SEMIANNUAL REPORT

ANIMAL CARE AND USE PROGRAM REVIEW AND FACILITY INSPECTION OF THE

NIAAA				
	April 2020			

Section A - Site Visits & Program Review

 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	Туре	Date	ACUC Members
Redacted	AF, Surg	03/27/2020	Kechrid

^{*}Note: Inspections were performed by only one ACUC member in accordance with OLAW Notice Number NOT-OD-20-088.

- 2) Visits by at least one member of the ACUC to areas where animal activities were performed were conducted. These areas include Redacted by agreement These visits occurred during the previous six months and findings and corrective actions are described in this semiannual report. Other animal activity areas not listed were inspected during the Fall 2019 semiannual inspection and findings and corrective actions were described in that semiannual report.
- 3) The following document(s) was/were used as the basis for review of the animal care and use program:

	Document/Resource:				
Χ	Guide for the Care & Use of Laboratory Animals, 8th Edition (Guide)				
Χ	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 <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
	Other, please describe:

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.

<u>Section C – Program Changes:</u>

The following administrative and procedural changes have occurred since the program was last evaluated:

1) Administrative/Procedural Changes:

The new husbandry contract was recently awarded to FEFA, LLC. Based upon FEFA's technical abilities and realistic cost proposal in relation to the work to be performed, the Technical Evaluation Panel (TEP), the LARC IV Project Manager and the Contracting Officer recommended the award of the task order to FEFA, LLC. FEFA took over the animal care contract starting April 1st, 2020.

SOP 4250 – Training Animals: This SOP was submitted for its triennial review by the ACUC during the past six months. The goals and procedures have not changed since the last review was done on February 2017. No changes to the SOP were suggested and the ACUC approved it again as written.

Animal Irradiation Handbook: An Animal Irradiation Handbook was created by the NIAAA OLAS to outline irradiation procedures for investigators that have irradiation of animals approved on their ASPs. This information was previously provided in an SOP format. The Redacte SOPs are intended to be used by the facility staff, but most of the information included in this SOP was intended for the investigators and was not applicable to the Redacte staff. The OLAS decided it would be better to alter the format and create the Handbook, which is more relevant for the intended audience. The information did not change from the SOP to the Animal Irradiation Handbook; however, it was simplified and reorganized. The ACUC reviewed the new Handbook and agreed with its content.

Minor Updates to Investigator Orientation Handbook: The Investigator Orientation Handbook was revised to clarify the cage sanitation procedures and our NIAAA ACUC approved performance standard described on page 16 of the Handbook. A facility-wide extended change frequency for filter tops and wire-bar lids used on micro-isolation style caging was previously implemented. This approved performance standard allowed cleaning and changing of these items monthly. This also includes stainless steel feeders that may or may not be integral with the wire bar lids, so these items were specifically mentioned in the Handbook as well to clarify the current procedures.

Animal Use Database – Stopping Cards: The Committee discussed the Animal Use Database and the necessity of scanning animal cards to stop them in the database once the animals are no longer present in the Redacted Animal cards were being scanned out and inactivated in the database as they were turned into the Redacte front office by investigators and the data from the Animal Use Database is posted to the OLAS SharePoint site weekly for investigators to reference. The Committee was informed that the database is not currently accurate with respect to the number of animals that are presently in the Redacted as there are many more active cards in the database than there are animals in the Redacted The OLAS identified that this issue is primarily caused by investigators choosing to keep their animal cards rather than turn them in to be inactivated in the database. Members of the Committee commented that many of the investigators write important information on these cards and this is likely why they choose to keep them. The OLAS does not require investigators to turn in the animal cards once they are removed from the Redacted and OLAS does not retain the cards once they are inactivated, so it is extremely difficult to keep the active card

data accurate. The investigators also do not have the opportunity to scan the cards out of the database themselves due to the limitations of our network accessibility. This may be an issue that can be corrected in the future, but if the date of card inactivation is not useful to the investigators, OLAS proposed discontinuing the process altogether. The ACUC members commented that they do not need this information and do not oppose discontinuing the process; therefore, animal cards and breeder cards are no longer regularly inactivated in the Animal Use Database. However, every six months, groups of animal cards that are greater than 24 months old and not currently housed in the Redacted will be stopped in the database.

Triennial review of ACUC Policies

Administration of Agents that may induce Hypothermia: The Committee performed the triennial review of the NIAAA ACUC Policy on Administration of Agents that may induce Hypothermia. No changes were made to the policy and none were suggested during review at the meeting. The policy was re-approved as written.

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)
	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 by	Redacted converted from a storage room to an animal
	-7	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 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.	Page 29	Scientific
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:

Other than the remaining deficiencies listed in the table below, 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.

	Deficiency and Plan	¹ M/S	SA 1st noted	Location	Responsible Party	Status update	Revised completion date mm/dd/yy
1	BSC out of certification	М		Redacted by agreeme	PI	In progress. Reported to DOHS by PI.	12/31/2020
2	Downdraft table certification expired	М	Fall 2019	nt	PI	In progress. Reported to DOHS by PI.	12/31/2020

¹M=minor; S=Significant

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	Non-compliance with the OLAS Rodent Survival Surgery Handbook	М	Redacted	Day 0 post-operative cage found containing both an isopad and corncob bedding should be changed to corncob bedding only on Day 1	PI, surgeon	03/27/2020	С

¹M=minor; S=significant

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
3/16/2020	2 mice found dead in the holding room live pest	Resolved 4/28/20
	trap	

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.

²C=corrected; P=pending

NIAAA Member Signatures:

Bin Gao - S Date: 2020.04.28 15:42:17 -04'00'			
Dr. Bin Gao, Chair, ACUC	Dr. Raouf Kechrid, Attending Veterinarian		
ledacted by agreement	n		

NIAAA Member Signatures:	
Dr. Bin Gao, Chair, ACUC	Dr. Raouf Kechrid, Attending Veterinarian
	,
Redacted by agreement	

NIAAA Member Signatures:	
	Raouf M. Digitally signed by Raouf M. Kechrid -S Date: 2020.04.28 15:41:42 -04:00
Dr. Bin Gao, Chair, ACUC	Dr. Raouf Kechrid, Attending Veterinarian
Redacted by agreement	

NIAAA Member Signatures:	
Dr. Bin Gao, Chair, ACUC	Dr. Raouf Kechrid, Attending Veterinarian
Redacted by agreement	

NIAAA Spring Semiannual Report, April 2020	Page 5
NIAAA Member Signatures:	
Dr. Bin Gao, Chair, ACUC	Dr. Raouf Kechrid, Attending Veterinarian
Redacted by agreement	
(Revised - 03/2020)	

NIAAA Member Signatures:

Bin Gao - S Date: 2020.04.28 15:42:17 -04'00'	
Dr. Bin Gao, Chair, ACUC	Dr. Raouf Kechrid, Attending Veterinarian
Redacted by agreement	

NIAAA Member Signatures:	
Dr. Bin Gao, Chair, ACUC	Dr. Raouf Kechrid, Attending Veterinarian
dacted by agreement	