

SEMIANNUAL REPORT

ANIMAL CARE AND USE
PROGRAM REVIEW AND FACILITY INSPECTION
OF THE

NIDCR

April 2020

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	2/11/2020	Redacted by agreement	Davidson	Redacted by agreement
	Surg	2/19/2020	Davidson,	Redacted by agreement	Hoon

- 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 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
	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 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:

- a. JST was awarded the NIDCR animal contract starting February 1, 2020. Priority One Services contract was closed.
- b. In October 2019, an NIDCR SD memo established the criteria on who can be a PI of an animal study proposal.

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)
NIDCR Animal Program Coordinator	Redacted by agreement	Joined

3) Animal Facility/Area Changes:

Facility Type (AF/SF)	Location	Action (opened, closed, under renovation, etc.)
Redacted by agreement		Closed in December 2019

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)
Mice are exposed to temperatures of 4 ⁰ C or 35 ⁰ 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	Page 115	Scientific

wound treatment procedures. (mice)		
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
No acclimation period for mice that are procured (JAX) with surgically implanted jugular vein catheters. Daily catheter flushing is required for catheter patency, hence animal wellbeing.	Page 111	Clinical/Scientific

2. Exceptions to the AWAR: **N/A**

Species	# Animals affected (this period)	9CFR title/section	Description and Rationale

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	Redacted by agreement				ORF	Pending	September 30, 2020

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	1)Sharps box full; 2) an MPW box was full (more than ¾ full).	M	Redacted by agreement	Sharps box replaced; MPW box emptied.	VRC	2/11/2020	C
2	Recapped needles in sharps box	M		users are always reminded to not	Users	2/11/2020	C

	Deficiency	¹ M/S	Location	Correction Plan	Responsible Party	Scheduled Completion Date (mm/dd/yy)	² Status: C/P
			Redacted by agreement	recap needles when placing in sharps box			
3	Outdated BioServ feed (phosphorous diet)	M		Feed discarded	VRC	2/11/2020	C
4	(b)(5)						
5	No alarm system for the refrigerator where feed is stored.	M	Redacted by agreement	alarm is not required. But, VRC may pursue other low-cost options such as a High-Low thermometer to know if temp stayed in range.	VRC	2/18/2020	C
6	expired irradiated feed	M		Expired feed discarded	VRC	2/11/2020	C
7	cage monitoring unit in alarm mode	M		The unit is no longer alarming	VRC	2/18/2020	C
8	(b)(5)						
9	1) inconsistent labeling of Clidox bottles. some bottles have no dates and some have expired dates. 2) expired soap bottle in hallway. 3) branch designations on cage cards should be changed to lab designation of the PI. 4) ASP information chart	M	Redacted by agreement	1)consistent labeling system established; 2) soap bottle discarded; 3) the cage cards will be modified to current labeling; 4) the chart is updated and placed in rooms	VRC	2/18/2020	C

	Deficiency	¹ M/S	Location	Correction Plan	Responsible Party	Scheduled Completion Date (mm/dd/yy)	² Status: C/P
	was not in the holding rooms.						
10	Redacted by agreement						

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

SA 1 st noted	Description of event	Current Status

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	2/14/2020	Davidson,	Redacted by agreement
	2/19/2020	Davidson,	
	2/24/2020	Davidson,	

Section I – Minority Report

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

NIDCR ACUC Member Signatures

Members

See attached signature page

Mark Hoon, Chair

Redacted by agreement

See attached signature page

¹Lauren Davidson,
Attending Veterinarian

Redacted by agreement

Alternate Members

Redacted by agreement

(Revised – 03/2020)

Semiannual Report Attachment 3

Supplemental Information

Spring 2020

NIDCR

1. 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 (Trio-breeding): 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. (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. (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. (Guide, p.115)
Mice	Single-housed males: Male mice exhibit aggression and fight when housed in the same cage. Male 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. (Guide, p.64)
Mice/Rats	Multiple Species Housing: NIDCR rats/mice may be housed, when isolation is necessary, in a holding room that also houses mice/rats, but the species have separate ventilation. Rats are housed in the Redacted by agreement (Isolation room) and mice in Redacted by agreement (ABSL2/radioactive room) following DVR standard operating procedures. DVR uses these rooms to temporarily house mice/rats before the animals are transferred to respective rat or mouse holding rooms in the general colony at DVR or are transferred to other holding locations. (Guide, p.111)
Mice	Extended cage changing/sanitizing frequency – the ACUC/VRC approved cage change frequency is that all cages are changed once every 2 weeks with spot changing. There are two exceptions: cages with breeding animals are changed five days post birth of pups; and cages with three or more mice are changed weekly. Care is taken to ensure the environment remains dry throughout the 14-day period and adequate food and water are always provided. Food and water are checked daily and topped off as needed. (reference: Guide, p. 70)

2. Veterinary Verification & Consultation: *see attached NIDCR ACUC policy*

If your IC has a VVC policy, please include a copy with your semiannual report submission.

Assurance#: A4149-01

Date: April 30, 2020

Institutional Animal Care and Use Committee Roster

Member Name	Degree/Credentials	Position Title	PHS Policy Membership Role	New Member
Redacted by agreement				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
Davidson, Lauren	DVM, MS, DACLAM	Animal Program Director	Attending Veterinarian	<input type="checkbox"/>
Redacted by agreement				<input type="checkbox"/>
Hoon, Mark	PhD	Principal Investigator	Chair	<input type="checkbox"/>
Redacted by agreement				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>
				<input type="checkbox"/>

ACUC Chair Mailing Address and TEL:

Redacted by agreement

Attending Vet TEL:

Redacted by agreement

Assurance#: A4149-01

Date: April 30, 2020

Institutional Animal Care and Use Committee Roster

Member Name	Degree/Credentials	Position Title	PHS Policy Membership Role	New Member
Redacted by agreement				<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

Semiannual Report Submission Date: April 30, 2020

Spring Program Review Date(s):	3/19/2020	04/16/2020				
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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		
Redacted by agreement	2/11/2020		6999	1 Mice	2	3	1 6,816	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