

# SEMIANNUAL REPORT

## ANIMAL CARE AND USE PROGRAM REVIEW AND FACILITY INSPECTION OF THE NATIONAL INSTITUTE OF MENTAL HEALTH APRIL 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	2/28/2020	Redacted by agreement	
		SA	2/28/2020		
		SA	2/28/2020		
		SA	2/28/2020		
		SA	2/28/2020		
		SA	2/28/2020		
		Surg	2/28/2020		
		Surg	2/26/2020		
		SA	2/26/2020		
		Surg	2/26/2020		
		Surg	2/26/2020		
		SA	2/26/2020		
		SA	2/26/2020		
		SA	2/26/2020		
		Surg	2/26/2020		
		Surg	2/26/2020		
		SA	2/26/2020		
		SA	2/26/2020		
		SA	2/27/2020		
		SA	2/27/2020		
		SA	2/26/2020		
		SA	2/27/2020		
		SA	2/26/2020		
		SA	2/26/2020		
		SA	2/27/2020		
		Surg	2/27/2020		
		Surg	2/26/2020		
		Surg	2/27/2020		
		Surg	2/27/2020		
		SA	2/27/2020		
		SA	2/27/2020		
		SA	2/27/2020		
		SA	2/27/2020		
		Surg	2/27/2020		
		SA	2/27/2020		
		SA	2/26/2020		
		Surg	2/26/2020		
		SA	2/26/2020		

Bldg	Location	Type	Date	ACUC Members
Redacted by agreement		SA	2/26/2020	Redacted by agreement
		Surg	2/26/2020	
		Surg	2/26/2020	
		SA	3/2/2020	
		SA	3/2/2020	
		SA	3/2/2020	
		SA	3/2/2020	
		SA	3/2/2020	
		Surg	3/2/2020	
		SA	2/27/2020	
		SA	3/2/2020	
		SA	3/2/2020	
		SA	3/2/2020	
		SA	2/25/2020	
		SA	2/25/2020	
		SA	2/25/2020	
		Surg	2/25/2020	
		Surg/SA	2/24/2020	
		Surg	2/24/2020	
		Surg/SA	2/24/2020	
		Surg	2/24/2020	
		SA	2/24/2020	
		SA	2/24/2020	
		SA	2/24/2020	
		SA	2/24/2020	
		SA	2/24/2020	
		SA	2/24/2020	
		SA	2/24/2020	
		SA	2/25/2020	
		SA	2/25/2020	
		SA	2/25/2020	
		SA	2/25/2020	
		SA	2/25/2020	
		SA	2/25/2020	
		SA	2/24/2020	
		SA	2/25/2020	

- 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 <sup>th</sup> 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]*

<b>Program Review Process</b>	
	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
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 E, F, and G *[include or delete section letters as appropriate]* 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:

<b>Guide Departures</b>	<b>Guide Departure Citation (page #)</b>	<b>Justification (scientific, veterinary, or animal welfare)</b>
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	Veterinary justification

	111	
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	<sup>1</sup> M/S	Location	Correction Plan	Responsible Party	Scheduled Completion Date (mm/dd/yy)	<sup>2</sup> Status: C/P
1	Eyewash Stations not appropriately maintained	M	Various	Maintain station and re-train staff	PI	3/2/2020	C
2	(b)(5)						
3	On-Call schedule out of date	M	Redacted by agreement	Replace schedule and re-train staff	PI	3/2/2020	C
4	(b)(5)						
5	Expired drugs, chemicals, or supplies	M	Various	Discard items and re-train staff	PI	3/2/2020	C
6	Area not labeled with appropriate signage	M	Redacted by agreement	Label area and re-train staff.	PI	3/2/2020	C
7	Surgical instruments not appropriately sterilized	M		Re-train staff	PI	3/2/2020	C

	Deficiency	<sup>1</sup> M/S	Location	Correction Plan	Responsible Party	Scheduled Completion Date (mm/dd/yy)	<sup>2</sup> Status: C/P
8	Items stored on floor	M	Redacted by agreement	Remove items and re-train staff.	PI	3/2/2020	C
9	Drugs not appropriately sterilized	M		Re-train staff	PI	3/2/2020	C
10	Drugs or flammables inappropriately stored or labeled	M		Store and properly, label items and re-train staff.	PI	3/2/2020	C
11	Exposed Sharp	M		Dispose of Sharp and re-train staff	PI	3/2/2020	C
12	Inappropriate items disposed of in Sharps container; Re-capped needles in Sharps container	M		Re-train staff	PI	3/2/2020	C
13	Unsecured gas cylinder	M		Secure cylinder and re-train staff	PI	3/2/2020	C
14	Drugs, chemicals, or solutions inappropriately labeled	M		Label items correctly and re-train staff	PI	3/2/2020	C
15	Room requires additional cleaning or appears cluttered and difficult to sanitize	M		De-clutter and clean area and re-train staff	PI	3/2/2020	C
16	Feed or treats not appropriately labeled or stored	M		Label item and re-train staff	PI	3/2/2020	C
17	Equipment requires additional cleaning	M		Remove item and re-train staff	PI	3/2/2020	C
18	Induction chamber requires replacement	M		Replace	PI	3/2/2020	C

<sup>1</sup>M=minor; S=significant<sup>2</sup>C=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**

On February 7<sup>th</sup>, 2020, the ACUC suspended all activities on protocol Redacted by agreement for performance of activities outside of the scope of the approved protocol. After discussion and approval of a remediation plan, the protocol was reinstated on March 23<sup>rd</sup>, 2020.

**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	2/24-2/25/2020	Redacted by agreement
	2/28/2020	
	2/26-3/2/2020	

**Section I – Minority Report**

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

**NIMH ACUC Member Signatures:**

\_\_\_\_\_  
Dr. Ted Usdin  
Chairman

\_\_\_\_\_  
Dr. James Raber  
Attending Veterinarian

Redacted by agreement

Redacted by agreement

**(Revised – 4/2020)**

## Semiannual Report Attachment 3

### Supplemental Information

#### Spring 2020

**Instructions:** Submit the following information with your Spring 2020 Semiannual Report as a separate file called IC SI S20.

#### **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.

**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.

#### **Veterinary Verification & Consultation:**

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

#### **Significant changes that may undergo Veterinary Verification & Consultation (VVC):**

- a) Changes in anesthesia, analgesia, and sedation;
- b) Changes in the method of euthanasia (as long as the new euthanasia method is approved in the AVMA Guidelines for the Euthanasia of Animals and ARAC Guidelines);
- c) Changes in the method, route, dose, volume, or frequency of administration of a previously approved experimental substance; and
- d) Changes in duration, frequency, type, or number of procedures performed on an animal.

Changes to be approved must not alter the established scientific objectives, outcomes, or endpoints of the approved ASP. Changes should be refinements of previously approved procedures, rather than the approval of a new procedure or technique, that are not anticipated to adversely impact the health and/or well-being of the animal or increase the potential for side effects and/or toxicity. All changes must be appropriate for the species, age, size, and physical condition of the animal(s) in question.

The NIMH ACUC authorizes the NIMH Animal Program Director/Attending Veterinarian or, in their absence, the NIMH Senior Clinical Veterinarian, to make the changes as outlined above. The above veterinarians serve as subject matter experts for the ACUC and are approved to make changes in the anesthesia, analgesia, sedation, and/or euthanasia methods previously delineated on an approved ASP within the limits of: a) current publications and literature; b) the *Formulary for Laboratory Animals*

(Hawk, et. al.); c) the *Exotic Animal Formulary* (Carpenter); d) the *Veterinary Drug Handbook* (Plumb); e) *Lumb and Jones's Veterinary Anesthesia and Analgesia* (Tranquilli, et. al.); f) the *American College of Laboratory Animal Medicine Series*; g) the AVMA Guidelines for Euthanasia; and h) what is considered routine and customary in the practice of veterinary/laboratory animal medicine.

All changes must be documented as an amendment to the approved Animal Study Proposal (ASP) and be signed by the Principal Investigator and the endorsing veterinarian. The approved amendment shall subsequently be circulated to the appropriate animal facilities by the NIMH ACUC Coordinator and submitted to the NIMH ACUC for subsequent review and documentation in ACUC minutes.

**Animal Adoption:**

If applicable, please provide the number of animals adopted from your IC by species.

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

N/A

**NIMH ANIMAL PROGRAM SEMIANNUAL ASSESSMENT CHECKLIST**  
(Based upon 2011 Guide)

DATE: 4/30/2020

	PROGRAM AREAS	GUIDE Page	ACCEPT	Type of Deficiency	
				MINOR	SIGNIF
<b>I</b>	<b>ANIMAL CARE &amp; USE PROGRAM</b>				
<b>A</b>	<b>Program Management &amp; Responsibility</b>	13-24	X		
	• Key Management Personnel – IO, Attending Vet, ACUC	13-15	X		
	• Collaborations – Review of IAAs, 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, PM3044-2, Visitors)	17-23		F-4,11, 12,13, 14,15, 16,17, 18	
	• Personnel Security	23	X		
	• Investigating & Reporting Animal Concerns (ARAC C2)	23-24		F-6	
<b>B</b>	<b>Program Oversight</b>	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		
	o Use-Benefit Analysis	27	X		
	o Protocol Endpoints	27-28	X		
	o Unexpected Outcomes	28-29	X		
	o Physical Restraint (Prolonged)	29-30	X		
	o Multiple Survival Surgery Procedures	30	X		
	o Food & Fluid Regulation	30-31	X		
	o Non-Pharmaceutical Grade Compounds	31-32	X		
	• Post-approval Monitoring	33	X		
<b>C</b>	<b>Disaster Planning &amp; Emergency Preparedness</b>	35	X		
<b>II</b>	<b>ENVIRONMENT, HOUSING, &amp; MANAGEMENT</b>				
<b>A</b>	<b>Terrestrial Animal Environment</b> Temp, Humidity, Ventilation, Air Quality, Illumination, Noise & Vibration	42-50	X		
<b>B</b>	<b>Terrestrial Housing</b> – Primary Enclosure, Enrichment, Outdoor Housing, Naturalistic Environments, Space	50-63	X		
<b>C</b>	<b>Terrestrial Management</b> - 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		F-3,5,10,	
<b>D</b>	<b>Aquatic Animal Environment</b> - Water Quality, Support System, Temperature, Humidity, Ventilation, Illumination, Noise & Vibration	77-82	X		
<b>E</b>	<b>Aquatic Housing</b> – Primary Enclosure, Enrichment, Social Housing, Outdoor Housing, Naturalistic Environments, Space	82-83	X		
<b>F</b>	<b>Aquatic Management</b> - 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		
<b>III</b>	<b>VETERINARY CARE</b>				
<b>A</b>	<b>Animal Procurement &amp; Transportation</b> (ARAC A1a, A1b, CC Policy)	106-107	X		
<b>B</b>	<b>Preventive Medicine</b> - Biosecurity, Quarantine, Stabilization, Separation of Species, & Disease Surveillance, Diagnosis, Treatment, Control (PM3043-1, PM3044-1, ARAC D3)	109-113	X		
<b>C</b>	<b>Clinical Care &amp; Management</b> - Medical Management, Emergency Care, & Recordkeeping	113-115	X		
<b>D</b>	<b>Surgery</b> - Training, Planning, Facilities, Procedures, Aseptic Technique, Intra-Op Monitoring, Post-Op Care	115-120		F-7, 9	
<b>E</b>	<b>Pain &amp; Distress</b> (ARAC B12, P&D Memo)	120-121	X		
<b>F</b>	<b>Anesthesia &amp; Analgesia</b> (PM 1345)	121-123		F-2,	
<b>G</b>	<b>Euthanasia</b> (ARAC B4, B5)	123-124	X		
<b>IV</b>	<b>PHYSICAL PLANT</b>				
<b>A</b>	<b>Functional Areas</b> – Housing, Care, Sanitation, Receipt, Quarantine, Separation of Species, Storage	135-136		F-8,	
<b>B</b>	<b>Construction Guidelines</b> - 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		F-1	
<b>C</b>	<b>Special Facilities</b> - Surgery, Barriers, Imaging, Irradiators, Hazard Containment, Behavior Studies, Aquatics	143-150	X		
<b>D</b>	<b>Security &amp; Access Control</b>	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. 10/2012

**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: April 30, 2020**

Spring Program Review Date(s):	3/2/20					
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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	3/2/2020		1100	<sup>1</sup> Mouse	<sup>2</sup> Rat	<sup>3</sup> Hamster	<sup>1</sup> 70	<sup>2</sup> 12	<sup>3</sup> 28
				<sup>4</sup> Nile Grass Rat	<sup>5</sup>	<sup>6</sup>	<sup>4</sup> 100	<sup>5</sup>	<sup>6</sup>
				<sup>1</sup>	<sup>2</sup>	<sup>3</sup>	<sup>1</sup>	<sup>2</sup>	<sup>3</sup>
				<sup>4</sup>	<sup>5</sup>	<sup>6</sup>	<sup>4</sup>	<sup>5</sup>	<sup>6</sup>
				<sup>1</sup>	<sup>2</sup>	<sup>3</sup>	<sup>1</sup>	<sup>2</sup>	<sup>3</sup>
				<sup>4</sup>	<sup>5</sup>	<sup>6</sup>	<sup>4</sup>	<sup>5</sup>	<sup>6</sup>
				<sup>1</sup>	<sup>2</sup>	<sup>3</sup>	<sup>1</sup>	<sup>2</sup>	<sup>3</sup>
				<sup>4</sup>	<sup>5</sup>	<sup>6</sup>	<sup>4</sup>	<sup>5</sup>	<sup>6</sup>
				<sup>1</sup>	<sup>2</sup>	<sup>3</sup>	<sup>1</sup>	<sup>2</sup>	<sup>3</sup>
				<sup>4</sup>	<sup>5</sup>	<sup>6</sup>	<sup>4</sup>	<sup>5</sup>	<sup>6</sup>

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

IC Name: Select one --

Semiannual Report Submission Date: April 30, 2020

**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
				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 #

April 30, 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"/>
				<input type="checkbox"/>
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				<input type="checkbox"/>

ACUC Chair Mailing Address & Phone #:

NIMH

Redacted by agreement

Attending Vet Phone #:

Redacted by agreement

**NIMH ACUC Member Signatures:**

Theodore B.  
Usdin -S  
Dr. Ted Usdin  
Chairman

Digitally signed by Theodore  
B. Usdin -S  
Date: 2020.04.22 14:47:16  
+04'00'

Redacted by agreement

Dr. James Raber  
Attending Veterinarian

Redacted by agreement

(Revised – 4/2020)

**NIMH ACUC Member Signatures:**

\_\_\_\_\_  
Dr. Ted Usdin  
Chairman

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\_\_\_\_\_  
Dr. James Raber  
Attending Veterinarian

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