH ARAC Guideline C2; NIH Policy Memo) Procedures are in place for review and approval of significant changes to approved activities (PHS Policy, IV.B.; NIH ARAC Guideline C3) Policies are in place for special procedures (e.g., genetically modified animals, restraint, multiple survival surgery, food and fluid regulation, field investigations, agricultural animals) (<i>Guide</i>, p 27-32; NIH ARAC Guideline B7) Requests for exemptions from major survival surgical procedure restrictions are made to USDA/APHIS^v (<i>Guide</i>, p 32; NIH ARAC Guideline C10) [must] 					
6. IACUC Training ^{NEW} (NIH ACUC Member Course)	A*	M	S	C	NA
<ul style="list-style-type: none"> All IACUC members should receive: <ul style="list-style-type: none"> Formal orientation to institution's program (<i>Guide</i>, p 17;) Training on legislation, regulations, guidelines, and policies (<i>Guide</i>, p 17) Training on how to inspect facilities and labs where animal use or housing occurs (<i>Guide</i>, p 17) Training on how to review protocols as well as evaluate the program (<i>Guide</i>, p 17) Ongoing training/education (<i>Guide</i>, p 17) 					
7. IACUC Records and Reporting Requirements ^{vi}	A*	M	S	C	NA
<ul style="list-style-type: none"> Semiannual report to the IO (PHS Policy, IV.B.) <ul style="list-style-type: none"> Submitted to IO every 6 months Compiles program review and facility inspection(s) results (includes all program and facility deficiencies) Includes minority IACUC views Describes IACUC-approved departures from the <i>Guide</i> or PHS Policy and the reasons for each departure^{vii} Distinguishes significant from minor deficiencies (NIH ARAC Guideline C1) Includes a plan and schedule for correction for each deficiency identified^{viii} Reports to U.S. Department of Agriculture (USDA) or Federal funding agency^{ix} (NIH ARAC Guideline A1) <ul style="list-style-type: none"> Annual report to USDA contains required information including all exceptions/exemptions Records (PHS Policy, IV.E.) <ul style="list-style-type: none"> IACUC meeting minutes and semiannual reports to the IO are maintained for 3 years (OLAW; NIH Minutes) Records of IACUC reviews of animal activities include all required information^x Records of IACUC reviews are maintained for 3 years after the completion of the study 					
8. Veterinary Care (See also next section - Veterinary Care) (USDA #3; NIH PM 3040-2)	A*	M	S	C	NA
<ul style="list-style-type: none"> An arrangement for veterinarian(s) with training or experience in lab animal medicine is in place including backup veterinary care^{xi} Veterinary access to all animals is provided (<i>Guide</i>, p 14) [must] Direct or delegated authority is given to the veterinarian to oversee all aspects of animal care and use (<i>Guide</i>, p 14) [must] Veterinarian provides consultation when pain and distress exceeds anticipated level in protocol (<i>Guide</i>, p 5; NIH ARAC Guidelines: B12; C6) [must] Veterinarian provides consultation when interventional control is not possible (<i>Guide</i>, p 5) [must] 					

- If part time /consulting veterinarian, visits meet programmatic needs (*Guide, p 14*)
- Regular communication occurs between veterinarian and IACUC (*Guide, p 14*)
- Veterinarian(s) have experience and training in species used (*Guide, p 15*) [must]
- Veterinarian(s) have experience in facility administration/management (*Guide, p 15*)

9. Personnel Qualifications and Training (OLAW; NIH PM 3040-2; NIH OACU Training Program) A* M S C 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*)
 - IACUC members (*Guide, p 17*)
 - Animal care personnel (*Guide, p 16*)
 - Research investigators, instructors, technicians, trainees, and students (*Guide, pp 16-17*)
- Continuing education for program and research staff provided to ensure high quality care and reinforce training (*Guide, pp 16-17*)
- Training is available prior to starting animal activity (*Guide, p 17*)
- Training is documented (*Guide, p 15*)
- Training program content includes: (*Guide, p 17*)
 - Methods for reporting concerns (*Guide, p 17*)
 - Humane practices of animal care (e.g., housing, husbandry, handling) ^{xii}
 - Humane practices of animal use (e.g., research procedures, use of anesthesia, pre- and post-operative care, aseptic surgical techniques and euthanasia (*Guide, p 17*)^{xiii}
 - Research/testing methods that minimize numbers necessary to obtain valid results (PHS Policy, IV.A.1.g.)
 - Research/testing methods that minimize animal pain or distress (PHS Policy, IV.A.1.g.)
 - Use of hazardous agents, including access to OSHA chemical hazard notices where applicable (*Guide, p 20*)
 - Animal care and use legislation (*Guide, p 17*)
 - IACUC function (*Guide, p 17*)
 - Ethics of animal use and Three R's (*Guide, p 17*)

10. Occupational Health and Safety of Personnel (NIH Policy 1340; NIH AEP; NIH Laboratory Animal Allergy Prevention Program; NIH ARAC Guideline D2)

- Program is in place and is consistent with federal, state, and local regulations (*Guide, p 17*) [must]
- Program covers *all* personnel who work in laboratory animal facilities (*Guide, p 18*)
- Changing, washing, and showering facilities are available as appropriate (*Guide, p 19*)
- Hazardous facilities are separated from other areas and identified as limited access (*Guide, p 19*)
- Personnel training is provided based on risk (e.g., zoonoses, hazards, personal hygiene, special precautions, animal allergies) (*Guide, p 20*)
- Personal hygiene procedures are in place (e.g., work clothing, eating/drinking/smoking policies) (*Guide, p 20*)
- Procedures for use, storage, and disposal of hazardous biologic, chemical, and physical agents are in place (*Guide, p 21*) (NIH PMs: 1341, 3015, 3034, 3035)
- Personal Protective Equipment for the work area is appropriate and available (*Guide, p 21*) (NIH ARAC Guideline D2)
- Program for medical evaluation and preventive medicine for personnel includes: (NIH AEP)
 - Pre-employment evaluation including health history (*Guide, p 22*)

- Immunizations as appropriate (e.g., rabies, tetanus) and tests as appropriate (*Guide*, p 22)
- Zoonosis surveillance as appropriate (e.g., Q-fever, tularemia, Hantavirus, plague) (*Guide*, p 23)
- Procedures for reporting and treating injuries, including accidents, bites, allergies, etc. (*Guide*, p 23)
- Promotes early diagnosis of allergies including preexisting conditions (*Guide*, p 22; **NIH OMS LAAPP**)
- Considers confidentiality and other legal factors as required by federal, state and local regulations (*Guide*, p 22) **[must]**
- If serum samples are collected, the purpose is consistent with federal and state laws (*Guide*, p 22) **[must]**
- Waste anesthetic gases are scavenged (*Guide*, p 21; **NIH Waste & Anesthetic Gas Surveillance Program**)
- Hearing protection is provided in high noise areas (*Guide*, p 22; **NIH Hearing Conservation Program**)
- Respiratory protection is available when performing airborne particulate work (*Guide*, p 22; **NIH Respiratory Protection Program**)
- Special precautions for personnel who work with nonhuman primates, their tissues or body fluids include: (**NIH PM 3044-2**)
 - Tuberculosis screening provided for all exposed personnel (*Guide*, p 23; **NIH AEP; Tuberculosis Surveillance Program**)
 - Training and implementation of procedures for bites, scratches, or injuries associated with macaques (*Guide*, p 23; **Working Safely with NHPs; NHP Body Fluid Exposure**)
 - PPE is provided including gloves, arm protection, face masks, face shields, or goggles (*Guide*, p 21; **NIH ARAC Guideline D2**)
 - Injuries associated with macaques are carefully evaluated and treatment implemented (*Guide*, p 23; **NHP Body Fluid Exposure**)
- Occupational safety and health of field studies is reviewed by OSH committee or office (*Guide*, p 32)

11. Personnel Security ^{NEW} (**NIH PM 3047**)

- Preventive measures in place include pre-employment screening, and physical and IT security (*Guide*, p 23)

A* M S C NA

12. Investigating & Reporting Animal Welfare Concerns ^{NEW} (**NIH ARAC Guideline C2; NIH Policy Memo; NIH Incident Investigation**)

- Methods for investigating and reporting animal welfare concerns are established (*Guide*, p 23) **[must]**
- Reported concerns and corrective actions are documented (*Guide*, p 24)
- Mechanisms for reporting concerns are posted in facility and at applicable website with instructions (*Guide*, p 24)
 - Includes multiple contacts (*Guide*, p 24)
 - Includes anonymity, whistle blower policy, nondiscrimination and reprisal protection (*Guide*, p 24)

A* M S C NA

* 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

Date:

1. Clinical Care and Management ^{NEW} (USDA #3; NIH PM 3040-2; NIH Policy Memo)	A*	M	S	C	NA
• Veterinary program offers high quality of care and ethical standards (Guide, p 105) [must]					
• Veterinarian provides guidance to all personnel to ensure appropriate husbandry, handling, treatment, anesthesia, analgesia, and euthanasia (Guide, p 106)					
• Veterinarian provides oversight to surgery and perioperative care (Guide, p 106)					
• Veterinary care program is appropriate for program requirements (Guide, pp 113-114)					
• Veterinarian(s) is familiar with species and use of animals and has access to medical and experimental treatment records (Guide, p 114)					
• Procedures to triage and prioritize incident reports are in place (Guide, p 114)					
• Procedures are in place to address:					
o Problems with experiments to determine course of treatment in consultation with investigator (Guide, p 114)					
o Recurrent or significant health problems with the IACUC and documentation of treatments and outcomes (Guide, p 114)					
o Veterinary review and oversight of medical and animal use records (Guide, p 115)					
• Procedures established for timely reporting of animal injury, illness, or disease (Guide, p 114; NIH Policy Memo) [must]					
• Procedures established for veterinary assessment, treatment, or euthanasia (Guide, p 114; NIH Policy Memo; NIH ARAC Guideline A2) [must]					
• Veterinarian is authorized to treat, relieve pain, and/or euthanize (Guide, p 114) [must]					
2. Animal Procurement and Transportation/Preventive Medicine (OLAW; NIH PM: 3040-3, 3043-1, 3044-1)	A*	M	S	C	NA
• Procedures for lawful animal procurement are in place (Guide, p 106) [must]					
• Sufficient facilities and expertise are confirmed prior to procurement (Guide, p 106)					
• Procurement is linked to IACUC review and approval (Guide, p 106)					
• Random source dogs and cats are inspected for identification (Guide, p 106)					
• Population status of wildlife species is considered prior to procurement (Guide, p 106)					
• Appropriate records are maintained on animal acquisition (Guide, p 106)					
• Animal vendors are evaluated to meet program needs and quality (Guide, p 106)					
• Breeding colonies are based on need and managed to minimize numbers (Guide, p 107)					
• Procedures for compliance with animal transportation regulations, including international requirements, are in place (Guide, p 107; USDA#18) [must]					
• Transportation is planned to ensure safety, security and minimize risk (Guide, p 107; ARAC Guidelines: B1a; B1b)					

- Movement of animals is planned to minimize transit time and deliveries are planned to ensure receiving personnel are available (*Guide*, pp 107- 108)
- Appropriate loading and unloading facilities are available (*Guide*, p 109)
- Environment at receiving site is appropriate (*Guide*, p 109)
- Policies in place on separation by species, source, and health status (*Guide*, pp 109, 111-112; **ARAC Guideline D1**)
- Procedures in place for quarantine to include zoonoses prevention (*Guide*, p 110; **NIH ARAC Guideline D3**)
- Quarantined animals from different shipments are handled separately or physically separated (*Guide*, p 110)
- Procedures in place for stabilization/acclimation (*Guide*, pp 110-111)
- Policies in place for isolation of sick animals (*Guide*, p 112)
- Program is in place for surveillance, diagnosis, treatment and control of disease to include daily observation (*Guide*, p 112)
- Diagnostic resources are available for preventive health program (*Guide*, p 112)

3. Surgery (OLAW; NIH ARAC Guideline B6)

A* M S C NA

- Surgical outcomes are assessed and corrective changes instituted (*Guide*, p 115)
- Researchers have appropriate training to ensure good technique (*Guide*, p 115) [must]
- Pre-surgical plans are developed and include veterinary input (e.g., location, supplies, anesthetic and analgesic use, peri-operative care, recordkeeping) (*Guide*, p 116)
- Aseptic surgery is conducted in dedicated facilities or spaces, unless exception justified and IACUC approved (*Guide*, p 116)
- Surgical procedures including laparoscopic procedures are categorized as major or minor (*Guide*, pp 117-118)
- For nonsurvival surgery, the site is clipped, gloves are worn and instruments and area are clean (*Guide*, p 118)
- Aseptic technique is followed for survival surgical procedures (*Guide*, pp 118-119)
- Effective procedures for sterilizing instruments and monitoring expiration dates on sterile packs are in place (*Guide*, p 119)
- Procedures for monitoring surgical anesthesia and analgesia are in place (*Guide*, p 119)
- For aquatic species, skin surfaces are kept moist during surgical procedures (*Guide*, p 119; **NIH ARAC Guideline B11**)
- Post-operative monitoring and care are provided by trained personnel and documented (e.g., thermoregulation, physiologic function, analgesia, infection, removal of skin closures) (*Guide*, pp 119-120)

7

4. Pain, Distress, Anesthesia and Analgesia (USDA#11; NIH ARAC Guideline B12)

A* M S C NA

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

5. Euthanasia (OLAW; AVMA Guidelines 2013; NIH ARAC Guidelines: B4, B5)

- Methods are consistent with AVMA Guidelines on Euthanasia unless approved by the IACUC (*Guide*, p 123)
- CO2 regulators & flowmeters are present and functioning. Flow rate is appropriate for the euthanasia chamber size. (**ARAC Guideline B5**)
- Standardized methods are developed and approved by the veterinarian and IACUC that avoid distress and consider animal age and species (*Guide*, pp 123-124)
- Training is provided on appropriate methods for each species and considers psychological stress to personnel (*Guide*, p 124)
- Procedures and training are in place to ensure death is confirmed (*Guide*, p 124) [must]

A* M S C NA**6. Drug Storage and Control ^{NEW} (NIH PM 1345)**

- Program complies with federal regulations for human and veterinary drugs (*Guide*, p 115) [must]
-
- Drug records and storage procedures are reviewed during facility inspections (*Guide*, p 115)
- Procedures are in place to ensure analgesics and anesthetics are used within expiration date (*Guide*, p 122; **OLAW; NIH ARAC Guideline C11**) [must]
- Anesthetics and analgesics are acquired, stored, and their use and disposal are recorded legally and safely (*Guide*, p 122)

A* M S C NA* **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. Semiannual Facility Inspection Checklist

Terrestrial Animal Housing and Support Areas

Date:

Location:

	A*	M	S	C	NA
• Location: <ul style="list-style-type: none"> o animal areas separate from personnel areas (<i>Guide</i>, p 134) o separation of species (<i>Guide</i>, p 111; NIH ARAC Guideline D1) o separation by disease status (<i>Guide</i>, p 111) o security and access control (<i>Guide</i>, p 151; NIH PM 3047) 					
• Construction: <ul style="list-style-type: none"> o corridors (<i>Guide</i>, p 136) o animal room doors (<i>Guide</i>, p 137) o exterior windows (<i>Guide</i>, p 137) o floors (<i>Guide</i>, p 137) o drainage (<i>Guide</i>, p 138) o walls and ceilings (<i>Guide</i>, p 138) o heating ventilation and air conditioning (<i>Guide</i>, p 139) o power and lighting (<i>Guide</i>, p 141) o noise control (<i>Guide</i>, p 142) o vibration control (<i>Guide</i>, p 142) o environmental monitoring (<i>Guide</i>, p 143) 					X
• Room/Cage: <ul style="list-style-type: none"> o temperature and humidity (<i>Guide</i>, p 43) o ventilation and air quality (<i>Guide</i>, p 45) o illumination (<i>Guide</i>, p 47) o noise and vibration (<i>Guide</i>, p 49) 					
• Primary Enclosure: (OLAW) <ul style="list-style-type: none"> o space meets physiologic, behavioral^{xv}, and social^{xvi} needs (<i>Guide</i>, pp 51, 55-63) o secure environment provided (<i>Guide</i>, p 51) o durable, nontoxic materials in good repair and no risk of injury (<i>Guide</i>, p 51) o flooring is safe and appropriate for species (<i>Guide</i>, p 51) o adequate bedding and structures for resting, sleeping, breeding (<i>Guide</i>, p 52; NIH ARAC Guideline B15) o objective assessments of housing and management are made (<i>Guide</i>, p 52) o procedures for routine husbandry are documented (<i>Guide</i>, p 52) o socially housed animals can escape or hide to avoid aggression (<i>Guide</i>, p 55) o cage height provides adequate clearance (<i>Guide</i>, p 56) o animals express natural postures, can turn around, access food and water, and rest away from urine 					

and feces (<i>Guide</i> , p 56) [must]		
o rationale ^{xvii} for <i>Guide</i> /USDA space exceptions approved by IACUC and based on performance indices (<i>Guide</i> , p 56)		
o dogs and cats allowed to exercise and provided human interaction (<i>Guide</i> , p 58)		7
o nonhuman primates are socially housed except for scientific, veterinary or behavior reasons (<i>Guide</i> , pp 58-59)		
o single housing of nonhuman primates is for shortest duration possible (<i>Guide</i> , p 60)		
o opportunities for release into larger enclosures is considered for single caged nonhuman primates (<i>Guide</i> , p 60)		
o agricultural animals are housed socially (<i>Guide</i> , p 60)		
o food troughs and water devices for agricultural animals allow access for all animals (<i>Guide</i> , p 60)		
• Environmental Enrichment, Behavioral and Social Management: (OLAW; USDA#7)		
o structures and resources promote species typical behavior (<i>Guide</i> , pp 52-54)		
o novelty of enrichment is considered (<i>Guide</i> , p 53)		
o species specific plans for housing including enrichment, behavior and activity are developed and reviewed regularly by IACUC, researchers and veterinarian (<i>Guide</i> , pp 53, 58, 60, 63)		
o animal care personnel receive training to identify abnormal animal behaviors (<i>Guide</i> , p 53)		
o stability of pairs or groups is monitored for incompatibility (<i>Guide</i> , p 64)		
o single housing is justified for social species (<i>Guide</i> , p 64)		
o single housing is limited to the minimum period necessary (<i>Guide</i> , p 64)		
o single housing is in compliance with ARAC Guidelines (AAALAC)		
o additional enrichment for single housed animals is provided (<i>Guide</i> , p 64)		
o single housing is reviewed regularly by IACUC and veterinarian (<i>Guide</i> , p 64)		
o habituation to routine procedures is part of enrichment program (<i>Guide</i> , p 64)		
o housing multiple species in same room is reviewed & approved by ACUC (<i>Guide</i> , p 64; ARAC Guideline D1)		
• Sheltered or Outdoor Housing: (e.g., barns, corrals, pastures, islands)		
o weather protection and opportunity for retreat (<i>Guide</i> , p 54) [must]		
o appropriate size (<i>Guide</i> , p 54)		
o ventilation and sanitation of shelter (no waste/moisture build-up) (<i>Guide</i> , p 54)		
o animal acclimation (<i>Guide</i> , p 55)		
o social compatibility (<i>Guide</i> , p 55)		
o roundup/restraint procedures (<i>Guide</i> , p 55)		
o appropriate security (<i>Guide</i> , p 55)		
• Naturalistic Environments:		
o animals added /removed with consideration of effect on group (<i>Guide</i> , p 55)		
o adequate food, fresh water, and shelter ensured (<i>Guide</i> , p 55)		
• Food: (OLAW; NIH ARAC Guideline D7)		
o feeding schedule and procedures including caloric intake management (<i>Guide</i> , pp 65-67)		
o contamination prevention (<i>Guide</i> , p 65)		
o vendor quality control (<i>Guide</i> , p 66)		
o storage in sealed containers (<i>Guide</i> , p 66)		
o expiration date labeling (<i>Guide</i> , p 66)		
o vermin control (<i>Guide</i> , p 66)		

o rotation of stocks (<i>Guide</i> , p 66)			
• Water:			
o ad libitum unless justified (<i>Guide</i> , pp 67-68)			
o QC procedures (<i>Guide</i> , pp 67-68)			
• Bedding and Nesting Materials:			
o species appropriate (<i>Guide</i> , pp 68-69)			
o keeps animals dry (<i>Guide</i> , pp 68-69)			
o QC procedures (<i>Guide</i> , pp 68-69)			
o minimizes scientific variables (<i>Guide</i> , pp 68-69)			
• Sanitation:			
o frequency of bedding/substrate change (<i>Guide</i> , p 70)			
o cleaning and disinfection of microenvironment (<i>Guide</i> , pp 70-71)			
o cleaning and disinfection of macroenvironment (<i>Guide</i> , p 72)			
o assessing effectiveness (<i>Guide</i> , p 73)			
• Waste Disposal: (NIH Waste Disposal Guide)			
o procedures for collection (<i>Guide</i> , pp 73-74)			
o procedures for storage and disposal (<i>Guide</i> , pp 73-74)			
o hazardous wastes are rendered safe before removal from facility (<i>Guide</i> , pp 73-74) [must]			
o animal carcasses (<i>Guide</i> , pp 73-74)			
• Pest Control: (NIH Integrated Pest Management Program)			
o regularly scheduled (<i>Guide</i> , p 74)			
o documented program including control of rodent pests and insecticide use (<i>Guide</i> , p 74)			
• Emergency, Weekend, and Holiday Animal Care: (OLAW)			
o care provided by qualified personnel every day (<i>Guide</i> , p 74)			
o provision for accessible contact information (<i>Guide</i> , p 74)			
o monitoring of backup systems (<i>Guide</i> , p 143)			
o veterinary care available after hours, weekends, and holidays (<i>Guide</i> , pp 74, 114) [must]			
o a disaster plan that takes into account both personnel and animals (<i>Guide</i> , p 75)			
• Identification: (USDA#13; NIH ARAC Guideline B9)			
o cage/rack cards contain required information (<i>Guide</i> , p 75)			
o genotype information included and standardized nomenclature used when applicable (<i>Guide</i> , p 75)			
• Recordkeeping: (NIH ARAC Guideline A2)			
o clinical records accessible and contain appropriate information (<i>Guide</i> , pp 75-76)			
o records are provided when animals are transferred between institutions (<i>Guide</i> , p 75)			
• Breeding Genetics and Nomenclature:			
o appropriate genetic records, management and monitoring procedures (<i>Guide</i> , p 76)			
o phenotypes that affect wellbeing are reported to IACUC and effectively managed (<i>Guide</i> , p 77)			
• Storage:			
o adequate space for equipment, supplies, food, bedding and refuse (<i>Guide</i> , p 141)			
o bedding in vermin-free area and protected from contamination (<i>Guide</i> , p 141)			
o food in vermin-free, temperature and humidity controlled area and protected from contamination (<i>Guide</i> , p 141)			
o refuse storage is separate (<i>Guide</i> , p 141)			
o carcass and animal tissue storage is separate, refrigerated below 7°C and cleanable (<i>Guide</i> , p 141)			

• **Personnel:**

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

* **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:

Aquatic Animal Housing and Support Areas ^{NEW} (**NIH ARAC Guideline B14**)

Date:

Location:

	A*	M	S	C	NA
• Location:					
○ animal areas separate from personnel areas (<i>Guide, p 134</i>)					
○ separation of species (<i>Guide, p 111</i>)					
○ separation by disease status (<i>Guide, p 111</i>)					
○ security and access control (<i>Guide, p 151</i>)					
• Construction:					
○ corridors (<i>Guide, p 136</i>)					
○ animal room doors (<i>Guide, pp 137, 150</i>)					
○ exterior windows (<i>Guide, p 137</i>)					
○ floors (<i>Guide, pp 137, 150</i>)					
○ drainage (<i>Guide, pp 138, 150</i>)					
○ walls and ceilings (<i>Guide, pp 138, 150</i>)					
○ heating ventilation and air conditioning (<i>Guide, pp 139, 150-151</i>)					
○ power and lighting (<i>Guide, pp 141, 150</i>)					
○ noise control (<i>Guide, p 142</i>)					
○ vibration control (<i>Guide, p 142</i>)					
○ environmental monitoring (<i>Guide, p 143</i>)					
• Water Quality:					
○ standards for acceptable quality are established (<i>Guide, p 78</i>)					
○ chlorine, chloramines, chemical, and reactive bioproducts are removed or neutralized prior to use in aquatic systems (<i>Guide, pp 78, 86</i>) [must]					
• Life Support System:					
○ water source is based on appropriate controls and research requirements (<i>Guide, p 79</i>)					
○ biofilter is of sufficient size to process bioload (<i>Guide, p 80</i>) [must]					
• Temperature, Humidity and Ventilation/Illumination/Noise and Vibration:					
○ temperature and humidity (<i>Guide, pp 43, 80-81</i>)					
○ ventilation and air quality (<i>Guide, pp 45, 81</i>)					
○ illumination (<i>Guide, pp 47, 81</i>)					
○ noise and vibration (<i>Guide, pp 49, 81</i>)					
• Primary Enclosure:					
○ allows for normal physiological and behavioral needs (<i>Guide, p 82</i>)					
○ allows social interaction for social species (<i>Guide, p 82</i>)					
○ provides a balanced, stable environment (<i>Guide, p 82</i>)					
○ provides appropriate water quality and monitoring (<i>Guide, p 82</i>)					

o allows access to food and waste removal (<i>Guide, p 82</i>)			
o restricts escape and entrapment (<i>Guide, p 82</i>)			
o allows undisturbed observation (<i>Guide, p 82</i>)			
o constructed of nontoxic materials (<i>Guide, p 82</i>)			
o prevents electrical hazards (<i>Guide, p 82</i>)			
o space needs of species are evaluated by IACUC during program evaluations and facility inspections (<i>Guide, p 83</i>)			
• Environmental Enrichment, Social Housing, Behavioral and Social Management:			
o enrichment elicits appropriate behaviors and is safe (<i>Guide, p 83</i>)			
o semi-aquatic reptiles are provided terrestrial areas (<i>Guide, p 83</i>)			
o handling is kept to a minimum and appropriate techniques are in place at facility or protocol level (<i>Guide, p 84</i>)			
o nets are cleaned, disinfected and managed to avoid contamination of systems (<i>Guide, p 84</i>)			
• Food:			
o storage to prevent contamination, preserve nutrients and prevent pests (<i>Guide, p 84; NIH Integrated Pest Management Program</i>)			
o delivery ensures access to all, minimizing aggression and nutrient loss (<i>Guide, p 84</i>)			
o storage times are based on manufacturer recommendations or accepted practice (<i>Guide, p 84</i>)			
o a nutritionally complete diet is provided (<i>Guide, p 84</i>)			
• Substrate:			
o amount, type and presentation of substrate is appropriate for the system and the species (<i>Guide, p 85</i>)			
• Sanitation, Cleaning and Disinfection			
o frequency of tank/cage cleaning and disinfection is determined by water quality, permits adequate viewing and health monitoring (<i>Guide, p 86</i>)			
o cleaning and disinfection of macroenvironment (<i>Guide, p 86</i>)			
• Waste Disposal: (NIH Waste Disposal Guide)			
o procedures for collection (<i>Guide, pp 73-74</i>)			
o hazardous wastes are rendered safe before removal from facility (<i>Guide, pp 73-74</i>) [must]			
o animal carcasses (<i>Guide, pp 73-74</i>)			
• Pest Control: (NIH Integrated Pest Management Program)			
o regularly scheduled (<i>Guide, p 74</i>)			
o documented program including control of pests and insecticide use (<i>Guide, p 74</i>)			
• Emergency, Weekend, and Holiday Animal Care: (OLAW)			
o care provided by qualified personnel every day (<i>Guide, pp 74, 87</i>)			
o provision for accessible contact information (<i>Guide, pp 74, 87</i>)			
o emergency response plans in place to address major system failures (<i>Guide, 87</i>)			
o veterinary care available after hours, weekends, and holidays (<i>Guide, pp 74, 114</i>) [must]			
• Identification:			
o cage/tank cards contain required information (<i>Guide, pp 75, 87</i>)			

○ genotype information included and standardized nomenclature used when applicable (<i>Guide</i> , pp 75, 87)			
• Recordkeeping:			
○ water quality parameters and frequency of testing recorded (<i>Guide</i> , p 88)			
○ records kept on feeding, nonexpired food supplies, live cultures (<i>Guide</i> , p 88)			
• Storage:			
○ adequate space for equipment, supplies, food, substrate and refuse (<i>Guide</i> , p 141)			
○ substrate protected from contamination (<i>Guide</i> , p 141)			
○ food in vermin-free, temperature and humidity controlled area and protected from contamination (<i>Guide</i> , p 141)			
○ refuse storage is separate (<i>Guide</i> , p 141)			
○ carcass and animal tissue storage is separate, refrigerated below 7°C and cleanable (<i>Guide</i> , p 141)			
• Personnel:			
○ adequate space for locker rooms, administration and training (<i>Guide</i> , p 135)			
* 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:

Cagewash

Date:

Location:

	A*	M	S	C	NA
• Construction and Operation:					
o dedicated central area for sanitizing cages and equipment is provided (<i>Guide, p 143</i>)					
o cage-washing equipment meets need (<i>Guide, p 143</i>)					
o doors, windows, floors, drainage, walls, ceilings (<i>Guide, pp 136-138</i>)					
o convenient to animal areas/waste disposal (<i>Guide, p 143</i>)					
o ease of access (including door size) facilitates use (<i>Guide, p 143</i>)					
o sufficient space for staging and maneuvering (<i>Guide, p 143</i>)					
o safety precautions/clothing/equipment used for waste disposal/prewash/acid wash (<i>Guide, p 143</i>)					
o traffic flow clean to dirty with no contamination of clean equipment by dirty equipment and appropriate air pressurization (<i>Guide, p 143</i>)					
o insulation and/or sound attenuation present as needed (<i>Guide, p 143</i>)					
o utilities are appropriate (<i>Guide, p 143</i>)					
o ventilation meets heat and humidity load (<i>Guide, p 143</i>)					
o safety features (e.g., SOPs, warning signs, eyewash stations, showers) are in use. Eyewash stations (weekly) & showers (yearly) are present, flushed at appropriate intervals & documented. (<i>Guide, p 143; NIH Chemical Hygiene Plan</i>)					
o functioning safety devices to prevent entrapment in washer/sterilizers (<i>Guide, p 143</i>)					
o instructional safety signage is present for use of de-energizing and emergency exit devices. Staff training has occurred & been documented. (<i>Guide, p 143; AAALAC</i>)					
o cage wash temperatures are monitored and records are available (<i>Guide, p 73</i>)					
o appropriate clean cage storage (<i>Guide, p 141</i>)					

* 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:

Special Facilities: Aseptic Surgery

Date:

Location:

	A*	M	S	C	NA
<ul style="list-style-type: none"> • General Considerations: (NIH ARAC Guideline B6) <ul style="list-style-type: none"> o location minimizes traffic/contamination (<i>Guide, p 144</i>) o functional components (surgical support, animal preparation, surgeon scrub, operating room, postoperative recovery) are designed and separated (physically or otherwise) (<i>Guide, p 144</i>) o appropriate drug storage, control, expiration date monitoring (<i>Guide, pp 115, 122; NIH PM 1345</i>) o safe sharps disposal system (<i>Guide, p 74</i>) o adequate records of anesthesia and perioperative care (<i>Guide, p 122</i>) o aseptic procedures in use for all survival surgery (<i>Guide, pp 118-119</i>) • Operating Room: <ul style="list-style-type: none"> o effective contamination control procedures (<i>Guide, p 144</i>) o effective cleaning procedures/dedicated tools (<i>Guide, p 145</i>) o interior surfaces smooth and impervious to moisture (<i>Guide, p 145</i>) o HVAC system meets <i>Guide</i> requirements (<i>Guide, p 145</i>) o lighting safe and appropriate (<i>Guide, p 145</i>) o outlets safe and appropriate (<i>Guide, p 145</i>) o scavenging of anesthetic gases implemented (<i>Guide, p 145; NIH Waste & Anesthetic Gas Surveillance Program</i>) • Surgical Support: <ul style="list-style-type: none"> o facility for washing, sterilizing, storing instruments and supplies (<i>Guide, p 145</i>) o autoclave monitoring procedures are implemented (<i>Guide, pp 119, 145</i>) o storage of autoclaved materials maintains sterility (<i>Guide, p 145</i>) o cold sterilization procedures are appropriate (<i>Guide, p 119</i>) • Animal Preparation: contains large sink to facilitate cleaning of animal and operative site (<i>Guide, p 145</i>) • Surgeon Scrub: outside operating room, non-hand-operated sink (<i>Guide, p 145</i>) • Postoperative Recovery: allows adequate observation, easily cleaned, supports physiologic functions, minimizes risk of injury (<i>Guide, p 145</i>) • Dressing Area: place for personnel to change (<i>Guide, p 145</i>) 					
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NOTES:

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

Date:

Location:

	A*	M	S	C	NA
<ul style="list-style-type: none"> • General Considerations: <ul style="list-style-type: none"> o labs used to house animals only when scientifically required and limited to minimum period necessary (<i>Guide</i>, p 134; ARAC Guideline C4) o drug storage, control, and expiration dates (<i>Guide</i>, pp 115, 122; NIH PM 1345) o sharps disposal (<i>Guide</i>, p 74) o anesthetic monitoring (<i>Guide</i>, p 120; NIH Waste & Anesthetic Gas Surveillance Program) o scavenging of anesthetic gases (<i>Guide</i>, p 21; NIH Waste & Anesthetic Gas Surveillance Program) o safety features (e.g., SOPs, safety signs, eyewash stations, showers, secure gas cylinders) are in place. Eyewash stations (weekly) & showers (yearly) are present, flushed at appropriate intervals & documented. (<i>Guide</i>, p 19 & p 143; NIH Chemical Hygiene Plan) o carcass disposal (<i>Guide</i>, pp 73-74; NIH Waste Disposal Guide) • Additional Concerns for Survival Surgery: (rodent and minor procedures only) (NIH ARAC Guideline C6) <ul style="list-style-type: none"> o rodent survival surgery clean and uncluttered, not used for anything else during surgery (<i>Guide</i>, p 144) o records of peri-operative care (<i>Guide</i>, p 120) o aseptic procedures (<i>Guide</i>, pp 118-119) o autoclave monitoring procedures (<i>Guide</i>, pp 119, 145) o storage of autoclaved materials (<i>Guide</i>, p 145) o cold sterilization procedures are appropriate (<i>Guide</i>, p 119) • Imaging/Whole Body Irradiation: ^{NEW} (NIH PM 1341) <ul style="list-style-type: none"> o location of resource limits contamination risk (<i>Guide</i>, p 147) o appropriate transportation methods are in place (<i>Guide</i>, p 147) o gas anesthesia provision, scavenging and monitoring are appropriate (<i>Guide</i>, p 147; NIH Waste & Anesthetic Gas Surveillance Program) o appropriate sensors and ventilation are provided for cryogen gases (<i>Guide</i>, p 147) [must] o imaging console is located away from radiation source (<i>Guide</i>, p 147) • Hazardous Agent Containment: ^{NEW} (NIH PMs: 1341, 3015, 3034, 3035) <ul style="list-style-type: none"> o facility adheres to APHIS, USDA and CDC Select Agent Regulations and other federal, state and local regulations including security measures (<i>Guide</i>, p 148) [must] o Biological Safety Cabinets (BSCs) serviced annually. Grills/airflow not covered or 					

impeded.					
• Behavioral Studies: NEW					
○ facility minimizes airborne transmission of noise and ground-borne transmission of vibration (<i>Guide, p 149</i>)					
○ floor coverings reduce sound transmission (<i>Guide, p 149</i>)					
○ testing equipment allows for surface disinfection (<i>Guide, p 150</i>)					
○ components that cannot be cleaned are not in ready contact with animals and kept covered when not in use (<i>Guide, p 150</i>)					
○ housing areas are contiguous with testing areas when appropriate (<i>Guide, p 150</i>)					
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