

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 foaae #) | Justification (scientific, veterinary, or animal welfare) |
|---|---|--|
| <p>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.</p> | <p>Chapter 3, Environment, Housing, and Management, Page 70</p> | <p>Animal Welfare Neterinary justified and approved by the Institute or Facility Veterinarian.</p> |

| | | |
|---|--|--|
| <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 | ¹ M/S | Location | Correction Plan | Responsible Party | Scheduled Completion Date (mm/dd/vv) | ² Status: 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 currentlv | 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 piqs | | 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 loa 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=significant

²C=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



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"/> |
| | | | | <input type="checkbox"/> |

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 | | | | | |
|--------------------------------|---------|--|--|--|--|--|

| | | | | | | |
|------------------------------|----------|--|--|--|--|--|
| Fall Program Review Date(s): | 10/15/19 | | | | | |
|------------------------------|----------|--|--|--|--|--|

| Bldg/Area/Rm | Facility Insp. Date(s) Spring / Fall | | AF/SF; Gross Sq. Ft. | Species Housed | | | Average Daily Inventory | | |
|-----------------------|---|---------|-------------------------|----------------|-------------|-----------------|-------------------------|-------|-------|
| | | | | 1 | 2 | 3 | 4 | 5 | 6 |
| 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 | 1 Mice | 2 | 3 | 1 | 10 | 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 | |
| | | | | 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 | ✓ | | |
| | | 24-34 | ✓ | | |
| B | Program Oversight | | | | |
| | • 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, FCR, 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