

SEMI-ANNUAL REPORT

ANIMAL CARE AND USE
PROGRAM REVIEW AND FACILITY INSPECTION
OF THE
NATIONAL INSTITUTE OF MENTAL HEALTH
October 2020

Section A – Site Visits & Program Review

- 1) Inspections of the NIMH 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:

Bldg	Location	Type	Date	ACUC Members
Redacted by agreement		AF	10/2/2020	Redacted by agreement
		Surg	9/10/2020	
		Surg	9/30/2020	
		Surg	9/30/2020	
		Surg	9/30/2020	
		Surg	9/30/2020	
		Surg	9/30/2020	
		Surg	9/30/2020	
		Surg	9/30/2020	
		Surg	9/30/2020	
		Surg	9/30/2020	
		Surg	9/30/2020	
		Surg	9/30/2020	
		Surg	9/28/2020	
		SA	10/7/2020	
		SA	10/7/2020	
		SA	10/7/2020	
		Surg	10/2/2020	
		Surg	10/2/2020	
		Surg	10/2/2020	
		SA	10/2/2020	
		SA	10/2/2020	
		SA	10/2/2020	
		SA	10/2/2020	
		SA	10/2/2020	
		SA	10/2/2020	
		SA	10/2/2020	
		SA	10/2/2020	
		SA	10/2/2020	
		SA	10/2/2020	
		SA	10/2/2020	
		SA	10/2/2020	

- 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:
X	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)
X	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: *[check the process that applies]*

	Program Review Process
	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
X	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 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:

Guide Departures	Guide Departure Citation (page #)	Justification (scientific, veterinary, or animal welfare)
Light cycles	Chapter 3, Environment, Housing, and Management, Page 48	Scientific justification
Euthanasia of rodents in the animal holding room	Chapter 4, Veterinary Care, Page 123	Veterinary justification
Extended staple/suture removal	Chapter 4, Veterinary Care, Page 120	Animal welfare justification
Cage change frequency	Chapter 3, Environment, Housing, and Management, Page 70	Animal welfare justification
Multiple species housing	Chapter 4, Veterinary Care, Page 111	Veterinary justification
Food and/or water control	Chapter 3, Environment, Housing, and Management, Page 65-68	Scientific justification
Food placed on floor	Chapter 3, Environment, Housing, and Management, Page 65-68	Animal welfare justification

2 Exceptions to the AWAR:

Species	# Animals Affected (this Period)	9CFR title/section	Description and Rationale
NHP	54	Part 3, Subpart D-3.83/Watering	Chronic water control has been approved when scientifically justified in an ASP as a methodology to motivate performance of specific operant tasks.

Section E – Previous Deficiencies & Plans:

The committee validated that the plans and schedules for deficiencies noted during the previous NIMH 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 the NIMH program review, facility inspections, and laboratory inspections, are as follows:

	Deficiency	M/S	Location	Correction Plan	Responsible Party	Scheduled Completion Date (mm/dd/yy)	Status C/P
1	F-Air can sternot appropriately maintained	M	Redacted by agreement	Dispose of tems and re-train staff	PI	10/30/2020	C
2	On-Cal schedule out of date	M	Various	Update schedules and re-train staff	PI	10/30/2020	C
3	(b)(5)						

	Deficiency	¹ M/S	Location	Correction Plan	Responsible Party	Scheduled Completion Date (mm/dd/yy)	² Status C/P
4	Expired drugs chemicals disinfectant or supplies	M	Redacted by agreement	Discard items and re-train staff	PI	10/30/2020	C
5	Controlled drugs not appropriately stored	M		Secure and retrain staff	PI	10/30/2020	C
6	Treats or diet expired or inappropriately stored	M		Discard items store appropriately and re-train staff	PI	10/30/2020	C
7	Items stored on floor in a manner which does not allow adequate sanitation	M		Remove items and re-train staff	PI	10/30/2020	C
8	MPW box overfilled	M		Dispose of and re-train staff	PI	10/30/2020	C
9	Human food found in animal area	M		Remove and re-train staff	PI	10/30/2020	C
10	Exposed Sharp	M		Dispose of Sharp and re-train staff	PI	10/30/2020	C
11	Inappropriate items disposed of in Sharps container re-capped needles in Sharps container or container overfilled	M		Re-train staff	PI	10/30/2020	C
12	Drugs chemicals or solutions inappropriately labeled	M		Label items correctly and re-train staff	PI	10/30/2020	C
13	Room requires additional cleaning or appears cluttered and difficult to sanitize	M		De-clutter and clean area and re-train staff	PI	10/30/2020	C
14	Equipment requires cleaning	M		Clean item and re-train staff	PI	10/30/2020	C
15	Required signage not present	M		Post signage	PI	10/7/2020	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: [X] **None**

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	10/1/2020	Redacted by agreement
	9/10/2020	
	8/26/2020	
	9/28/2020	

Section I – Minority Report

There is not a minority report filed with this semi-annual report

NIMH ACUC Member Signatures:

Dr. Ted Usdin
Chairman

James M. Raber -S

Digitally signed by
James M. Raber -S
Date: 2020.10.29
16:50:24 -0400

Dr. James Raber
Attending Veterinarian

Redacted by agreement

Redacted by agreement

(Revised – 8/2020)

NIMH ACUC Member Signatures:

Dr. Ted Usdin
Chairman

Dr. James Raber
Attending Veterinarian

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NIMH ACUC Member Signatures:

Dr. Ted Usdin
Chairman

Dr. James Raber
Attending Veterinarian

Redacted by agreement

Redacted by agreement

(Revised – 8/2020)

NIMH ACUC Member Signatures:

Theodore

Dr. Ted Usdin
Chairman

Signature signed by Theodore B. Usdin, M.D.
NIMH, U.S. Government
601 Bethesda North Avenue
Room 2347
Bethesda, MD 20814
Telephone: 301-427-1411
Fax: 301-427-1411

Dr. James Raber
Attending Veterinarian

Redacted by agreement

Redacted by agreement

(Revised – 8/2020)

NIMH ACUC Member Signatures:

Dr. Ted Usdin
Chairman

Dr. James Raber
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Dr. Ted Usdin
Chairman

Dr. James Raber
Attending Veterinarian

Redacted by agreement

Redacted by agreement

(Revised – 8/2020)

October 31, 2020

Assurance#: A-4149-01

Date: _____

Institutional Animal Care & Use Committee Roster

Member Name	Degree/Credentials	Position Title	PHS Policy Membership Role	New Member
Ted Usdin	MD, PhD	Senior Investigator	Chair	<input type="checkbox"/>
James Raber	DVM, PhD	Animal Program Director	Attending Veterinarian	<input type="checkbox"/>
Redacted by agreement				<input type="checkbox"/>
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ACUC Chair Mailing Address & Phone #: NIMH

Redacted
by
agreement

Attending Vet Phone #:

Redacted
by
agreement

NIMH ANIMAL PROGRAM SEMIANNUAL ASSESSMENT CHECKLIST

(Based upon 2011 Guide)

DATE: 10/30/2020

	PROGRAM AREAS	GUIDE Page	ACCEPT	Type of Deficiency	
				MINOR	SIGNIF
I	ANIMAL CARE & USE PROGRAM				
A	Program Management & Responsibility	13-24	X		
	• Key Management Personnel - IO Attending vet ACUC	13-15	X		
	• Collaborations - Review of IAA's, MOUs, Contracts (PM 3040.3)	15	X		
	• Training & Education - Vets/Professional Staff, Animal Care, Researchers, ACUC	15-17	X		
	• Occupational Health & Safety - Control & Prevention, Hazard ID & Risk Assessment, Facilities, Equipment & Monitoring, Training, Hygiene, Research Hazards, Protection, Medical Eval (LAAPP, PM 3044-2, Visitors)	17-23		3, 6, 8, 9, 10, 11, 12, 13, 14	
	• Personnel Security	23	X		
	• Investigating & Reporting Animal Concerns (ARAC C2)	23-24		16	
B	Program Oversight	24-34	X		
	• Animal Care and Use Committee - Role, Constitution & Function (ARAC C1, C5)	24-25	X		
	• Standard Operating Procedure Review	25	X		
	• Animal Study Proposal Review - de novo, Annual Reviews, Amendments, FCR, DMR	25-33	X		
	Use-Benefit Analysis	27	X		
	Protocol Endpoints	27-28	X		
	Unexpected Outcomes	28-29	X		
	Physical Restraint (Prolonged)	29-30	X		
	Multiple Survival Surgery Procedures	30	X		
	Food & Food Regulation	30-31	X		
	Non-Pharmaceutical Grade Compounds	31-32	X		
	• Post-approval Monitoring	33	X		
C	Disaster Planning & Emergency Preparedness	35	X		
II	ENVIRONMENT, HOUSING, & MANAGEMENT				
A	Terrestrial Animal Environment - Temp, Humidity, Ventilation, Air Quality, Illumination, Noise & Vibration	42-50	X		
B	Terrestrial Housing - Primary Enclosure, Enrichment, Outdoor Housing, Naturalistic Environments, Space	50-63	X		
C	Terrestrial Management - Behavior & Social Management (Activity, Social Environment, Habituation & Training), Husbandry (Food & Water), Bedding/Nesting Materials, Sanitation (Bedding Change, Waste Disposal, & Effectiveness), Pest Control, Emergency, Weekend & Holiday Care, Population Management (Identification, Recordkeeping, Breeding, Nomenclature, & Genetics)	63-77		2, 4, 5	
D	Aquatic Animal Environment - Water Quality, Support System, Temperature, Humidity, Ventilation, Illumination, Noise & Vibration	77-82	X		
E	Aquatic Housing - Primary Enclosure, Enrichment, Social Housing, Outdoor Housing, Naturalistic Environments, Space	82-83	X		
F	Aquatic Management - Behavior & Social Management, Husbandry (Food, Water, Substrate, Sanitation (Micro & Macroenvironment), Waste Disposal, Pest Control, Emergency, Weekend & Holiday Care, Population Management (Identification, Recordkeeping)	84-88	X		
III	VETERINARY CARE				
A	Animal Procurement & Transportation (ARAC A1a, A1b, CC Policy)	106-107	X		
B	Preventive Medicine - Biosecurity, Quarantine, Stabilization, Separation of Species & Disease Surveillance, Diagnosis, Treatment, Control (PM 3043-1, PM 3044-1, ARAC D3)	109-113	X		
C	Clinical Care & Management - Medical Management, Emergency Care, & Recordkeeping	113-115	X		
D	Surgery - Training, Planning, Facilities, Procedures, Aseptic Technique, Intra-Op Monitoring, Post-Op Care	115-120	X		
E	Pain & Distress (ARAC B12, P&D Memo)	120-121	X		
F	Anesthesia & Analgesia (PM 1345)	121-123		1	
G	Euthanasia (ARAC B4, B5)	123-124	X		
IV	PHYSICAL PLANT				
A	Functional Areas - Housing, Care, Sanitation, Receipt, Quarantine, Separation of Species, Storage	136-136			
B	Construction Guidelines - Corridors, Doors, Windows, Floors, Drains, Walls/Ceilings, HVAC, Power, Lighting/Light Timer Override, Storage, Noise, Vibration, Sanitization Facilities, Environmental Monitoring	136-143	X		
	• Safety Devices - Showers, Eyewashes, Escape for Cage/Rack Washers, Autoclaves	143	X		
C	Special Facilities - Surgery, Barriers, Imaging, Irradiators, Hazard Containment, Behavior Studies, Aquatics	143-150	X		
D	Security & Access Control	151	X		

ACCEPT = Category found to be in accordance with regulations & policies.

SIGNIF = Significant Deficiency; i.e. may present a threat to the health and safety of animals or humans.

Rev. 10/2017

Semiannual Report Attachment 3 Supplemental Information Fall 2020

Instructions: Submit the following information with your Fall 2020 Semiannual Report as a separate file called (IC) SI-F20

Performance Standards:

Provide a description of ACUC approved performance standards associated with achieving a specific *Guide* goal while deviating from the *Guide's* recommended procedures for achieving that specific goal. For additional information and examples, see the OACU "Guide Exceptions, Departures, and Performance Standards" document.

Cage Size Allowance/Multiple Litters per Cage: The NIMH ACUC has approved "Fourteen Heads – Fourteen Days" policy. As an engineering standard, on day fourteen postpartum, the maximum number of mice permitted in the cage is fourteen. This includes the three adults (one male, two females) and up to eleven pups whose birthdays are not more than 7 days apart. Separation of the litter on day fifteen, rather than at an earlier date is facilitated by the fact that by fourteen days postpartum, most pups are supplementing their milk diet with solid food. Therefore, if one of the dams is a poor milk producer, the negative impact of separating the litter and placing some of the pups solely with the poorly lactating female is minimized.

Multiple Species Housing: There are currently two animal rooms housing multiple rodent species in the same room, in Redacted by agreement Rats and mice are used as sentinels for Nile Grass Rats and for hamsters. Rats, mice, and hamsters do not have direct or visual contact. Exhaust air from the rack passes through HEPA filters. Rodents are monitored for normal behavior and have not had issues of poor breeding/neonatal care indicative of stress. Investigators are aware of the housing situation and have evaluated the practice for its potential impact on their research. The veterinary staff has reviewed literature cited by the Guide and AAALAC to ensure appropriate management practices for these situations.

Non-affiliate Participation:

Please indicate whether a nonaffiliated ACUC member was able to participate in any part of the semiannual facility inspections for the following reporting periods:

2018:

X Spring

X Fall

2019:

X Spring

X Fall

2020:

[] Spring

[] Fall

Program Response to COVID-19:

If applicable, briefly describe staffing and/or animal care changes implemented by your animal program in response to COVID-19.

Our program utilized alternate work schedules, social distancing and wearing of face masks and in some cases face shields, in response to the COVID-19 pandemic

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

IC Name: National Institute of Mental Health

Semiannual Report Submission Date: October 31, 2020

Most Recent Spring Program Review Date(s)	3/2/20
Most Recent Fall Program Review Date(s)	10/2/2020

Bldg/Area/Rm	Most Recent Inspection Date(s)		Gross Sq. Ft. AF/SF	Species Housed			Average Daily Inventory		
	Spring	Fall		1	2	3	4	5	6
Reduced by agreement	3/2/2020	10/2/2020	1100	Mouse	Rat	3 Hamster	1 65	2 10	3 20
				4 Nile Grass Rat	5	6	4 100	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

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

IC Name: Select one --

Semiannual Report Submission Date: October 31, 2020

CONTINUATION PAGE

Bldg/Area/Rm	Most Recent Inspection Date(s)		Gross Sq. Ft. AF/SF	Species Housed			Average Daily Inventory		
	Spring	Fall		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
				1	2	3	1	2	3
				4	5	6	4	5	6

Page