

SEMIANNUAL REPORT

ANIMAL CARE AND USE
PROGRAM REVIEW AND FACILITY INSPECTION
OF THE

NIAAA

October 2019

Section A – Site Visits & Program Review

- 1) Inspections of the **NIAAA** 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	10/15/2019	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 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
	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
	Other, please describe:

Section B – Regulatory Compliance:

Except as noted in Sections 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:**PPE:**

The [Redacted] Investigator Orientation Handbook requires that “All people intending to enter the [Redacted] must wear shoe covers over their street shoes and a disposable lab coat over their street clothes. To minimize the risk of penetrating injury, closed toe shoes should be worn when sharps are in use. Gloves should be worn when handling animals and should be donned before handling any animal equipment or materials”. The handbook further explains that “disposable lab coats and shoe covers are stocked in the gowning area and must be donned before entry. Hair covers and masks are available for individuals who desire to wear them for additional allergen protection”. The ACUC determined that it would be ideal and best practice to update the [Redacted] PPE requirements to include full length pants as well to minimize exposure of skin on the limbs. OLAS has purchased disposable coveralls that are available outside the entrances to the [Redacted] for investigators that may need them.

Chemical Hazards:

Updates were made to the NIAAA OLAS Chemical Hazard Administration Handbook. The revisions were initiated by comments received from the ACUC DOHS member during ASP reviews. All chemical hazards are required to be listed in Section K of the ASPs. This handbook provides standard procedures that must be followed when working with chemical hazards that are listed on approved ASPs and are associated with animal research within the [Redacted]. Specifically, the Chemical Hazard Administration Handbook addresses the following:

- 1- Preparation, Transportation and Storage
- 2- Administration in the [Redacted]
- 3- Cleanup and Waste Management
- 4- Containment Following Hazard Administration

Proper signage for procedure room postings and animal cage identification for when these hazardous chemicals are in use was moved from the body of the Handbook to Appendix A. Appendix B specifies which compounds are associated with each ASP. The Chemical Hazard Administration Handbook is provided to all animal users listed on ASPs that contain the hazards described.

Moving forward, the NIAAA OLAS Chemical Hazard Administration Handbook will be referenced in Section K of NIAAA ASPs to provide the necessary information for working with chemical hazards as described above. If procedures differ from this handbook, they will be specifically described within Section K of the ASP.

Laser Handbook:

The Laser Handbook has been updated following completion and approval of new laser signs by the NIH Laser Safety Officer for use by the LIN within the [Redacted]. Currently, LNCB does not have any lasers present in the [Redacted] so this lab was removed from the updated handbook. They will update their signage, and have it approved by the NIH Laser Safety Officer before they install any lasers in the [Redacted] for their experiments.

NIAAA ASP Form revisions:

Revisions were made to Section K of the NIAAA ASP Form to correlate with recent changes to the

NIAAA OLAS Chemical Hazard Administration Handbook. The NIAAA OLAS Chemical Hazard Administration Handbook will be referenced in Section K of NIAAA ASPs to provide the necessary information for working with chemical hazards (preparation, administration, containment, disposal, etc.). If procedures differ from this handbook, they will be specifically described within Section K of the ASP. A link to an online database of SDS' was added to the NIAAA ASP Form to aid in accessing this information and to fulfill the requirement that an SDS for each experimental compound be readily available to investigators and staff.

Triennial review of ACUC Policies

Policy on Special Care:

Revisions were made to this policy to reflect current procedures. New animal users added to an ASP are provided with the Special Care Instructions through provision of the ASP (each ASP has links to relevant Special Care Instructions in Section M). If new Special Care Instructions are added to an ASP through submission and approval of an amendment, the link to the specific set of special care instructions is included in the amendment. PIs are notified by email and provided with an updated ASP each time an amendment is approved, but it is the PIs responsibility to further notify their lab members as the ASP is updated. Hard copies of Special Care Instructions and logs are also maintained in the first and second floor staging areas of the FLAC.

Policy on Submission of ASPs and Amendments:

A purpose paragraph was added at the beginning of the document to briefly describe the intent of the policy.

The 4 possible outcomes following ACUC review of submitted ASPs and amendments were put into numbered list format and reworded to correlate with what is currently written in the PHS Policy and ARAC Guideline for Review, Approval, and Post Approval Monitoring of Animal Study Proposals Including Designated Member Review.

The section of the policy concerning amendments was reorganized and categories were established to classify the types of amendments that are submitted to the ACUC for review. There are now 3 categories of amendments (Category 1 has 2 sub-categories, 1a and 1b), which align with OLAW guidance and the ARAC Guideline Regarding Significant Changes to Animal Study Proposals.

Category 1a amendments are those that require mandatory, non-administrative ACUC review by the full committee (FCR). Examples of these types of amendments are provided.

Category 1b amendments are those that also require mandatory, non-administrative ACUC review, but it may be done through the use of designated member review (DMR). Examples of these types of amendments are provided. The PHS Policy requires that all ACUC members have the opportunity to review amendments submitted for approval by DMR and request FCR for any reason. ACUC members will have 2 business days from the time of notification to respond if they would like to request FCR and have the amendment presented at the next convened meeting of a quorum of the ACUC. Committee members are not required to respond to the notification, but no response will be taken as an endorsement of the DMR procedure.

Category 2, conditional administrative amendments, will be reviewed and approved through Veterinary Verification and Consultation (VVC). Examples of the types of amendments that may be approved through the use of VVC are provided. It was specifically noted that the veterinarian is not conducting DMR on behalf of the ACUC, but is serving as a subject-matter expert to verify that compliance with the ACUC Policies and ARAC Guidelines, etc. are appropriate for the animals in

these particular circumstances. The veterinarian may approve of the amendment as written, request modifications required to secure approval or refer any request to FCR for any reason. The veterinarian must refer any request to FCR that does not meet the parameters of the ACUC-reviewed and approved policies.

Category 3 amendments are those that may be handled and processed as unconditional administrative amendments. Examples of these types of amendments are listed in the policy and were reviewed by the ACUC. The APD will approve by DMR.

Studies Requiring Only Animal Tissue:

Triennial review of the NIAAA ACUC Policy on Studies Requiring Only Animal Tissue was performed. No revisions were needed and the policy was re-approved as written.

Rodent Breeding Policy:

Revisions were made to the Rodent Breeding Policy for consistency with the NIAAA ACUC Policy on Submission of ASPs and Amendments. The associated sample add strain memorandum was also updated to correct a typo and correct the name of an ARAC Guideline referred to in the document.

Updates to the FLAC Mouse Colony Health Status Report:

The biggest change in this report is that Mouse Parvovirus (MPV) will no longer be excluded from the [Redacted] mouse colony and it has been added to the acceptable pathogen list. The pattern of positive results experienced within the [Redacted] is consistent with other institutions housing mice on a largely MPV resistant C57BL/6 genetic background held in microisolation style caging on individually ventilated racks. The acceptance of MPV, Mouse Norovirus, and Helicobacter sp. within the [Redacted] makes this animal facility the same health status as almost all other NIH animal holding facilities.

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)
Animal Facility Manager	Redacted by agreement	Departed
Animal Facility Manager		Joined

3) Animal Facility/Area Changes:

Facility Type (AF/SF)	Location	Action (opened, closed, under renovation, etc.)
AF	Redacted	Storage room [Redacted] is currently under renovation to become a procedure room.

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)
Physical restraint (e.g., restraint stress in a plastic restrainer for up to	Page 29	Scientific

2 hours per day, head fixed awake electrophysiology and photometry recordings for up to 4 hours per day) of mice without prior use of sedatives or tranquilizers is approved in two ASPs.		
In eight ASPs, the Committee approved individual housing of rodents in specialized cages with wire bar or perforated flooring for no more than eight continuous days.	Page 51	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 **NIAAA** 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 **NIAAA** 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 hydrogel pack	M	Redacted by agreement	Discard the expired hydrogel	FM	10/16/2019	C
2	Unlabeled bag of hydrogel	M		Notify the responsible investigator to properly label the bag	PI	10/15/2019	C
3	Expired bag of shake and pour powder to make ethanol liquid diet	M		Discard the expired diet	PI	10/16/2019	C
4	Loose insulation in the ceiling duct	M		Put in a ticket for building maintenance to repair	FM	Ticket placed and repair completed 10/16/2019	C
5	No documentation of weekly eyewash flush on tag since 9/24/2019	M		Ensure that FLAC staff record eyewash flush dates on the tags as well as the logs	FM	Confirmed completed on Procedure Room Log. Staff reminded 10/16/19.	C
6	(b)(5)						

				properly label them			
7	(b)(5)						
8							
9							
10							
11							
12							

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
4/20/2019	3 mice found dead in their cage with no feed	Resolved 5/20/2019

Section H – Shared & Central Facilities:

This section does not apply to this IC.

Section I – Minority Report

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

NIAAA ACUC Member Signatures:

Redacted by agreement

Dr. Bin Gao, Chair, ACUC

Redacted by agreement

Dr. Raouf Kechrid, Attending Veterinarian

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.

19

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.

Extended Cage Change Frequency: Consistent with efforts to minimize disruption to the animals’ microenvironment, the NIAAA ACUC approved a facility-wide extended change frequency for filter tops and wire-bar lids as described within the NIAAA Investigator Orientation Handbook. Rodent filter tops and wire-bar lids used on micro-isolation style caging may be changed monthly. A facility study of the impact of monthly lid change showed no negative impact to IVC air flow or diet. Parameters monitored included IVC supply and exhaust and feed pellet condition. Care is taken to ensure feed is available *ad libitum*, the interior cage surface remains free of visible moisture and feed pellets retain character with no evidence of mold growth. (reference: *Guide*, p. 70)

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

IC Name: National Institute on Alcohol Abuse and Alcoholism

Fall Semiannual Report Submission Date: October 31, 2019

Spring Program Review Date(s):	4/23/19					
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Fall Program Review Date(s):	10/29/2019					
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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 10,517	2 101	3
Redacted by agreement	4/8/2019	10/15/2019	AF; 18149	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