

SEMIANNUAL REPORT

ANIMAL CARE AND USE
PROGRAM REVIEW AND FACILITY INSPECTION
OF THE

_____NIEHS_____

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 (Surg) are performed (as applicable) were conducted as indicated below:

Location	Type	Date	ACUC Members	
Redacted by agreement	AF, Surg	8/26/2019-8/28/2019	Redacted by agreement	Laber,
	Surg	9/12/2019		
	SF	9/17/2019		
	AF	8/28/2019		

- 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)
X	NIEHS Semiannual walk through summary
X	NIEHS Animal Facility Checksheet
X	NIEHS Laboratory Inspection Log
X	NIEHS Standard Operating Procedures and Guidelines

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

	Program Review Process
	Full committee member review for <i>ALL</i> 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 Section F 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:

- a) The NIEHS SOP for Social Housing Procedures for Mice and Rats was presented, discussed, and unanimously approved by the ACUC 7/25/2019.
- b) The NIEHS SOP for Set Up and Operation of the Kent Scientific CODA Blood Pressure System was presented, discussed, and approved by the ACUC 7/25/2019.
- c) On July 25, 2019 the ACUC discussed and voted unanimously to approve the review of contract SOW by Designated Member Review.
- d) The annual review transitioned to an eSirius electronic process May 1, 2019. On July 25, 2019 the committee discussed and voted unanimously to have the annual reviews reviewed by DMR. A list of the reviewed protocols will be included on the monthly meeting agenda and minutes and the ACUC meeting date will serve as the DMR approval date.

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)
NA		

3) Animal Facility/Area Changes:

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

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)
Rodents housed on wire flooring	Guide page 51	Protocols approved include a scientific justification for the use of metabolism cages if housed on perforated

		<p>stainless-steel flooring for greater than 24 hours. These animals are acclimated to the chambers and are monitored by the CMB Veterinary Medicine Section. No problems have been observed. Currently there are four approved studies for housing mice and rats in metabolism cages for >24 hours.</p> <p>A protocol is approved with a scientific justification for a maternal bedding restriction study involving the housing of mouse dams and pups from PND 2-9 in a standard cage with fine mesh and a nesting square to induce stress in the mothers and pups.</p>
Ambient Housing temperature not in accordance with Guide recommendations	Guide page 43	<p>A protocol is approved with a scientific justification for housing mice at 4C for a maximum of 16 hours in order to study specific gene expression involved in energy metabolism. These animals have been monitored by the CMB Veterinary Medicine Section and no problems have been observed.</p> <p>A protocol is approved with scientific justification for housing mice at 12-17C for 4 weeks to study the effects of cold exposure on metabolism. Animals are monitored daily and then more frequently as core body temperature begins to drop. The CMB Veterinary Medicine Section will actively monitor the animals with the lab.</p>
Prolonged Restraint	Guide page 29-30	<p>One protocol is approved for prolonged restraint for a period of three hours repeated five consecutive days without acclimation to the restraint system to induce stress-related feeding behavior. The study participants continuously monitor mice during the restraint protocol. If mice fail to acclimate within fifteen minutes as determined by intense persistent struggling behavior, the restraint procedure will be terminated and the animal removed from the protocol.</p>

		One protocol is approved for prolonged restraint for a period of three hours repeated thirty consecutive days to restrict vertical activity to induce stress. The animal is still able to move forward and backward. Intense distress is not expected because horizontal movement is not impeded. Study participants continuously monitor mice during the vertical restriction protocol.
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2. Exceptions to the AWAR:

Species	# Animals Affected (this Period)	9CFR title/section	Description and Rationale
NA			

Section E – Previous Deficiencies & Plans:

The committee validated that the plans and schedules for deficiencies noted during the previous NIEHS 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 NIEHS 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	Expired Buprenorphine	M	Redacted by agreement	PI was not using the expired Buprenorphine and indicated it was to be returned to the CSO	Investigator	09/25/19	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:

This section does not apply to this IC.

Section I – Minority Report

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

NIEHS ACUC Member Signatures:

Don Cook, PhD
Chair, ACUC

Redacted by agreement

Kathy Laber, DVM

Redacted by agreement

Redacted by agreement

Redacted by agreement

(Revised - 09/2019)

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

IC Name: National Institute of Environmental Health Sciences

Fall Semiannual Report Submission Date: October 31, 2019

Spring Program Review Date(s):	3/28/19					
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Fall Program Review Date(s):						
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Bldg/Area/Rm	Facility Insp. Date(s) Spring / Fall		AF/SF; Gross Sq. Ft.	Species Housed			Average Daily Inventory		
				1 Mice	2 Rats	3	1 41,772	2 229	3
Redacted by agreement	3/4/19-3/6/19	8/26/19-8/28/19	72,250	4	5	6	4	5	6
	3/1/29	8/28/2019	953	1 Mice	2	3	1 34	2	3
				4	5	6	4	5	6
	3/28/019	9/17/2019	197.5	1 Mice	2	3	1 0	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

Member Name	Degree/Credentials	Position Title	PHS Policy Membership Role	New Member
Don Cook	PhD	Principal Investigator	Chair	<input type="checkbox"/>
Kathy Laber	DVM, DACLAM	Animal Program Director	Attending Veterinarian	<input type="checkbox"/>
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Don Cook, PhD

Redacted by agreement

Attending Vet Phone

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