

SEMIANNUAL REPORT
ANIMAL CARE AND USE
PROGRAM REVIEW AND FACILITY INSPECTION
OF THE

National Eye Institute (NEI)

October 2019

Section A - Site Visits & Program Review

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

Location	Type	Date	ACUC Members
Redacted by agreement	AF	9/24/19	Redacted by agreement
	SF	9/24/19	
	SF	9/24/19	
	SF	9/30/19	
	SF	10/2/19	

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

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

	Program Review Process
	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
X	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/section and then report back to the full committee the results of their designated review
	Other, please describe:

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: None

3) Animal Facility/Area Changes: 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	Guide Departure Citation (foaa #)	Justification (scientific, veterinary, or animal welfare)
An extended cage changing frequency of two-weeks has been approved for mice (5.5/cage). Mice and rats in isolation/quarantine, as well as for ground squirrels during breeding, or hibernation housed in the [Redacted by] GAF may also have an extended cage change frequency depending on the number of animals in a cage. In addition, to avoid disturbing a new mother and her litter, microisolators may be left unchanged for up to two-weeks post-partum, unless the cage is excessively soiled. In all cases, care is taken to ensure that the environment remains dry and to ensure the presence of adequate food and water.	Chapter 3, Environment, Housing, and Management, Page 70	Animal Welfare Neterinary justified and approved by the Institute or Facility Veterinarian.

<i>Housing rodents on wire mesh has been approved when scientifically justified in an ASP and is commonly approved for experimental paradigms inducing polyuria or where uniformity of light penetration into a cage would be impeded by bedding or solid flooring.</i>	<i>Chapter 3, Environment, Housing , and Management, Pages 51-52</i>	<i>Scientifically justified in an approved ASP</i>
<i>Modification of light cycles.</i>	<i>Chapter 3, Environment, Housing , and Management , Page 48</i>	<i>Scientifically justified in an approved ASP</i>
<i>Food and/or water control</i>	<i>Chapter 3, Environment, Housing , and Management , Page 65-68</i>	<i>Scientifically justified in an approved ASP</i>
<i>Extended staple/suture removal intervals to minimize stress and handling of post-partum mice.</i>	<i>Chapter 4, Veterinary Care, Page 120</i>	<i>Scientifically justified in an approved ASP or Animal Welfare</i>

2. Exceptions to the AWAR:

Species	# Animals Affected (this Period)	9CFR title/section	Description and Rationale
NHP	36	Part 3, Subpart D-3.83/Watering	<i>Chronic water control has been approved when scientifically justified in an ASP as a methodology to motivate performance of soecific operant tasks .</i>
MOU	100	Part 2, Subpart C-2.38, (k)	<i>Dark adaptation 24 hours has been approved when scientifically justified in an ASP as part of the experimental oaradigm.</i>

Section E - Previous Deficiencies & Plans:

The committee validated that the plans and schedules for deficiencies noted during the previous NEI 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 NEI program review, facility inspections, and laboratory inspections, are as follows:

	Deficiency	¹M/S	Location	Correction Plan	Responsible Party	Scheduled Completion Date (mm/dd/vv)	²Status: C/P
1	(b)(5)						

2	(b)(5)						
3	Sodium Chloride bag found open and not dated	M	Redacted by agreement	Disposed of bag	PI	9-24-19	C
4	Needle that attaches to microscope found laying exposed and sticking up	M		Corrected problem	PI	9-24-19	C
5	(b)(5)						
6	Phone jack loose from the wall	M	Redacted by agreement	Phone jack re-mounted to wall	Redacted by CAF management	9-29-19	C
7	Multiple insulin syringes found recapped in sharps box	M		The box was disposed of	Redacted by CAF management	10-16-19	C
8	Portable eyewash station located in place where personnel cannot reach it	M		Eyewash station relocated	Redacted by CAF management	10-16-19	C
9	Expired drug and chemical found opened and not dated	M		Items were disposed of	Redacted by CAF management	9-24-19	C
10	Pedasure and Similac on shelf (one was not dated) and both were not refrigerated and past "use within date"			Items were disposed of	Redacted by CAF management	9-24 -19	C
11	MMF 72 hrs sign was posted but no tag was on the cage			Removed sign, no animal under treatment currently	PI	10-7-19	C
12	Carbolime in portable Iso machine expired 8/2015			Item to be discarded and replaced	Redacted by CAF management	10-16-19	C
13	(b)(5)						
14	In refrigerator Mislabeled Bevacizumab HLR/SPRCC inj 25mg/ml exp date 4-30-2019 changed with pen to 2020 for use in pigs		Redacted by agreement	Stored unopened drugs in this refrigerator and open ones in procedure room	Redacted by CAF management	9-24-19	C
15	10% bleach container found with no lot or date			Dispose of container	PI	9-24-19	C
16	(b)(5)						
17							
18							

19	(b)(5)						
20	Multiple items not properly refrigerated or with expired dates of use. Emergency safety shower needs to be certified.	M	Redacted by agreement	Refrigerate items correctly and ensure they are within use date. Certify emergency shower	PI	10-18-19	C
21	Masking tape found holding some aluminum foil in place on some equipment	M		Replace tape	PI	10-18-19	C
22	Hood not in use nor certified	M		Post a "Do not use" sign onto the hood	PI	10-18-19	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: [**X**] **None**

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	9/30/19	Redacted by agreement
	10/2/19	
	10/2/19	

Section I - Minority Report

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

NEI ACUC Member Signatures:

Redacted by agreement

Bruce Cumming, M.D., Ph.D. Chair, ACUC
Scientist

ecm;

James M. Raber, *O.V.;* *tD.*
Attending Veterinarian

Redacted by agreement

Redacted by agreement

(Revised - 09/2019)

Semiannual Report Attachment 3
Supplemental Information
Fall 2019

1. Number of approved Animal Study Proposals (ASPs) as of 31 October 2019:

- 72

2. Performance standards:

- The NEI ACUC has approved "Fourteen Heads – Fourteen Days" policy. As an engineering standard, on day fourteen postpartum the maximum number of animals permitted in the cage is fourteen. This includes the three adults (one male, two females) and up to eleven pups whose birthdays are not more than 7 days apart. Separation of the litter on day fifteen, rather than at an earlier date is facilitated by the fact that by fourteen days postpartum most pups are supplementing their milk diet with solid food. Therefore, if one of the dams is a poor milk producer, the negative impact of separating the litter and placing some of the pups solely with the poorly lactating female is minimized.
- [Redacted by agreement] Animal Holding Rodent. Issue: Low room humidity. Reference: GUIDE, p. 44, the acceptable range of relative humidity is 30 to 70% for most species. Mitigation: This room is in a laboratory area with limited humidity control. All animals are monitored for the presence of any effects associated with low humidity environment during daily rounds. No adverse health issues have been noted due to low humidity in this room and the short holding periods used within this satellite facility.
- An extended cage changing frequency of 14 days has been approved for mice housed in the [Redacted by] CAF unless the cage is found to be excessively wet or soiled. The manufacturer of the ventilated caging system used in the facility reported that multiple sites were already using an extended cage changing schedule of 14 days with no adverse effects. The program contacted and reviewed several references that documented this and conducted an internal study using the maximum cage density approved by the manufacturer, five adult mice, which yielded no adverse consequences to the health and/or in the animal's breeding efficiencies. Per program policy, cages housing more than 5 animals/cage (i.e. breeding units) are still changed on a weekly basis. In addition, the [Redacted by] CAF has worked with various vendors to: a) develop new sipper tube that reduce the nonsensical water loss (i.e. water lost by dripping) which provides a drier microenvironment; and b) the development of a new larger water bottle. The net result of the two changes is that the water bottles can now support a 2-week change cycle. At all times, care is taken to ensure that the cage environment is not compromised, remains dry and that the animals have adequate food and water.

Institutional Animal Care & Use Committee Roster

Member Name	Degree/Credentials	Position Title	PHS Policy Membership Role	New Member
Bruce Cumming	MD, PhD	Branch Chief	Chair	<input type="checkbox"/>
James Raber	DVM, PhD	Animal Program Director	Attending Veterinarian	<input type="checkbox"/>
Redacted by agreement				<input type="checkbox"/>
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ACUC Chair Mailing Address & Phone #: National Eye Institute
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 Eye Institute

Fall Semiannual Report Submission Date: October 31, 2019

Spring Program Review Date(s):	4/16/19					
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Fall Program Review Date(s):	10/15/19					
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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	3/20/19	9/24/19	65251	¹ Mice	² Rats	³ Rabbit	¹ 26,221	² 629	³ 0
				⁴ Macaques	⁵ Marmosets	⁶ Ground Squir.	⁴ 314	⁵ 258	⁶ 150
	3/20/19	9/24/19		¹ Pigs	² Sand Rats	³ Geckos	¹ 6	² 24	³ 19
				⁴	⁵	⁶	⁴	⁵	⁶
	3/20/19	9/24/19	150	¹ Zebra fish	²	³	¹ 2,546	²	³
				⁴	⁵	⁶	⁴	⁵	⁶
	3/20/19	9/24/19	150	¹ Zebra fish	²	³	¹ 3,597	²	³
				⁴	⁵	⁶	⁴	⁵	⁶
	3/26/19	9/30/19	90	¹ Zebra fish	²	³	¹ 498	²	³
				⁴	⁵	⁶	⁴	⁵	⁶

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

IC Name: National Eye Institute

Spring Semiannual Report Submission Date: October 31, 2019

CONTINUATION PAGE

Bldg/Area/Rm	Facility Insp. Date(s) Spring / Fall		AF/SF; Gross Sq. Ft.	Species Housed			Average Daily Inventory		
				1	2	3	1	2	3
Redacted by agreement	3/26/19	10/2/19	100	Mice			10		
				4	5	6	4	5	6
				1	2	3	1	2	3
				4	5	6	4	5	6
				1	2	3	1	2	3
				4	5	6	4	5	6
				1	2	3	1	2	3
				4	5	6	4	5	6
				1	2	3	1	2	3
				4	5	6	4	5	6

ANIMAL PROGRAM SEMIANNUAL ASSESSMENT CHECKLIST
(Based upon 2011 Guide)

DATE: 10/15/19

	PROGRAM AREAS	GUIDE Page	ACCEPT	Type of Deficiency	
				MINOR	SIGNIF
I	ANIMAL CARE & USE PROGRAM				
A	Program Management & Responsibility	13-24	✓		
	• Key Management Personnel – IO, Attending Vet, ACUC	13-15	✓		
	• Collaborations – Review of IAAs, MOUs, Contracts (PM 3040-3)	15	✓		
	• Training & Education – Vets/Professional Staff, Animal Care, Researchers, ACUC	15-17	✓		
	• Occupational Health & Safety – Control & Prevention, Hazard ID & Risk Assessment, Facilities, Equipment & Monitoring, Training, Hygiene, Research Hazards, Protection, Medical Eval (LAAPP, PM 3044-2, Visitors)	17-23	✓		
	• Personnel Security	23	✓		
	• Investigating & Reporting Animal Concerns (ARAC C2)	23-24	✓		
B	Program Oversight	24-34	✓		
	• Animal Care and Use Committee – Roles, Constitution, & Function (ARAC C1, C5); Non-affiliate participation; DMR Policy in place.	24-25	✓		
	• Standard Operating Procedure Review	25	✓		
	• Animal Study Proposal Review – de novo, Annual Reviews, Amendments, FGR, DMR	25-33	✓		
	o Use-Benefit Analysis	27	✓		
	o Protocol Endpoints (ARAC B13)	27-28	✓		
	o Unexpected Outcomes	28-29	✓		
	o Physical Restraint (Prolonged)	29-30	✓		
	o Multiple Survival Surgery Procedures	30	✓		
	o Food & Fluid Regulation (ARAC B7)	30-31	✓		
	o Non-Pharmaceutical Grade Compounds (ARAC B14)	31-32	✓		
	• Post-approval Monitoring	33	✓		
C	Disaster Planning & Emergency Preparedness	35	✓		
II	ENVIRONMENT, HOUSING, & MANAGEMENT				
A	Terrestrial Animal Environment Temp, Humidity, Ventilation, Air Quality, Illumination, Noise & Vibration	42-50	✓		
B	Terrestrial Housing – Primary Enclosure, Enrichment, Outdoor Housing, Naturalistic Environments, Space	50-63	✓		
C	Terrestrial Management – Behavior & Social Management (Activity, Social Environment, Habituation, & Training) (ARAC D4, D4a, D4b), Husbandry (Food & Water), Bedding/Nesting Materials, Sanitation (Bedding Change, Waste Disposal, & Effectiveness), Pest Control, Emergency, Weekend, & Holiday Care, Population Management (Identification, Recordkeeping, Breeding, Nomenclature, & Genetics); ACUC Review & Approval of Multiple Species in Same Room; Rodent & Aquatic Social Housing Policy.	63-77	✓		
D	Aquatic Animal Environment – Water Quality, Support System, Temperature, Humidity, Ventilation, Illumination, Noise & Vibration	77-82	✓		
E	Aquatic Housing – Primary Enclosure, Enrichment, Social Housing, Outdoor Housing, Naturalistic Environments, Space	82-83	✓		
F	Aquatic Management – Behavior & Social Management, Husbandry (Food, Water, Substrate, Sanitation (Micro & Macroenvironment), Waste Disposal, Pest Control, Emergency, Weekend, & Holiday Care, Population Management (Identification, Recordkeeping)	84-88	✓		
III	VETERINARY CARE				
A	Animal Procurement & Transportation (ARAC A1a, A1b, CC Policy)	106-107	✓		
B	Preventive Medicine – Biosecurity, Quarantine, Stabilization, Separation of Species, & Disease Surveillance, Diagnosis, Treatment, Control (PM 3043-1, PM3044-1, ARAC D3)	109-113	✓		
C	Clinical Care & Management – Medical Management, Emergency Care, & Recordkeeping	113-115	✓		
D	Surgery – Training, Planning, Facilities, Procedures, Aseptic Technique, Intra-Op Monitoring, Post-Op Care	115-120	✓		
E	Pain & Distress (ARAC B12, P&D Memo)	120-121	✓		
F	Anesthesia & Analgesia (PM 1345)	121-123	✓		
G	Euthanasia – Flowmeters present; flow rate appropriate for chamber size (ARAC B4, B5: Flow Calculator)	123-124	✓		
IV	PHYSICAL PLANT				
A	Functional Areas – Housing, Care, Sanitation, Receipt, Quarantine, Separation of Species, Storage	135-136	✓		
B	Construction Guidelines – Corridors, Doors, Windows, Floors, Drains, Walls/Ceilings, HVAC, Power, Lighting/Light Timer Override, Storage, Noise, Vibration, Sanitization Facilities, Environmental Monitoring	136-143		✓	
	Safety Devices – Showers, Eyewashes (flushing intervals & documentation), Escape for Cage/Rack Washers, Autoclaves & Instructional Safety Signage & Staff Training; BSCs (annual servicing: air flow not impeded)	143		✓	
C	Special Facilities – Surgery, Barriers, Imaging, Irradiators, Hazard Containment, Behavior Studies, Aquatics	143-150	✓		
D	Security & Access Control	151	✓		

ACCEPT = Category found to be in accordance with regulations & policies.

SIGNIF = Significant Deficiency; i.e. may present a threat to the health and safety of animals or humans.

Rev 12/2016