

SEMIANNUAL REPORT

ANIMAL CARE AND USE
PROGRAM REVIEW AND FACILITY INSPECTION
OF THE

NIDCR

October 2019

Section A – Site Visits & Program Review

- 1) Inspections of the ***NIDCR*** 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	9/13/2019	Redacted by agreement Davidson, Redacted by agreement Hoon,
	Surg	9/16/2019	Davidson, 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
X	OACU “Animal Program Semiannual Assessment Checklist” (1 page summary)
	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
X	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
	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
X	Other, please describe: The check list is completed and presented by the Animal Program Director (APD)/Attending Veterinarian to the Committee for review. The APD/Attending Veterinarian presents the review in Part I and II at a full Committee

	convened meeting.

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:

<i>Guide Departures</i>	<i>Guide Departure Citation (page #)</i>	<i>Justification (scientific, veterinary, or animal welfare)</i>
Mice are exposed to temperatures of 4°C or 35°C for up to 3 hours in a temperature-controlled home cage, to investigate how animals control their core body temperature.	Page 43	Scientific
Surgical staples are not removed for the duration of the experiments for subcutaneous implants of bone/marrow progenitor cells. (mice).	Page 120	Scientific
Mice are single housed in metabolic cages, or for behavioral tests, or post skin biopsy/wounding surgery.	Page 64	Scientific
Skin wound is left open in wound closure and wound treatment procedures. (mice)	Page 115	Scientific
Mice may be held in a dolognawmeter chamber for a maximum of 8 hours. Used to test gnawing function in orofacial nociception animal model.	Page 29	Scientific
Mice undergoing optogenetic stimulation are connected to a light-delivering optical patch	Page 29	Scientific

cord that limits movement by a tether. The restraint lasts from 30 minutes to 2 hours.		
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2. Exceptions to the AWAR: **Not applicable**

Section E – Previous Deficiencies & Plans:

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

	Deficiency and Plan	¹ M/S	SA 1 st noted	Location	Responsible Party	Status update	Revised completion date mm/dd/yy
1	(b)(5)					Pending	12/31/2019
2						Pending	12/31/2019

¹M=minor; S=Significant

Section F – Current Deficiencies & Plans:

Deficiencies found *over the past 6 months* during **NIDCR** 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	Lab door was left open. The door to the laboratory should be kept closed at all times to ensure negative airflow into the laboratory, all laboratory doors must be closed at all times, even when animal work is not performed.	M	Redacted by agreement	The door will be closed as recommended by safety.	Lab users	9/19/2019	C
2	Eye wash station was not flushed weekly since 8/29/19	M		Eye wash station will be flushed weekly	PI	9/17/2019	C
3	There was no start date on chemical waste container	M		Start dates should be written on the chemical waste container label	PI	9/13/2019	C

4	Safety showers do not have dated tags.	M	Redacted by agreement	Ensure that the showers are flushed annually	ORF	10/19/2019	C
5	Eye wash station was not flushed the week of the site visit.	M		Eye wash station will be flushed weekly	VRC	10/13/2019	C
6	Rag1 mice are maintained on TMS water. Neomycin is approved on ASP but not TMS water. TMS was recommended by 14C vet staff.	M		Submit an amendment to add TMS water to the ASP.	PI	9/23/2019	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:

SA 1 st noted	Description of event	Current Status
Spring 2019	An animal user, who was not approved on an ASP, performed a major surgery; and 2 animal users, who were also not approved on the ASP were involved in assisting during the surgery; the surgery had not been demonstrated to the Veterinarian or observed by the Veterinarian as stipulated on the ASP; the surgery was not documented on the cage cards for the animal care staff to perform post-op follow up observations/treatment as described in the ASP; and an incorrect ASP number was used for the mice that were used in the surgical procedure.	closed
Fall 2019	Mice were found dead or moribund a few days following 5 fluorouracil (5FU) injection. The responsible investigator did not monitor the 5FU injected mice as specified in the ASP. The approved monitoring plan was twice-daily from the start date to experimental endpoint.	Closed

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	9/9/2019	Davidson, Redacted by agreement
	9/16/2019	Davidson, Redacted by agreement

Section I – Minority Report

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

NIDCR ACUC Member Signatures

Members

Personal Info

Mark Hoon, Chair

Personal Info

Lauren Davidson,
Attending Veterinarian

Redacted by agreement

Alternate Members

Redacted by agreement

Semiannual Report Attachment 3

Supplemental Information

Fall 2019

NIDCR

Instructions: Submit the following information with your Fall 2019 Semiannual Report as a separate file called IC SI F19.

NOTE: Guide Exceptions (IC REP Fall 2019, section D): a reminder that a new column was added in the spring 2019 cycle asking for the *Guide* citation for Exceptions (*Guide* chapter, section, and page number).

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

Provide the total number of active/approved ASPs as of the October 31, 2019 cutoff date.

66 ASPs

2. 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.

Species	ACUC approved performance standards
Mice	Cage Size Allowance/Multiple Litters per Cage: Two dams may be housed in the same cage until mouse pups are up to 21 days of age, provided there are no more than 12 pups in the cage. Pups have access to solid food while housed with dams, and separation of pups and dams occurs when pups are 21 days of age. An SOP outlines the procedures for investigators and VRC staff to follow. (Reference: Guide, pp 55-57)
Mice	Extended weaning: Some strains of transgenic mouse pups produced at NIDCR require more time with the dam, because pups are phenotypically small for their age. Weaning the pups at 28 to 30 days of age is approved on ASPs. Extended weaning increases the survival rate of pups by allowing them to get bigger before they are separated from the dam. An SOP outlines the procedures for investigators and VRC staff to follow. (Reference: Guide, pp 55-57)
Mice	Single-housed following surgery: The single-housing of mice after surgery is approved in ASPs. Single-housing prevents the chewing or disruption of implants, cannulas, wounds and incisions by other rodents. An SOP outlines the procedures for investigators and VRC staff to follow. (Reference: Guide, p 115)
Mice	Single-housed males: Male mice exhibit aggression and fight when housed in the same cage. Males mice may be housed in separate cages to prevent injury. Environmental enrichment is provided to single-housed males. An SOP outlines the procedures for investigators and VRC staff to follow. (Reference: Guide, p 64)
Rats	Multiple Species Housing: NIDCR rats may be housed, when isolation is necessary, in a holding room that also houses mice, but the species are on separate ventilated racks. They are housed in the Redacted by agreement (Isolation room) following DVR standard operating procedures. The Redacted by animal facility uses this room to temporarily isolate mice and rats for testing before the animals are transferred to respective rat or mouse holding rooms in the general colony. (Reference: Guide, p 111)

Assurance#: A4149-01

Date: October 31, 2019

Institutional Animal Care and Use Committee Roster

Member Name	Degree/Credentials	Position Title	PHS Policy Membership Role	New Member
Redacted by agreement	MS, CIH, CSP, CHMM	Occupational Safety and Health Specialist, DOHS	Alternate Member	<input type="checkbox"/>
	PhD	Principal Investigator	Ex Officio; Non-Voting	<input type="checkbox"/>
	BSc	Biologist	Scientist	<input type="checkbox"/>
Davidson, Lauren	DVM, MS, DACLAM	Animal Program Director	Attending Veterinarian	<input type="checkbox"/>
Redacted by agreement	PhD	ACUC Coordinator	Member	<input type="checkbox"/>
Hoon, Mark	PhD	Principal Investigator	Chair	<input type="checkbox"/>
Redacted by agreement	MBA	Trainer	Nonaffiliated, Nonscientific	<input type="checkbox"/>
	BSc	Biologist	Scientist	<input type="checkbox"/>
	DVM	Clinical Veterinarian	Alternate Veterinarian	<input type="checkbox"/>
	MD, PhD	Principal Investigator	Scientist	<input type="checkbox"/>
	DVM, PhD	Animal Program Director	Alternate Veterinarian	<input type="checkbox"/>
	PhD	Principal Investigator	Scientist	<input type="checkbox"/>
	PhD	Biologist	Vice Chair	<input type="checkbox"/>
	PhD	Staff Scientist	Scientist	<input type="checkbox"/>
	DVM	Facility Veterinarian	Alternate Veterinarian	<input type="checkbox"/>
	MS, CHES	Occupational Safety and Health Specialist, DOHS	Member	<input type="checkbox"/>
	MS	Biologist	Scientist	<input type="checkbox"/>

ACUC Chair Mailing Address and TEL: Redacted by agreement

Attending Vet TEL: Redacted by agreement

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

IC Name: National Institute of Dental and Craniofacial Research

Fall Semiannual Report Submission Date: October 31, 2019

Spring Program Review Date(s):	4/25/2019					
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Fall Program Review Date(s):	10/24/2019					
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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	9/13/2019		6,999	1 Mice	2	3	1 10,888	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