SEMIANNUAL REPORT

ANIMAL CARE AND USE
PROGRAM REVIEW AND FACILITY INSPECTION
OF THE

National Eye Institute (NEI)

April 2020

Section A – Site Visits & Program Review

1) Inspections of the **NEI** 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	AF	02-24-20 thru 03-04-20	Redacted by agreement
	SF	02-24-20 thru 03-04-20	
	SF	02-24-20 thru 03-04-20	
	SF	02-26-20 and 03-04-20	
	SF	02-26-20	

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, 8th 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/sections 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:

Role (ACUC Chair, ACUC AV, IC APD, or IC Animal Program Manager)	**Name**	**Action** (joined or departed)
NEI Redacted by agreement CAF Animal Facility Manager	Redacted by agreement	Departed

3) Animal Facility/Area Changes: N/A

Facility Type (AF/SF)	**Location**	**Action** (opened, closed, under renovation, etc.)

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 (page #)***	***Justification** (scientific, veterinary, or animal welfare)*
An extended cage changing frequency of two-weeks has been approved for mice (≤5/cage). Mice and rats in isolation/quarantine, as well as for ground squirrels during breeding, or hibernation housed in the Redacted by *CAF 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/Veterinary justified and approved by the Institute or Facility Veterinarian.*
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.	*Chapter 3, Environment, Housing, and Management, Pages 51-52*	*Scientifically justified in an approved ASP*
Modification of light cycles.	*Chapter 3, Environment, Housing, and Management, Page 48*	*Scientifically justified in an approved ASP*
Food and/or water control	*Chapter 3, Environment, Housing, and Management, Page 65-68*	*Scientifically justified in an approved ASP*
Extended staple/suture removal intervals to minimize stress and handling of post-partum mice.	*Chapter 4, Veterinary Care, Page 120*	*Scientifically justified in an approved ASP or Animal Welfare*

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	*Chronic water control has been approved when scientifically justified in an ASP as a methodology to motivate performance of specific operant tasks.*
MOU	100	Part 2, Subpart C-2.38, (k)	*Dark adaptation ≥ 24 hours has been approved when scientifically justified in an ASP as part of the experimental paradigm.*

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/yy)	[2]Status: C/P
1	(b)(5)						
2							
3	Posting of outdated NIH Institutional Official letter on reporting animal welfare concerns	M	Redacted by agreement	Posted updated letter.	Redacted by CAF management and NEI ACUC coordinator	Corrected on the spot	C
4	Animals Present signage (for potential animal allergens present) not posted	M		Posted Animals Present signage.	NEI animal program personnel and ACUC coordinator	Corrected on the spot	C
5	Several expired drugs and containers with solutions found not labelled or dated properly	M		Items were disposed of	NEI animal program personnel and ACUC coordinator	Corrected on the spot	C
6	Instructions for the proper use of CO2 for rodent euthanasia not posted	M		Posted the CO2 flow rate guidance document	NEI animal program personnel and ACUC coordinator	Corrected on the spot	C

[1]M=minor; S=significant **[2]C=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	03-03-20	Redacted by agreement
	02-25-20	
	12-06-19	
	02-06-20	
	03-05-20	

Section I – Minority Report

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

NEI ACUC Member Signatures:

Redacted by agreement

Redacted by agreement

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

James M. Raber, D.V.M., Ph.D.
Attending Veterinarian

Redacted by agreement

(Revised – 03/2020)

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ANIMAL PROGRAM SEMIANNUAL ASSESSMENT CHECKLIST

(Based upon 2011 Guide)

DATE: 02-24-20/03-04-20

	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, ECR, DMR*	25-33	✓		
	○ Use-Benefit Analysis	27	✓		
	○ Protocol Endpoints *(ARAC B13)*	27-28	✓		
	○ Unexpected Outcomes	28-29	✓		
	○ Physical Restraint *(Prolonged)*	29-30	✓		
	○ Multiple Survival Surgery Procedures	30	✓		
	○ Food & Fluid Regulation *(ARAC B7)*	30-31	✓		
	○ 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

April 16, 2020

Redacted by agreement Staff Reduction Plan

10-49% Staff Reduction:

- **Suspend staff training**
- **Shift underutilized labor & retrain staff as needed**
- **Reduce rodent plastic lid & wire bar changes to once every four (4) weeks**
- Maintain routine rodent cage bottom change frequency [≤ 5 mice, 2 wk.; >5 mice, 1 wk.; rat, 1 wk.]
- Maintain all mouse water bottle changes to once every two (2) weeks and rat water bottle changes to once (1) per week
- Maintain established facility sanitation programs, **except suspend the monthly animal room wall and ceiling decontamination**
- Dependent upon labor availability, **reduce health checks to once per day** (Large & Small)
- **Old World NHP pans changed every other day (EOD) throughout the week**; racks once every 2 weeks
- No change in marmoset pan liner (2x/week) or rack changeout (2x/week)
- Consider asking PIs and investigative staff to reduce technical requests (e.g. special food/water, etc.)
- Ask investigators to coordinate their visits to the facility with the Building 49 Government management, the Facility Manager or Chief, Operations Management (Mr. Plemons)

≥50% Staff Reduction:

- **Reduce mouse cage bottom change frequency [≤ 5 mice, 4 wk.: >5 mice, 2 wk.]** with spot changing
- Maintain rat cage bottom changeout at 1x/week
- **Reduce rodent plastic lid & wire bar changes to as needed and transfer feed to the new feeder**
- Maintain all mouse water bottle changes to once every two (2) weeks and rat changes to once per week
- **Top off feed with each water bottle change,** once every two (2) weeks for mice and once per week for rats
- No change in Old World NHP pan change schedules (EOD); racks change outs once every 2 weeks
- No change in marmoset pan liner (2x/week) or rack changeout (2x/week)
- **Suspend imports, exports, and transfers**
- **Suspend sentinel submissions & TB testing**
- **Depending on staff availability, provide investigators/APDs a 24-48-hour notice that standing technical requests will be suspended**
- **Depending on staff availability, suspend non-essential fruit and vegetable supplementation/feeding, enrichment programs, etc.**
- **Require investigators to perform their own special food/water requests or approve routine, ad lib food/water for their animals**

≥75% Staff Reduction:

- **Suspend daily census**
- Every other day Old-World NHP pan change; racks **as needed**
- Change marmoset pan liners 2x/week; racks **as needed**

≥90% Staff Reduction:

- **Ensure all animals are provided with food and water**
- **All cage change on an as-needed basis**
- **Consider recruitment of outside help to support facility functions (e.g. investigators, etc.)**
- **Consider changes in feeding frequency/intervals where possible depending on species**
- **Consider colony reduction**

Item Number	Phamaceutical Name	Source	Form to be obtained (liquid/powder)	Pharmaceutical grade (Yes/No) If "No", Provide Grade to be	*Modification for use? (Dissolve/dilute/filter/etc. Buffer/excipient/pH	Precautions taken to assure sterility	Route of administration and volume	Dose	* Other significant considerations (potential toxity, safety issues, etc.)	Reference (literature/prior experience, as appropriate)

* Briefly state details here, if a expanded discussion is required, place it in the appropriate section of ASP

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Eye Institute
Bethesda, Maryland 20892

Date: March 17, 2020

From: Redacted by agreement
Redacted by agreement NEI Animal Care and Use Committee

Dr. Bruce Cumming
Chair, NEI Animal Care and Use Committee

Dr. James M. Raber
NEI Animal Program Director

Subject: Waiver of Voting Rights at Unattended, Fully Convened NEI ACUC Meetings

I, _____, as a full voting member of the NEI Animal Care and Use Committee (ACUC), do hereby agree that if I am unable to attend a regularly scheduled, fully convened meeting of the ACUC that a unanimous vote by the quorum of ACUC members present may choose Designated Member Review (DMR) subsequent to full Committee review when modifications are required to secure approval of an item before the Committee. I may also, at any time, request to see the revised protocol or amendment and/or request Full Committee Review (FCR) of the protocol or amendment.

This waiver does not affect the voting ability of my alternate, if any, who might attend the meeting, nor does it affect my right to submit comments to the Chair or the ACUC Executive Secretary prior to the fully convened meeting.

About The Workshop

SCAW's IACUC Training Workshop educates and trains individuals who work with laboratory animals in research, testing and education. They include IACUC members and administrators, Principal Investigators, Attending Veterinarians, regulatory personnel and laboratory animal care staff. The regional workshop format lets small groups discuss specific topics that are relevant to IACUC functions. Each workshop is structured in similar design, with slight changes made to meet local needs.

It is expected that this course will be approved for 6 hours of continuing education credit in jurisdictions which recognize **AAVSB RACE** approval; however, participants should be aware that some boards have limitations on the number of hours accepted in certain categories and/or restrictions on certain methods of delivery of continued education. Call the SCAW office at 301.345.3500 for further information.

This workshop will help meet the requirement stated in the *Guide for the Care and Use of Laboratory Animals* 8th edition, 2011 that states "All personnel involved with the care and use of animals must be adequately educated, trained, and/or qualified in basic principles of laboratory animal science to help ensure high-quality science and animal well-being." It will also address USDA/APHIS/AC Policy 15.

SCAW encourages local institutions and others to co-sponsor SCAW's IACUC Training Workshops. Please contact the SCAW office if you are interested in sponsoring a workshop.

SCAW's IACUC Training Workshop is Sponsored with: OACU/NIH/DHHS; OLAW/NIH/DHHS; CITI Program at BRANY; e-tune software, Inc; Tech Software, Inc; Merck Inc.

Funding for this conference was made possible in part by the Office of Laboratory Animal Welfare, NIH. The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of HHS; nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government.

If you receive a duplicate of this announcement, our apologies. Please share any duplicates with your colleagues.

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2660 NE Hwy 20, Suite 610-115
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Email: info@scaw.com
Web: www.scaw.com

"...promoting best practices in animal research and testing"

Redacted by agreement
Chief, Animal Program Administration
National Institutes of Health

Redacted by agreement

T2/P468

Remember you can register on-line at *www.scaw.com*

SCAW | SCIENTISTS CENTER FOR ANIMAL WELFARE

IACUC Training Workshop

National Institutes of Health
Natcher Conference Center
Building 45
William H. Natcher Building
Bethesda, MD

May 18, 2020

NIH National Institutes of Health
Turning Discovery Into Health

NIH National Institutes of Health
Office of Laboratory Animal Welfare

" ...promoting best practices in animal research and testing"

Program

8:00 **Registration and Continental Breakfast**

8:30 **Introduction and Welcome to IACUC Training**
Gregory R. Reinhard, DVM, MBA, DACLAM, CPIA

8:45 **Keynote: The Ethics of Using Animals In Research: A Question of Science, Humaneness and Societal Need**
Ernest D. Prentice, PhD

9:30 **Collateral Damage: How IACUC Actions Could Have Far-Reaching Effects**
Randall J. Nelson, PhD

10:00 **Break**

10:30 **Concepts on Compliance for an IACUC**
Gregory R. Reinhard, DVM, MBA, DACLAM, CPIA

11:00 **The IACUC: A View From Inside the Cage**
John F. Bradfield, DVM, PhD, DACLAM

11:30 **Quality Data and Reproducibility in Animal Research: Does the IACUC Have a Role?**
Paul G. Braunschweiger, PhD

Noon **Lunch**

1:00 **Are You Up to Date with APHIS, OLAW and AAALAC International? Q & A for You and Me**
Introduction and Moderator:
Gregory R. Reinhard, DVM, MBA, DACLAM, CPIA
Panelists:
Axel V. Wolff, MS, DVM; OLAW Representative
Carol Clarke, DVM, DACLAM; USDA/APHIS/AC Representative
Randall J. Nelson, PhD; AAALAC International Representative

2:00 **Under the Microscope: Examining Your Programs Before Others Do**
Ernest D. Prentice, PhD
Axel V. Wolff, MS, DVM; OLAW Representative
Carol Clarke, DVM, DACLAM; USDA/ APHIS/ AC Representative
Randall J. Nelson, PhD; AAALAC International Representative

3:00 **Break**

Afternoon Concurrent Sessions - Choose One Track

3:30-5:00
(1st Track)
Active Learning as a Component of IACUC Training; **The Guide's 15 Topics for Protocol Review: The Rationale and Purpose for Each**
J. G. Collins, PhD
Patricia A. Brown, VMD, MS, DACLAM; OLAW Representative
(Registration limited to 20 participants. Please email info@scaw.com to become a registrant. You will receive a return email confirming that you are a participant.)

3:30-5:00
(2nd Track)
Case Studies Involving Noncompliance and Research Misconduct: Your Recommendations?
Ernest D. Prentice, PhD
Randall J. Nelson, PhD
Axel V. Wolff, MS, DVM; OLAW Representative
Carol Clarke, DVM, DACLAM; USDA/ APHIS/AC Representative

Workshop Information: **SCAW's IACUC Training Workshop** will be held at the NIH-Natcher Conference Center, Auditorium, Lower Level, 45 Center Dr, Bethesda, MD 20894.

The campus is located on the Red Line at the Medical Center Metro stop. Proceed to the NIH Gateway Center for security clearance. Check SCAW 's website for security, general and parking information at www.scaw.com.

Hotel Information:
Bethesda Marriott
5151 Pooks Hill Road
Bethesda, MD 20814
Sleeping Room rate: $199.00 plus taxes
For reservations call reservations at, 800.393.3412 and referencing the SCAW Group Block or go to the SCAW website to book online.
Cutoff date: April 24, 2020
Hotel will provide transportation services for one daily round-trip transport to and from NIH for hotel guests only.

Additional sponsors;

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CITI PROGRAM

Registration Form:

_____Individual	399.00
_____SCAW Institutional Member NIH Employees	325.00
_____Student	160.00

Name: (Attendees please print clearly)

_____

Job Title:

_____

Company Name, Street Address, City, State, Zip:

_____

_____

_____

_____

E-mail and Telephone (Please print clearly)

_____

_____

Registration fee includes attendance at all sessions, workshop materials and food. Checks must be made payable to SCAW. Please return fee along with this form to SCAW by **May 13, 2020**. Confirmation of registration will be e-mailed to you. There will be no refund of the registration fee.

I will pay for my registration with:

___Check enclosed ___ Credit Card

_ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _
Card number

Expiration Date: __ __ /__ __ Security Code# _____

Billing zip code _ _ _ _ _

Name and e-mail address of cardholder:
(Please print clearly)

_____

_____

Authorized signature:

_____

Semiannual Report Attachment 3
Supplemental Information
Spring 2020

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 agreement 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 agreement 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.

Veterinary Verification & Consultation:

- See ***attachment 1*** NEI VVC policy.

Animal Adoption:

No animals were adopted from the NEI.

- See ***attachment 2*** NEI adoption policy.

NEI Animal Care and Use Committee Policy Regarding Significant Changes to Previously Approved Animal Activities

All amendments to approved animal study protocols will be reviewed by the NEI ACUC Executive Secretary, in consultation with the ACUC Chair and/or Animal Program Director, for compliance with this approved policy. Amendments approved for Veterinary Verification & Consultation (VVC) approval are subsequently submitted to the NEI ACUC for review and documentation in the Committee minutes.

1. **Significant changes that must undergo either Full NEI ACUC Committee Review (FCR) or Designated Member Review (DMR) and be documented in the minutes of the ACUC:**
    a) Changes from non-survival to survival surgery;
    b) Changes resulting in greater pain, distress, or degree of invasiveness;
    c) Changes in housing and or use of animals in a location that is not currently part of the animal program overseen by the ACUC;
    d) Changes in species;
    e) Changes in animal numbers > 15%;
    f) Changes in study objectives;
    g) Changes in Principal Investigator (PI);
    h) Changes that could impact personnel safety;
    i) Other changes not specifically outlined in this policy.

2. **Significant changes that may undergo Veterinary Verification & Consultation (VVC):**
    a) Changes in anesthesia, analgesia, sedation, or experimental substances;
    b) Change in method of euthanasia (as long as the new method is approved in the AVMA Guidelines for the Euthanasia of Animals and ARAC Guidelines); and
    c) Change in duration, frequency, type, or number of procedures performed on an animal.

    The NEI ACUC authorizes the NEI Animal Program Director/Attending Veterinarian or, in their absence, the NEI Institute Veterinarian to make VVC approved changes as outlined above. **All changes made under VVC shall not impact the parameters outlined in #1 above.** All changes must be documented as an amendment to the approved Animal Study Proposal (ASP) and be signed by the Principal Investigator and the endorsing veterinarian. The approved amendment shall subsequently be circulated to the appropriate animal facilities by the NEI ACUC Coordinator and submitted to the NEI ACUC for subsequent review and documentation in ACUC minutes.

    The above veterinarians serve as subject matter experts for the ACUC and are approved to make changes in the anesthesia, analgesia, sedation, and/or euthanasia methods previously delineated on an approved ASP within the limits of: a) current publications and literature; b) the *Formulary for Laboratory Animals* (Hawk, et. al.); c) the *Exotic Animal Formulary* (Carpenter); d) the *Veterinary Drug Handbook* (Plumb); e) *Lumb and Jones's Veterinary Anesthesia and Analgesia* (Tranquilli, et. al.); f) the *American College of Laboratory Animal Medicine Series*; g) the AVMA Guidelines for Euthanasia; and h) what is considered routine and customary in the practice of veterinary/laboratory animal medicine. All changes must be appropriate for the species, age, size, and physical condition of the animal(s) in question. Care must be taken to ensure that the changes do not alter the established scientific objectives, outcomes, or endpoints. Furthermore, care must be taken to ensure that VVC changes shall not impact the parameters outlined in #1 above.

    The veterinarians identified above are authorized by the ACUC to approve modifications to the duration, frequency, type, or number of procedures performed on an animal. The modifications should be refinements of previously approved procedures, rather than the approval of new procedure or techniques, and not anticipated to impact the health and/or well-being of the animal. Changes which result in additional major survival surgeries must undergo FCR or DMR.

The veterinarians identified above are authorized by the ACUC to approve modifications to the route, method, dose, volume, and frequency of an experimental substance being administered under an approved ASP. In addition, modifications can be made in the approved experimental substance if the new substance belongs to the same class of compounds and/or is anticipated to produce similar physiological outcomes (i.e. immunosuppression, vasodilation, etc.) and has the same or fewer side effects/toxicity. All changes must be appropriate for the species, age, size, and physical condition of the animal(s) in question. Changes that could increase the potential for side effects and toxicity, or require a different vehicle or composition for safe administration must undergo FCR or DMR.

3. **Significant changes that may be handled administratively:**

   a) With the concurrence of the ACUC Chair, an increase in previously approved animal numbers up to ***a total of 15% of the approved original allocation may be handled administratively during the three year life of an ASP***. The change must be documented as an amendment to the approved ASP and include a justification for the increase that supports the original study objectives outlined on the approved ASP. The amendment must be signed by the Principal Investigator and the endorsing ACUC Chair. The approved amendment shall subsequently be circulated to the appropriate animal facilities by the NEI ACUC Coordinator and submitted to the NEI ACUC for review and documentation in the ACUC minutes.

   b) With the concurrence of the ACUC Chair, ***additional stock or strain of animals may be added to an approved ASP*** and handled administratively if the new stock or strain does not possess the potential for adverse physiological outcomes requiring special husbandry or support. The change must be documented as an amendment to the approved ASP and include a justification for the addition that supports the original study objectives outlined on the approved ASP. The amendment must be signed by the Principal Investigator and the endorsing ACUC Chair. The approved amendment shall subsequently be circulated to the appropriate animal facilities by the NEI ACUC Coordinator and submitted to the NEI ACUC for review and documentation in the ACUC minutes.

   c) ***Changes in the animal holding or procedure locations*** identified on an approved ASP can be handled administratively with the concurrence of the ACUC Chair if: a) the new holding location is not a new satellite location; b) the animal holding location is part of the NIH animal program and overseen by an IC ACUC at the NIH; c) the new holding or procedure location is endorsed by both the APD and SD; and d) there are no safety issues resulting from the changes. The change must be documented as an amendment to the approved ASP and include a justification for the addition that supports the original study objectives outlined on the approved ASP. The amendment must be signed by the Principal Investigator and the endorsing ACUC Chair. The approved amendment shall subsequently be circulated to the appropriate animal facilities by the NEI ACUC Coordinator and submitted to the NEI ACUC for review and documentation in the ACUC minutes.

Approved by the NEI ACUC: March 3, 2015
Revised and approved by the NEI ACUC: August 18, 2015
Revised and approved by the NEI ACUC: January 19, 2016
Revised and approved by the NEI ACUC: May 16, 2017

GUIDELINES FOR ANIMAL TRANSFER TO PRIVATE OWNERSHIP

The transfer of ownership of a laboratory animal from the Federal Government to a private recipient is endorsed by the National Institutes of Health as described in the attached memorandum dated June 5, 2014. This Guideline delineates the process, including the roles and responsibilities of the involved Government parties.

1. A ***Transfer of Animal Ownership Agreement*** (Attached) must be completed for each animal or transfer. Original signed agreements shall be maintained on file with the Animal Study Proposal from which the animal(s) were transferred.
2. The NIH program transferring the animal(s) must assess the appropriateness of the transfer with regard to the species being transferred, age and health status of the animal, as well as the husbandry and care required of the recipient, and previous use. In general, exotic species and genetically modified animals are not good candidates for transfer to private ownership.
3. The Animal Program Director of the providing institution must ensure that previous research manipulations, medical history, and current health status all support the proposed animal's candidacy for transfer of ownership.
4. In most situations, the Approving Official will be the providing institution's Scientific Director or their agent. The Approving Official:
    a. ensures the animal is of no current monetary value or functional use to the NIH or other entities of the Government;
    b. determine if the cost of continued care and handling of the animal exceeds the cost of any potential sale of the animal; and
    c. ensures that the original cost to acquire the animal was less than $500.
5. Both the Animal Program Director and Approving Official have the responsibility to ensure that there is no conflict of interest throughout the process, from animal procurement to the animal's transfer.

TRANSFER OF ANIMAL OWNERSHIP AGREEMENT

This Transfer of Animal Ownership Agreement has been adopted for use by the National Institutes of Health (NIH) to transfer the legal ownership of an animal(s) from the Federal Government to a ***private recipient*** pursuant to 41 C.F.R. 102-36.305-330.

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Provider (name of the NIH program transferring ownership of the animal(s)):

Recipient (name of individual receiving the animal(s)):

The Provider agrees to transfer the following animal(s) to the Recipient (describe the animal(s)):

TERMS OF AGREEMENT

- *Recipient agrees to use the animal(s) solely for non-commercial purposes and will not sell or otherwise transfer the animal.*
- *Provider has attached to this Agreement documents concerning the animal's relevant medical history and current health status.*
- *Recipient agrees that it will adhere to all applicable national and local standards for the humane care and handling of the animal(s), and assures the Provider that they understand the animal's husbandry requirements and have the resources to provide the required care.*
- *In accepting the animal(s), Recipient accepts full ownership, custody, and control of the animal(s), except that to the extent the Government has any patent, invention or any other intellectual property rights in the animal(s), the Government retains these rights. Additionally, to the extent that any party other than the Government has any patent, invention or other intellectual property rights in the animal(s), these rights are not transferred to the Recipient.*
- *The animal(s) is/are transferred to the Recipient with no warranties, express or implied, including any warranty of merchantability or fitness for a particular purpose. Unless prohibited by law from doing so, Recipient agrees to hold the United States Government harmless and to indemnify the Government from all liabilities, demands, damages, expenses and losses arising out of Recipient's care, use, or treatment of the animal(s).*
- *Recipient agrees not to claim, infer, or imply Governmental endorsement of the Recipient, the institution or personnel.*
- *The undersigned Recipient expressly certifies and affirms that the statements made herein are truthful and accurate.*
- *The undersigned Provider expressly certifies and affirms that he or she is authorized to sign this Agreement on behalf of their institution, the animal is of no current monetary value or functional use to NIH or to other entities of the Government, that the costs of continued care and handling of the animal exceed the costs of any potential sale of the animal, that the original cost to acquire the animal was less than $500.00 and that the statements made herein are truthful and accurate.*

This animal transfer agreement shall be construed in accordance with Federal law as applied by the United States Court of Appeals for the District of Columbia.

_____ _____

Date Recipient Signature

_____

Recipient's Name, Title, Mailing Address (Please Print)

_____ _____

Date Animal Program Director's Signature

_____

Animal Program Director's Name, Mailing Address (Please Print)

_____ _____

Date IC Approving Official's Signature

_____

IC Approving Official's Name, Title, Mailing Address (Please Print)

April 30, 2020

Assurance#: A-4149-01

Date: _____

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	☐
James Raber	DVM, PhD	Animal Program Director	Attending Veterinarian	☐
Redacted by agreement				☐
				☐
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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

Semiannual Report Submission Date: April 30, 2020

Spring Program Review Date(s):	4/21/20					

Fall Program Review Date(s):						

Bldg/Area/Rm	Facility Insp. Date(s) Spring / Fall	AF/SF; Gross Sq. Ft.	Species Housed			Average Daily Inventory		
Redacted by agreement	2-24-20 to 3-4-20	65251	1 Mice	2 Rats	3 Rabbit	1 20,590	2 613	3 0
			4 Macaques	5 Marmosets	6 Ground Squir.	4 296	5 243	6 178
	2-24-20 to 3-4-20		1 Pigs	2 Geckos	3	1 9	2 16	3
			4	5	6	4	5	6
	2-24-20 to 3-4-20	150	1 Zebra fish	2	3	1 2,483	2	3
			4	5	6	4	5	6
	2-26-20 to 3-4-20	150	1 Zebra fish	2	3	1 3,316	2	3
			4	5	6	4	5	6
	2-26-20 and 3-4-20	90	1 Zebra fish	2	3	1 547	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

Semiannual Report Submission Date: April 30, 2020

CONTINUATION PAGE

Bldg/Area/Rm	Facility Insp. Date(s) Spring / Fall		AF/SF; Gross Sq. Ft.	Species Housed			Average Daily Inventory		
Redacted by agreement	2-26-20		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