

SEMIANNUAL REPORT

ANIMAL CARE AND USE  
PROGRAM REVIEW AND FACILITY INSPECTION  
OF THE

NIAID DIR

April 2020

**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	10/9/2019	Cunningham, Redacted by agreement
	10/9/2019	Cunningham,
	10/18/2019	Cunningham,
	11/21/2019	Cunningham, Redacted by agreement, Paré, Redacted by agreement
	12/6/2019	Cunningham, Redacted by agreement
	1/14/2020	Cunningham,
	N/A	N/A (Inspection not conducted as per approved waiver from OLAW)

Satellite Facility (SF):	Date:	ACUC Members:
Redacted by agreement	1/ 16/2020	Redacted by agreement

USDA-defined Study Area (SA):	Date:	ACUC Members:
Redacted by agreement	12/8/2019	Cunningham, Redacted by agreement
	12/8/2019	Cunningham,
	12/8/2019	Cunningham,
	11/8/2019	Cunningham,

NIAID DIR Laboratory <i>In-vivo</i> Procedure Location (Surg):	Date:	ACUC Members:
Redacted by agreement	11/5/2019	Cunningham, Redacted by agreement, Paré, Redacted by agreement
	11/5/2019	Cunningham, Paré,
	11/5/2019	Cunningham, Paré,
	11/5/2019	Cunningham, Paré,
	11/5/2019	Cunningham, Paré,
	11/8/2019	Cunningham,
	11/8/2019	Cunningham,
	11/8/2019	Cunningham,
	11/8/2019	Cunningham,
	12/8/2019	Cunningham, Redacted by agreement
	12/8/2019	Cunningham,
	12/8/2019	Cunningham,
	12/8/2019	Cunningham,
	12/8/2019	Cunningham,
	12/8/2019	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)

**[NOTE: If the Program Review is done incrementally, use the table below to document the topics reviewed and the dates of review (see README instructions). If an incremental review was performed, it is critical that a 6-month review schedule (+/-30 days) was followed. Failure to follow this 6-month review schedule will result in an ACUC report of noncompliance with the PHS Policy. NOTE: If this table is used to capture additional topics that were reviewed by the ACUC, it must be made clear in this part of the report what the topics listed in the table represent. In the narrative prior to this table it must be clear that a comprehensive review was also completed.]**

**Program Review Dates and Topics:**

Spring Program Review Date & Topics	3/17/2020 All topics were assessed.
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- 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
X	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:

**Administrative/Procedural Changes:**

Euthanasia	In compliance with new AVMA and ARAC guidelines the SOP for CO2 euthanasia was changed to a flow rate of 30% chamber volume/minute
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**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)
Vice Chair	Redacted by agreement	Joined
ACUC Coordinator role		Joined

**3) Animal Facility/Area Changes:**

Facility Type (AF/SF)	Location	Action (opened, closed, under renovation, etc.)

**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: *[As defined by OLAW, ACUC-approved Guide departures must have a scientific, animal welfare, or veterinary justification. List only departures that are included on the list provided in the README file.]*

Guide Departures	Guide Departure Citation (page #)	Justification (scientific, veterinary, or animal welfare)
Mice are euthanized in the animal holding room.		Mice in murine pathogen-study rooms, and mice in rooms under quarantine for adventitious murine 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 Redacted

2. Exceptions to the AWAR:

Species	# Animals	9CFR	Description and Rationale
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	Affected (this Period)	title/section	
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-kitted 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 (*IC name*) 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: [√] **None**

**[NOTE: Complete the table only for deficiencies that have not been resolved. Delete this statement AND the table if they are not needed. See the “README” file for further guidance.]**

	Deficiency and Plan	<sup>1</sup> M/S	SA 1 <sup>st</sup> noted	Location	Responsible Party	Status update	Revised completion date mm/dd/yy
1							
2							

<sup>1</sup>M=minor; S=Significant

***[If deficiencies have not been resolved since the last semiannual (SA), the ACUC needs to review those specific items, and reassess the timeline for correction. In addition, OACU should be informed if it is an ongoing issue that is not easily resolvable and that may require input and support directly from the Institutional Official.]***

### **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

***[See the “README” file for guidance on Section F.] If a significant deficiency is being contemplated; the Director, OACU must be contacted prior to finalizing your report. For a significant deficiency to be listed it must be agreed upon by both the ACUC and IO/DDIR. The Director, OACU will facilitate this discussion with the IO/DDIR.***

### **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**

**[OR]**



**[Please give a very short description of the event and its current status, i.e. resolved (month/year). Delete this statement AND the table if they are not needed. See the "README" file for complete guidance.]**

SA 1 <sup>st</sup> noted	Description of event	Current Status
11/20/19	Thicket rats were administered a non-approved dosage of an approved substance (azithromycin.)	Resolved 2/20

**[If reportable events have not been resolved since the last semiannual (SA), the ACUC needs to review those specific items and verify what actions need to occur for timely resolution. In addition, OACU should be informed if it is an ongoing issue that is not easily resolvable and that may require input and support directly from the IO.]**

### **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	12/11/2019	Cunningham, Redacted hv, Paré, Redacted hv
	1/17/2020	Cunningham, Redacted by agreement
	2/6/2019	Cunningham,
	2/6/2019	Cunningham,
	2/6/2019	Cunningham,
	3/13/2020	Cunningham,
	3/13/2020	Cunningham,
	3/13/2020	Cunningham,
	3/5/2020	Redacted by agreement (approved as qualified ad hoc inspectors)

### **Section I – Minority Report**

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



# 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.

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/6NCr 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]. 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	Ph.D.	ARAC Ombudsman	Ex Officio; Non-Voting	
Kirk Cunningham	Ph.D.	Chair	Member	
Redacted by agreement				X
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

**Spring Semiannual Report Submission Date: April 30, 2020**

Spring Program Review Date:	3/13/2020
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Fall Program Review Date:	
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Building number	Facility Insp. Date(s) Fall/Spring		Gross Square Footage	Species Housed			Average Daily Inventory		
Redacted by agreement	3/15/2019	3/27/2020	8,309	<sup>1</sup> Mice	<sup>2</sup>	<sup>3</sup>	<sup>1</sup> 4,454	<sup>2</sup>	<sup>3</sup>
				<sup>4</sup>	<sup>5</sup>	<sup>6</sup>	<sup>4</sup>	<sup>5</sup>	<sup>6</sup>
	4/19/2019	10/18/2019	14,781	<sup>1</sup> Mice	<sup>2</sup> Rats /Thicket Rats	<sup>3</sup> Ferrets	<sup>1</sup> 3,887	<sup>2</sup> 2/150	<sup>3</sup> 42
				<sup>4</sup> Hamsters	<sup>5</sup> Chickens	<sup>6</sup> Guinea Pigs	<sup>4</sup> 78	<sup>5</sup> 18	<sup>6</sup> 2
	4/12/2019	10/9/2019	1,243	<sup>1</sup> Mice	<sup>2</sup>	<sup>3</sup>	<sup>1</sup> 2,403	<sup>2</sup>	<sup>3</sup>
				<sup>4</sup>	<sup>5</sup>	<sup>6</sup>	<sup>4</sup>	<sup>5</sup>	<sup>6</sup>
	4/12/2019	10/9/2019	2,397	<sup>1</sup> Mice (isolators)	<sup>2</sup>	<sup>3</sup>	<sup>1</sup> 22	<sup>2</sup>	<sup>3</sup>
				<sup>4</sup>	<sup>5</sup>	<sup>6</sup>	<sup>4</sup>	<sup>5</sup>	<sup>6</sup>
	5/23/2019	11/21/2019	18,105	<sup>1</sup> Mice	<sup>2</sup> Rats	<sup>3</sup> Thicket Rats	<sup>1</sup> 18,933	<sup>2</sup> 5	<sup>3</sup> 382
				<sup>4</sup> Hamsters	<sup>5</sup> Guinea Pigs	<sup>6</sup>	<sup>4</sup> 12	<sup>5</sup> 10	<sup>6</sup>

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

**IC Name:** NIAID DIR

**Spring Semiannual Report Submission Date: April 30, 2020**

**CONTINUATION PAGE**

Building number	Facility Insp. Date(s) Fall/Spring		Gross Square Footage	Species Housed			Average Daily Inventory		
Redacted by agreement	7/16/2019	1/14/2020	19,756	<sup>1</sup> Mice	<sup>2</sup> Dormice	<sup>3</sup> NHPs: Macaques: 16 Marmosets:19	1 7,036	2 124	3 35
				<sup>4</sup> Rabbits	<sup>5</sup> Rats	<sup>6</sup> Ferrets	4 29	5 87	6
	7/16/2019	1/16/2020	1,009	<sup>1</sup> Mice	<sup>2</sup> Ferrets	<sup>3</sup>	1 2	2	3
				<sup>4</sup>	<sup>5</sup>	<sup>6</sup>	4	5	6
	6/05/2019	12/6/2019	18,184	<sup>1</sup> Mice	<sup>2</sup>	<sup>3</sup>	1 10,982		
				<sup>4</sup>	<sup>5</sup>	<sup>6</sup>			

**LABORATORY ANIMAL CARE AND USE PROGRAM EVALUATION**  
**SEMI-ANNUAL SELF-ASSESSMENT SUMMARY**  
Meeting March 17<sup>th</sup>, 2020

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	√			Footnote I.A
B.	Semi-annual Assessment (Facility Inspections & Animal Program Review)	25	√			Footnote I.B
C.	Animal Study Proposal Review ( <i>de novo</i> , Annual Reviews, & Amendments)	25-26	√			
D.	Continuing Review of On-going Animal Activities	33-34	√			
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	√			Footnote I.I
J.	Veterinary Care Program	105-106	√			Footnote I.J
K.	Animal Colony Health Management Program	109-113	√			
L.	Personnel Qualifications/Training & Continuing Education Program Assessment	20, 115-116	√			Footnote I.L.1 Footnote I.L.2
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	√			Footnote II.F

<b>III.</b>	<b>LABORATORY ANIMAL HOUSING AND DAILY CARE</b>					
A.	Primary Enclosures/Shelter	41-75	√			
B.	Social Environment/Exercise	63-65	√			
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	√			
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	√			Footnote IV.I
J.	Safety	22-23, 109-111	√			

## Spring Semi-Annual Assessment Period, 2020

**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 [ ] joined the Committee as the Vice Chair.  
Redacted by [ ] assumed the role of ACUC Coordinator.

#### 1.B Semi-annual Assessment

OLAW conducted a site visit of the NIH campus-based animal program.

#### I.I Animal Procurement/Transport/Quarantine

Due to the Coronavirus pandemic, social distancing is in practice on the loading docks for deliveries of animals and supplies.

#### I.J Veterinary Care Program

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

#### I.L.1 Personnel Qualifications/Training & Continuing Education Program Assessment

ACUC members and officers are enrolled for a local SCAW IACUC conference.

#### I.L.2 Personnel Qualifications/Training & Continuing Education Program Assessment

The following personnel achieved AALAS certification:

Redacted by agreement [ ] ALAT  
[ ] – ALAT  
[ ] LAT  
[ ] ALAT

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

In compliance with the new AVMA and ARAC guidelines, the SOP for CO2 euthanasia was changed to a flow rate of 30% chamber volume/minute.

#### IV.I Security

All cards readers at locked doors were upgraded.

Meeting attendees (due to the SARS CoV2 pandemic the meeting was held virtually with attendees phoning in):

Kirk Cunningham

Redacted by agreement [ ]

Date: March 17<sup>th</sup>, 2020

Time: 1:06 pm to 1:35 pm