

SEMIANNUAL REPORT

ANIMAL CARE AND USE
PROGRAM REVIEW AND FACILITY INSPECTION
OF THE

National Institute of Neurological Disorders and Stroke
National Institute on Deafness and Other Communication Disorders
National Center for Complementary and Integrative Health

October 2019

Section A – Site Visits & Program Review:

- 1) Inspections of the NINDS-NIDCD-NCCIH 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	Surg	7/19/19	Merrill, Redacted by agreement
	AF, Surg	8/1/19	Redacted by agreement
	AF, Surg	8/14/19	
	AF, Surg	8/20/19	Merrill, Redacted by agreement
	Surg	8/20/19	Merrill, Redacted by agreement
	SF	8/27/19	O'Malley, Redacted by agreement
	Surg	9/5/19	Redacted by agreement
	Surg	9/10/19	O'Malley, Redacted by agreement
	SF	9/10/19	O'Malley, Redacted by agreement
	Surg	9/17/19	Redacted by agreement
	SF	9/17/19	

- 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:
	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)
	OACU/OLAW "Semiannual Program Review & Facility Inspection Checklist" (24 pages)
X	Other documents/resources (please specify)
	NINDS/NIDCD/NCCIH Program Review Supplement F19

The NINDS/NIDCD/NCCIH ACUC reviews the program every Spring (usually April) and Fall (usually October). When topics related to program review come up at ACUC meetings or site visits, they are discussed when the topic is presented. These discussions are supplemental to the full reviews discussed at October and April meetings. Supplemental discussions which occurred at meetings during the Spring 2019 reporting period (October 2018 through March 2019) and during site visits are listed in the table below.

Additional Topic Review Dates and Topics:

Date of Program Review	Animal Program Topics Covered on this Date
4/11/19	<ol style="list-style-type: none"> 1. The Committee was informed that the protocol number format would be changing with the new ASP submission software; the year tag would be removed and just the four-digit number would remain. 2. The Attending Veterinarian asked the committee to discuss appropriate techniques for ensuring that surgery instruments remain sterile throughout the surgery. Some members wanted to know whether infections were a frequent problem. Some ideas were suggested, such as an aseptic techniques refresher course or vet supervision the first time the surgery was performed. Ultimately the committee felt it was the PI's responsibility to make sure that their investigators are aware of methods to keep their surgery implements sterile. 3. Another topic brought to the committee's attention by the Attending Veterinarian, was some new guidance for addressing sex as a biological variable. This guidance comes from some discussions with the new NINDS Scientific Director, who is asking for more detailed descriptions in ASPs. This guidance will be posted on the ACUC web site.
5/9/19	<ol style="list-style-type: none"> 1. The safety representative informed the Committee of two recent incidents at other institutes that involved injuries from non-human primates. The Committee discussed how these incidents occurred and the possible causes to determine whether there was anything they should change about our program. 2. The Chair summarized the discussion at the most recent ARAC meeting. Topics included: vehicle inspection on semi-annual visits, photography in animal facilities, and rodent transfer between buildings. 3. The Committee reviewed the facility's Rodent Environmental Enrichment Program SOP. The Attending Veterinarian pointed out a couple of changes to the SOP: the facility no longer uses Jell-O for enrichment, and cardboard tubes have been replaced with plastic tubes. The Committee approved the SOP. 4. The Committee started its triannual review of all of its policies and guidelines: <ol style="list-style-type: none"> a) Policy 5: Time Limits was approved without changes. b) Policy 7: Significant Changes (Modifications) was approved with one change, replace the IASP submission software with eSirius.

6/13/19	<ol style="list-style-type: none"> 1. eSirius is up and running and the coordinators are asking investigators to start using eSirius for all submissions. Plans for training are still being discussed with the software developers. 2. The Committee reviewed its SOP for NHP enrichment and approved it without making any changes. 3. The Committee continued its review of its policies and guidelines: <ol style="list-style-type: none"> a) Policy 1: Designated Review – The Attending Veterinarian provided copies of the policy with proposed changes. The Committee approved these changes with the addition of some language from the safety representative. b) Policy 11: Post-Approval Monitoring – This policy was approved as written.
7/11/19	<ol style="list-style-type: none"> 1. eSirius “Train the trainer” sessions are scheduled for the week of July 22. 2. The changes made to Designated Review policy discussed at the June ACUC meeting were brought back to the Committee for ratification. The language was revised to clarify that when safety registrations are pending, all mention of those hazardous agents needs to be removed in order for the item to be approved. Stating “no work with be done with these agents until the registration is approved” is not acceptable. 3. The Chair summarized the discussion at the most recent ARAC meeting. Topics included: centralizing the IRB at NIH, records retention, and an unusual string of recent NHP bite incidents. 4. The Committee continued its review of its policies and guidelines: <ol style="list-style-type: none"> a) Policy 3: Euthanasia of Rat and Mouse Neonates – This policy was approved as written. b) Policy 4: Tail Snips and Pup Identification – This policy was approved with a couple minor changes. c) Policy 8: Breeding Policy – This policy was approved as written. d) Policy 9: Euthanasia by Cervical Dislocation – This policy was approved as written. e) Policy 14: Guillotine Use and Maintenance – This policy was approved pending the update of contact information.
8/8/19	<ol style="list-style-type: none"> 1. The Committee discussed an incident in which mice in one cage were found dead due to a lack of food. The cage was out of the room during routine cage change, when they would have gotten a new supply of food. Animal care staff failed to notice the depleted food level. 2. A minor change to ACUC Policy 9, which was reviewed and approved at the July meeting, was brought back to the Committee for approval. This change allowed the veterinarian’s designee to also verify proficiency in the awake cervical dislocation procedure. The Committee approved this change. 3. A representative from the NIH Library met with the Chair, Vice-Chair, Attending Veterinarian, and coordinator prior to the ACUC meeting to discuss the possibility of coming to an ACUC meeting. The goal of this meeting would be to inform the Committee of the various services that the Library can perform to help facilitate scientific research. The Attending Veterinarian did suggest that the Library representative might have a broader audience if he presented at a faculty meeting instead. 4. The Committee continued its review of its policies and guidelines: <ol style="list-style-type: none"> a) Policy 6: Training Investigators to Use Aseptic Techniques in Survival Surgery – This policy was approved as written.

	<p>b) Policy 15: Scheduling Mammalian Survival Surgeries – This policy was approved with minor changes.</p> <p>c) Policy 16: Post-operative Care for Buildings Redacted by agreement – This policy was approved as written.</p> <p>d) Guideline 1: Performance of Multiple Major Survival Surgical Procedures – This policy was approved with a minor change.</p>
9/12/19	<p>1. The Committee described three incidents that occurred recently:</p> <p>a) The first incident involved a mouse with obvious malocclusion that was found dead. Animal facility staff failed to notice the lack of food consumption or the animal's worsening condition.</p> <p>b) The second incident involved the death of several fish due to stress from cold exposure. The low temperatures were due to a steam pipe break several days earlier.</p> <p>c) The third incident involved an investigator who performed surgery on a mouse under a protocol that had been closed early. The investigator was not informed when the protocol was closed.</p> <p>2. While discussing the incident in which a surgery was performed on a closed protocol, the committee discussed options for how to ensure that all investigators are informed when a protocol is closed. Further discussion was tabled for the next meeting.</p> <p>3. The Committee continued its review of its policies and guidelines:</p> <p>a) Policy 2: Testing of Tissue Cultures and Biologics – This policy was approved pending the removal of all references to hamsters and a couple other minor corrections.</p> <p>b) Policy 10: Training – This policy was approved with an additional sentence about awake cervical dislocation.</p> <p>c) Guideline 1: Extent of Detail Required from in vitro ASPs – This guideline was tabled without discussion.</p>

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
	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:
	Review of the NINDS/NIDCD/NCCIH Program Review Supplement F19 by the Attending Veterinarian

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:

- All caging equipment coming out of room [Redacted by agreement] continues to be autoclaved prior to washing due to the discovery of *Spironucleus muris* in the colony. This began January 31, 2019. On July 31, 2019, some animals from this room were moved to [Redacted by agreement] and are being held under the same quarantine procedures. The animals in this room are on study until springtime. Quarantine procedures are expected to be in place for the duration of the study.
- ACRF caging/equipment continues to be processed in the [Redacted by agreement] cagewash facility due to cagewash renovations. This is expected to be ongoing for the next 1-3 years.

2) Key Personnel Changes - ACUC Chair, ACUC Attending Vet, APD, or Program Manager: N/A

3) Animal Facility/Area Changes:

Facility Type (AF/SF)	Location	Action (opened, closed, under renovation, etc.)
AF	[Redacted by agreement]	In August 2019, two down-draft sinks and chemical waste collection lines were modified in the PNR. The modification removed the option to allow waste to go to the sanitary sewer line and should make the process to change the waste collection container easier. These two rooms were done to test the modification; if no problems are encountered, renovation will be scheduled for the remaining rooms.

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)
Prolonged restraint of NHPs during awake MRI.	29/30	Scientific
Hindlimb suspension in mice for muscular atrophy from disuse study.	29/30	Scientific
In conjunction, a raised metal grid may be used to provide traction.	51	
Animal placed in a jig to restrict movement for targeted irradiation	29/30	Scientific

without anesthesia.		
Dark-rearing rodents to study brain modification due to environmental stimulus.	47/48	Scientific
Black tetras are obtained from a pet store because no other vendors are available.	106/107	Scientific

2. Exceptions to the AWAR:

Species	# Animals Affected (this Period)	9CFR title/section	Description and Rationale
Marmosets	5	9CFR §2.31(d)(1)(iv)(A)	Experimental autoimmune encephalomyelitis (EAE) is a marmoset model for Multiple Sclerosis which may result in ataxia and paralysis. Pain is not expected, but restriction of movement may cause distress. EAE is a relapsing, remitting disease, and animals will be given a 24-hour chance to recover if hind limb paralysis occurs.
Marmosets	Protocol 1 – 1 animal Protocol 2 - 0 animals	9CFR §2.31(d)(1)(x)(A)	Multiple survival surgery is approved on two studies: <ul style="list-style-type: none"> • The surgery is minimally invasive and well tolerated by the animals with no functional losses and no adverse effects. • Viral injection requires time before optical imaging for cells to get properly infected, and regrowth of dura can degrade imaging quality if imaging window is implanted at the same time as viral injection. Surgeries will be repeated on different parts of the skull to allow the animal to be optimally utilized.
Marmosets	14	9CFR §3.80b	Some breeding marmosets are housed in family groups in cages with less floor space than described in the Guide and AWR. These cages provide extra height and perches for the marmosets that are an arboreal species. Juveniles are kept with parents to learn parenting skills when a younger litter is born. Using clinical appearance, aggression and reproductive success as performance standards, no adverse effects have been observed in animals housed under these conditions.

Section E – Previous Deficiencies & Plans:

The committee validated that the plans and schedules for deficiencies noted during the previous

Obtained by Rise for Animals.

Uploaded to Animal Research Laboratory Overview (ARLO) on 02/18/2021

(NINDS-NIDCD-NCCIH) 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	Downdraft table failed certification	M	S19	Redacted by agreement	Facility/Safety/ORF	Complete	06/04/2019

¹M=minor; S=Significant

Section F – Current Deficiencies & Plans:

Deficiencies found *over the past 6 months* during NINDS-NIDCD-NCCIH 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	Procedure location not kept clean and organized enough for use as a surgery location.	M	Redacted by agreement	Clean and organize room.	PI	9/16/19	C
2	Site for injection of hazardous toxin is located in the main walkway of the lab.	M		Move injection equipment to a lesser used area of the lab.	PI	9/20/19	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: [] **None**

SA 1 st noted	Description of event	Current Status
(b)(5)		Awaiting ACUC disposition
		Awaiting ACUC disposition
		Awaiting ACUC disposition

(b)(5)	Awaiting OLAW final approval
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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	7/19/19	Merrill, Redacted by agreement
	8/1/19	Redacted by agreement
	8/20/19	Merrill, Redacted by agreement
	8/21/19	Redacted by agreement

Section I – Minority Report

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

NINDS/NIDCD/NCCIH ACUC Member Signatures:

Dr. Marsha Merrill Acting Chairperson	Redacted by agreement
Redacted by agreement	
Dr. James O'Malley Attending Veterinarian	
Redacted by agreement	
Redacted by agreement	

Semiannual Report Attachment 3

Supplemental Information

Fall 2019

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 Oct 2019:

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

96

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.

All exceptions are approved on case by case basis for each ASP. We do not have any policies or guidelines approving exceptions on the basis of performance standards.

Assurance#: A-4149-01

Date: October 31, 2019

Institutional Animal Care & Use Committee Roster

Member Name	Degree/Credentials	Position Title	PHS Policy Membership Role	New Member
Marsha Merrill	PhD	Staff Scientist	Chair	<input type="checkbox"/>
James O'Malley	DVM, DACLAM, MPH	Animal Program Director	Attending Veterinarian	<input type="checkbox"/>
Redacted by agreement				<input type="checkbox"/>
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ACUC Chair Mailing Address & Phone #:

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: Select one --

Fall Semiannual Report Submission Date: October 31, 2019

Spring Program Review Date(s):	4/11/19					
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Fall Program Review Date(s):	9/10/19					
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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	2/22/19	8/14/19	AF; 59, 735	1 mice	2 rats	3 zebrafish	1 48,288	2 1,096	3 10,398
				4	5	6	4	5	6
	2/27/19	8/20/19	AF; 1,205	1 mice	2 rats	3	1 702	2 102	3
				4	5	6	4	5	6
	2/13/19	8/1/19	AF; 3,462	1 mice	2	3	1 2	2	3
				4	5	6	4	5	6
	3/4/19	9/17/19	SF; 63	1 xenopus	2	3	1 42	2	3
				4	5	6	4	5	6
	2/28/19	8/27/19	SF; 385	1 zebrafish	2	3	1 600	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: Select one --

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	3/19/19	9/10/19	SF; 210	1 zebrafish	2	3	1 546	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