

SEMIANNUAL REPORT

ANIMAL CARE AND USE  
PROGRAM REVIEW AND FACILITY INSPECTION  
OF THE

NIAID DIR

October 2019

**Section A – Site Visits & Program Review**

- 1) Inspections of the NIAID DIR 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:

Animal Facilities (AF):		Date	ACUC Members:		
Redacted by agreement		4/12/2019	Cunningham,	Redacted by agreement	
		4/12/2019	Cunningham,		
		4/19/2019	Cunningham,	Redacted by agreement	
		5/23/2019	Cunningham,	Redacted by agreement	
		6/5/2019	Cunningham,		
		7/16/2019	Cunningham,		
		9/24/2019	Cunningham,		

Satellite Facility (SF):		Date:	ACUC Members:	
Redacted by agreement		7/16/2019	Redacted by agreement	

USDA-defined Study Area (SA):		Date:	ACUC Members:	
Redacted by agreement		5/8/2019	Cunningham,	Redacted by agreement
		5/8/2019	Cunningham,	
		5/8/2019	Cunningham,	
		5/3/2019	Cunningham,	

NIAID DIR Laboratory <i>In-vivo</i> Procedure Location (Surg):		Date:	ACUC Members:	
Redacted by agreement		5/17/2019	Cunningham,	Redacted by agreement
		5/17/2019	Cunningham,	
		5/17/2019	Cunningham,	
		5/17/2019	Cunningham,	
		5/17/2019	Cunningham,	
		5/3/2019	Cunningham,	
		5/3/2019	Cunningham,	
		5/3/2019	Cunningham,	
		5/3/2019	Cunningham,	
		5/8/2019	Cunningham,	
		5/8/2019	Cunningham,	
		5/8/2019	Cunningham,	
		5/8/2019	Cunningham,	
		5/8/2019	Cunningham,	

- 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 <sup>th</sup> Edition (Guide)
	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: NIAID DIR Semi-Annual Self-Assessment Checklist (derived originally from OACU checklist)

#### Program Review Dates and Topics:

NIAID DIR Program Review Dates and Topics:	
Spring Program Review Date & Topics	3/13/2019 All topics were assessed.
Fall Program Review Date(s) & Topics	09/12/2019. All topics were assessed.

- 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
√	Other, please describe: Documents/resources listed in A3) are reviewed and discussed at a separate subcommittee meeting to which all ACUC members have been invited. The resultant checklist is then reported to the full committee at the next convened meeting.

#### **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:** [√]
- 2) **Key Personnel Changes:** [√]
- 3) **Animal Facility/Area Changes:** [√]

#### **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	Justification (scientific, veterinary, or animal welfare)
Mice are euthanized in the	Mice in murine pathogen-study rooms, and mice in rooms under quarantine for adventitious murine

animal holding room.	pathogens, must be euthanized in the same room in order to maintain biocontainment. All euthanasias are performed in Biological Safety Cabinets, so the other animals in their individually ventilated cages are not directly exposed to sights, sounds, or smells that might be associated with the euthanasia procedure.
Mice are raised under low-light conditions.	Mice will be raised under low-light (100 lux or less) conditions to examine the microphthalmia phenotype of gene-knockout strains. Light deprivation of neonate mice can lead to retinal deterioration and blindness, which is not painful or distressful, but results in microphthalmia. The retinal deterioration phenotype is influenced by genetic factors, including some involving innate immune responses studied by our investigators. The light-deprivation studies are conducted in collaboration with investigators from the National Eye Institute in a special low-light animal housing room in the <span style="border: 1px solid black; padding: 0 2px;">Redacted</span>

## 2. Exceptions to the AWAR:

Species	9CFR title/section	Description and Rationale
NHPs (macaques, African green monkeys, owl monkeys, marmosets, tamarins, and squirrel monkeys)	9CFR3.81(a)(2)	NHPs are singly housed for infectious-disease experiments. The scientific justification included prevention of cross-contamination of infectious agent groups, and prevention of infection of non-infected control group animals. The medical justification is to prevent injury of sick monkeys by healthier peers.
Guinea pigs, cotton rats, dormice, African thick-tailed rats, hamsters, rabbits, ferrets, and NHPs	9CFR2.31(d)(1)(iv)(A)	Regulated species are used in Column E (unrelieved pain and/or distress) experimental-endpoint studies. The scientific justification included the lack of alternatives to the painful or distressful procedures consistent with obtaining valid results and achieving the approved Study Objectives.

### **Section E – Previous Deficiencies & Plans:**

The committee validated that the plans and schedules for deficiencies noted during the previous NIAID DIR program review, and facilities and laboratory inspections were achieved within the time intervals projected on the previous semiannual report.

Deficiencies noted during the previous NIAID DIR program review: [√] **None**

Deficiencies noted during the previous semi-annual review facilities and laboratory inspections: [√]

### **Section F – Current Deficiencies & Plans:**

Deficiencies found *over the past 6 months* during NIAID DIR 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

<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:

SA 1 <sup>st</sup> noted	Description of event	Current Status

### **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	6/ 12/2019	Cunningham,	Redacted by agreement		
	7/26/2019	Cunningham,			
	8/6/2019	Cunningham,			
	8/6/2019	Cunningham,			
	8/6/2019	Cunningham,			
	9/5/2019	Cunningham,			
	9/5/2019	Cunningham,			
	9/5/2019	Cunningham,			
	9/19/2019	Cunningham,			
			Redacted d	Paré,	Redacted bv

**Section I – Minority Report**

There *is no* minority report filed with this semiannual report.

# Semiannual Report Attachment 3

## Supplemental Information

### Fall 2019

**Instructions:** Submit the following information with your Spring 2018 Semiannual Report as a separate file called IC-SI-S19.

#### **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.

1. We have mixed species animal holding rooms in the [Redacted by agreement] and [Redacted by agreement] animal facilities. No animal welfare concerns have been noted in their operation.  
In addition, mice are required as sentinels for the mixed-species housing. Mice are thus housed on used bedding from the other species, including rats, in order to maintain surveillance for mouse pathogens and protect our mouse colony resources. No negative effects have been observed in the sentinel mice. This is consistent with recent studies showing no negative effects of housing mice and rats in the same room: <http://www.ncbi.nlm.nih.gov/pubmed/25650970> J. Am. Assoc. Lab. Anim. Sci. 53(6): 647-52, 2014. Effects of rat visual, olfactory, or combined stimuli during cohousing on stress-related physiology and behavior in C57BL/6NCrI mice. <http://www.ncbi.nlm.nih.gov/pubmed/19807969> J. Am. Assoc. Lab. Anim. Sci. 48(5): 492-8, 2009. Breeding and housing of laboratory rats and mice in the same room does not affect the growth or reproduction of either species.
2. The [Redacted by agreement] clean-side cagewash operates at negative pressure relative to the facility. There is a solid wall between the clean and dirty cage wash areas, with only a rack washer connecting the two rooms. Clean and dirty cage wash rooms have separate openings onto a central corridor, and both are under negative pressurization. Cleaned cage components are assembled as needed with the micro-isolator lid on top, and autoclaved before use to house animals. Excess autoclaved cage set-ups are re-autoclaved before use if not used within 2 weeks. No animal health issues have been identified resulting from these room pressurization schemes.
3. For purposes of animal colony health maintenance, small Armenian hamsters are pair-housed in individually-ventilated mouse cages in [Redacted by agreement]. As these hamsters are less than 80 grams in weight, the floor area of the mouse cages is sufficient to house the animals socially and to allow the provision of physical enrichment (such as cardboard tubes for recreation). However, because the height of the cages is 5 inches, although sufficient for full behavioral posturing, this constitutes a departure from the Guide for the Care and Use of Laboratory Animals.

### Institutional Animal Care & Use Committee Roster

Member Name	Degree/Credentials	Position Title	PHS Policy Membership Role	New Member
Redacted by agreement				
Kirk Cunningham	Ph.D.	Chair	Member	
Redacted by agreement				
Daniel Pare	DVM	Veterinarian	Attending Veterinarian	
Redacted by agreement				

ACUC Chair Mailing Address & Phone #:

Dr. Kirk Cunningham

Redacted by agreement

Attending Veterinarian: Dr. Daniel Paré

Phone #: Redacted by

agreement

## Institutional Animal Care & Use Committee Roster

Member Name	Degree/Credentials	Position Title	PHS Policy Membership Role	New Member
Redacted by agreement				√
				√
				√

ACUC Chair Mailing Address & Phone #:

Dr. Kirk Cunningham

Redacted by agreement

Attending Veterinarian: Dr. Daniel Paré  
Phone #: Redacted by agreement



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

**IC Name:** NIAID DIR

**Fall Semiannual Report Submission Date:** October 31, 2019

Spring Program Review Date:	3/13/2019
-----------------------------	-----------

Fall Program Review Date:	9/12/2019
---------------------------	-----------

Building number	Facility Insp. Date(s) Fall/Spring		Gross Square Footage	Species Housed			Average Daily Inventory		
Redacted by agreement		3/15/2019	8,309	<sup>1</sup> Mice	<sup>2</sup> NHP	<sup>3</sup>	<sup>1</sup> 3,599	<sup>2</sup> 2	<sup>3</sup>
				<sup>4</sup>	<sup>5</sup>	<sup>6</sup>	<sup>4</sup>	<sup>5</sup>	<sup>6</sup>
	10/16/2018	4/19/2019	14,781	<sup>1</sup> Mice	<sup>2</sup> Rats	<sup>3</sup> Ferrets	<sup>1</sup> 4,052	<sup>2</sup> 1	<sup>3</sup> 17
				<sup>4</sup> Hamsters	<sup>5</sup> Chickens	<sup>6</sup> Thicket Rats	<sup>4</sup> 55	<sup>5</sup> 3	<sup>6</sup> 280
	10/19/2018	4/12/2019	1,243	<sup>1</sup> Mice	<sup>2</sup>	<sup>3</sup>	<sup>1</sup> 1,670	<sup>2</sup>	<sup>3</sup>
				<sup>4</sup>	<sup>5</sup>	<sup>6</sup>	<sup>4</sup>	<sup>5</sup>	<sup>6</sup>
	10/19/2018	4/12/2019	2,397	<sup>1</sup> Mice (isolators)	<sup>2</sup>	<sup>3</sup>	<sup>1</sup> 18	<sup>2</sup>	<sup>3</sup>
				<sup>4</sup>	<sup>5</sup>	<sup>6</sup>	<sup>4</sup>	<sup>5</sup>	<sup>6</sup>
	11/29/2018	5/23/2019	18,105	<sup>1</sup> Mice	<sup>2</sup> Rats	<sup>3</sup> Thicket Rats	<sup>1</sup> 16,120	<sup>2</sup> 15	<sup>3</sup> 242
				<sup>4</sup> Hamsters	<sup>5</sup> Guinea Pigs	<sup>6</sup>	<sup>4</sup> 38	<sup>5</sup> 1	<sup>6</sup>



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

**IC Name:** NIAID DIR

**Fall Semiannual Report Submission Date: October 31, 2019**

**CONTINUATION PAGE**

Building number	Facility Insp. Date(s) Fall/Spring		Gross Square Footage	Species Housed			Average Daily Inventory		
Redacted by agreement	1/25/2019	7/16/2019	19,756	<sup>1</sup> Mice	<sup>2</sup> Dormice	<sup>3</sup> NHPs: Macaques: 13 Marmosets: 20	1 4,613	2 110	<sup>3</sup> 33
				<sup>4</sup> Rabbits	<sup>5</sup> Rats	<sup>6</sup> Ferrets	4 20	5 42	6 0
	1/29/2019	7/16/2019	1,009	<sup>1</sup> Mice	<sup>2</sup> Ferrets	<sup>3</sup>	1 2	2 0	3
				<sup>4</sup>	<sup>5</sup>	<sup>6</sup>	4	5	6
	12/07/2018	6/05/2019	18,184	<sup>1</sup> Mice	<sup>2</sup>	<sup>3</sup>	1 11,151		
				<sup>4</sup>	<sup>5</sup>	<sup>6</sup>			

**LABORATORY ANIMAL CARE AND USE PROGRAM EVALUATION**  
**SEMI-ANNUAL SELF-ASSESSMENT SUMMARY**  
**Meeting September 12<sup>th</sup>, 2019**

THE NIAID DIR ACUC HAS REVIEWED THE FOLLOWING AREAS, AND CONCURS THAT, EXCEPT WHERE NOTED, THE NIAID DIR ANIMAL CARE AND USE PROGRAM IS IN ACCORDANCE WITH ALL APPLICABLE REGULATIONS, POLICIES, & GUIDELINES.

	PROGRAM AREAS	Guide Page	ACCEPT	Type of Deficiency		Program Changes and Deficiencies (if any)
				MINOR	SIGNIF	
<b>I.</b>	<b>INSTITUTIONAL ANIMAL CARE AND USE PROGRAM POLICIES &amp; PROCEDURES</b>					
A.	Animal Care and Use Committee Composition	24	√			I.A
B.	Semi-annual Assessment (Facility Inspections & Animal Program Review)	25	√			
C.	Animal Study Proposal Review ( <i>de novo</i> , Annual Reviews, & Amendments)	25-26	√			
D.	Continuing Review of On-going Animal Activities	33-34	√			I.D
E.	Prolonged Restraint	29-30	√			
F.	Multiple Survival Surgery	30	√			
G.	Animal Activities Suspension	25	√			
H.	Violation/Concerns Reporting by Personnel	23, 25	√			
I.	Animal Procurement/Transport/Quarantine	106-109	√			
J.	Veterinary Care Program	105-106	√			I.J
K.	Animal Colony Health Management Program	109-113	√			
L.	Personnel Qualifications/Training & Continuing Education Program Assessment	20, 115-116	√			I.L
M.	Personal Hygiene/Animal Exposure Program participation	18, 20-23	√			
N.	Procedures for Animal Research with Hazardous Agents	20-21	√			
O.	Record Keeping	75-77	√			
P.	Report Preparation and Submission	24-25	√			

<b>II.</b>	<b>VETERINARY MEDICAL CARE</b>					
A.	Daily Care Including Emergency/Weekend/Holiday	105-120	√			
B.	Prevention and Control of Animal Disease	109-113	√			
C.	Anesthesia, Analgesia	121-123	√			
D.	Surgery	115-120	√			
E.	Pre- & Post-Procedural Care, including medical record keeping	115	√			
F.	Euthanasia - Policies & Procedures	123-124	√			II.F

<b>III.</b>	<b>LABORATORY ANIMAL HOUSING AND DAILY CARE</b>					
A.	Primary Enclosures/Shelter	41-75	√			III.A
B.	Social Environment/Exercise	63-65	√			III.B
C.	Food/Water/Bedding	65-69, 84-85	√			
D.	Animal Handling	105	√			
E.	Sanitation	69-73	√			
F.	Animal Identification and Records	75-77	√			
G.	Transportation - within and between facilities	107-109	√			

<b>IV.</b>	<b>PHYSICAL FACILITIES</b>					
A.	Support Facilities and Arrangement	136-143	√			IV.A
B.	Facility Construction/Preventive Maintenance/Maintenance & Repair	136-143	√			
C.	Power and Lighting, including coverage by emergency generator(s)	81, 141	√			
D.	Ventilation - air changes and pressure differentials	80-81, 139-140	√			
E.	Temperature and Humidity Control	80-81, 139-140	√			
F.	Noise Control	142-143	√			
G.	Facility Sanitation/Waste Disposal	69-73, 143	√			
H.	Integrated Pest Management System - assessment	73	√			
I.	Security	23, 151	√			
J.	Safety	22-23, 109-111	√			

## Spring Semi-Annual Assessment Period, 2019

**ACCEPT = Category found to be in accordance with regulations & policies. SIGNIF = Significant deficiency, i.e. one that may present a threat to the health and safety of the animals. MINOR: Deficiency that does not present a threat to animal welfare or occupational health.** (See [ARAC Guidelines on Classifying Deficiencies Identified during Semiannual Reviews](#))

### Footnotes:

#### I.A Animal Care and Use Committee Composition

Redacted by [redacted] joined the Committee as the LISB member.

Redacted by [redacted] joined the Committee as the LID alternate member.

Redacted by [redacted] was promoted from LID alternate member to member.

#### 1.D Continuing Review of On-going Animal Activities

A new method of tracking Column D animals was instituted.

#### I.J Veterinary Care Program

Redacted by [redacted] assumed responsibility as the Facility Veterinarian for the [redacted by agreement]

#### I.L Personnel Qualifications/Training & Continuing Education Program Assessment

The following personnel achieved AALAS certification:

Redacted by [redacted] - LATG

Redacted by [redacted] - LATG

Redacted by [redacted] - ALAT

Redacted by [redacted] - ALAT

Redacted by [redacted] - ALAT

Redacted by [redacted] - ALAT

Redacted by [redacted] - LATG

#### II.F Euthanasia - Policies & Procedures

Two new 4 chamber Euthanex machines were purchased for use in [redacted by agreement] and [redacted by agreement]

#### III.A Primary Enclosures/Shelter

The [redacted by agreement] animal facility was closed.

The [redacted by agreement] Rodent facility was opened.

#### III.B Social Environment/Exercise

All mouse cages now receive hardwood chew sticks.

#### IV.A Support Facilities and Arrangement

A procedure room in the [redacted by agreement] was renovated.

#### Meeting attendees:

Kirk Cunningham

Dan Paré

Redacted by [redacted]  
agreement

Date: September 12<sup>th</sup>, 2019

Time: 3 pm to 3:27 pm