SEMIANNUAL REPORT

ANIMAL CARE AND USE
PROGRAM REVIEW AND FACILITY INSPECTION
OF THE

NIAID DCR IRF Redacted by agreement

April 2020

Section A – Site Visits & Program Review

1) Inspections of the ***IC name*** 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	Type	Date	ACUC Members
IRF – Redacted by agreement	AF	03/12/2020	Redacted by agreement St. Claire
IRF Redacted by agreement	AF		Redacted by agreement

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, 8th Edition (Guide)
	AAALAC Program Description
x	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
	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
	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:

Section B – Regulatory Compliance:

Except as noted in Sections E and 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:

Role (ACUC Chair, ACUC AV, IC APD, or IC Animal Program Manager)	**Name**	**Action** (joined or departed)
N/A		

3) Animal Facility/Area Changes:

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

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)***
N/A		

2. Exceptions to the AWAR:

Species	***# Animals Affected (this Period)***	***9CFR title/section***	***Description and Rationale***
Nonhuman Primates	69	3.81 Environment Enhancement to Promote Psychological Well-Being	Single housing of nonhuman primates is scientifically justified, to prevent cross-contamination of infectious agents that would interfere with study results and scientific integrity; due to social incompatibility; or at the veterinarians' discretion for medical reasons, as noted in the animal's record and/or the Animal Study Proposal.

Species	*# Animals Affected (this Period)*	*9CFR title/section*	*Description and Rationale*
Nonhuman Primates	36	2.36(7) Use of anesthetic, analgesic, or tranquilizing drugs to relieve pain and distress	Column E studies are performed under rigorous scientific justification to the IACUC. Literature references must be included in the Animal Study Proposal to justify that the withholding of analgesics or other forms of pain relief would interfere with the research integrity, data results, etc. A pain score sheet must be included in the study with veterinary discretion being the ultimate decision for euthanasia.

Section E – Previous Deficiencies & Plans:

The committee validated that the plans and schedules for deficiencies noted during the previous NIAID DCR IRF - 8200 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	Small chip in wall coating	M	10/30/2018	ABSL4 Redact Redacted by	ORF	See Note*	Jan. 2021
2	Two small chips in special coating	M	10/31/2019	ABSL4 Redac Redacted by	ORF	See Note*	Jan. 2021

[1]M=minor; S=Significant

*Note: The integrity of the surfaces is not affected. Secondary epoxy coating is not compromised and allows for proper sanitation. Repairs can only be made during Zone Shutdowns. There was not ample time to perform the repairs during the previous shutdown.

Section F – Current Deficiencies & Plans:

Deficiencies found *over the past 6 months* during NIAID DCR IRF – 8200 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	n/a						
2							

[1]M=minor; S=significant **[2]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: **[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
NIHAC Building Redacted by agreement	03/09/2020	Redacted by agreement St. Claire, Redacte d
NIH Redacted by agreement	03/09/2020	St. Claire

Section I – Minority Report

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

NIAID DCR IRF – 8200 ACUC Member Signatures:

Redacted by agreement

Estella Jones, Chair, ACUC

Redacted by agreement

Marisa St. Claire, Attending Vet

Redacted by agreement

Redacted by agreement

Redacted by agreement

(Revised – 03/2020)

Assurance#: A-4149-01

April 30, 2020

Institutional Animal Care & Use Committee Roster

Member Name	Degree/Credentials	Position Title	PHS Policy Membership Role	New Member
Estella Jones	DVM	US Public Health Srvs, Dep. Dir. OCET, OCS, OC	Chair	☐
Marisa St. Claire	DVM, DACLAM	Animal Program Director	Attending Veterinarian	☐
Redacted by agreement				☐
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ACUC Chair Mailing Address & Phone #: Estella Jones, NIAID/DCR/IRF Redacted by agreement

Attending Vet Phone #: Redacted by agreement

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

IC Name: National Institute of Allergy and Infectious Diseases/DCR

Semiannual Report Submission Date: April 30, 2020

Spring Program Review Date(s):	3/12/20					

Fall Program Review Date(s):						

Bldg/Area/Rm	Facility Insp. Date(s) Spring / Fall		AF/SF; Gross Sq. Ft.	Species Housed			Average Daily Inventory		
Redacted by agreement	03/12/20		16,169	1 NHP	2 Guinea Pig	3 Hamster	1 38	2 65	3 10
				4 Mice	5	6	4 2	5	6
	06/16/20		2,985	1 NHP	2	3	1 28	2	3
				4	5	6	4	5	6
	03/16/20		233	1 Guinea Pig	2	3	1 42	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

Semiannual Report Attachment 3
Supplemental Information
Spring 2020

Performance Standards:
N/A

Veterinary Verification & Consultation:
Please see NIAID DCR ACUC Policy #15, "Guidelines for Significant Changes to Approved ASPs", attached.

Animal Adoption:
N/A

NIAID DCR ACUC Policy # 15

Guidelines for Significant Changes to Approved ASPs

To fulfill the responsibilities regarding review of changes in previously approved ASPs, and to perform that review expeditiously, ACUCs may find it useful to delegate - one or more members, (e.g. the Chair, Vice Chair, the Attending Veterinarian or her/his alternate), to determine the significance of intended changes within the context of that ASP. The NIAID DCR ACUC establishes the following policies for review and approval of Major (Category 1), Significant (Category 2), or Minor (Category 3) amendments of previously approved NIAID DCR Animal Study Proposals (ASPs). The processes for review and approval differ for the specific categories of Major, Significant, or Minor changes. The determination of which classification and type of a proposed amendment is assigned by an ACUC Officer (i.e., Chair or Vice Chair), in consultation with the Attending Veterinarian or alternate (as described below) after the ACUC Coordinator has reviewed the submission for clarity and completeness.

This NIAID DCR ACUC policy:

I) Defines the nature of changes in Study Objectives that require non-administrative ACUC review as those that represent entirely new directions for the research (such as transitions from basic to translational studies, etc.). Changes in Study Objectives that are predictable, linear progressions of current approved work may be reviewed as a Significant Category 2 (below), provided none of the other requirements for mandatory Category 1 review (a through k below) are met, at the discretion of the ACUC Chair or Vice Chair.

II) Defines the procedures for amendment review to determine the potential for personnel safety impact of the proposed changes as follows:
   a. Upon receipt of the amendment, the ACUC Coordinator does an administrative review. Once the administrative review is complete, the amendment is sent to the Chair, Vice Chair, and Attending Veterinarian or alternate to review for use of potentially hazardous materials or procedures, utilizing lists of approved substances and materials reference resources (Safety Data Sheets), etc. for classification and type. All Major, Category 1 amendments must be approved for scientific merit by the Director, IRF or alternate.
   b. Amendments involving potentially hazardous materials may be reviewed as a Significant change, Category 2 (below), provided the NIAID DCR ACUC DOHS member or alternate has identified no other requirement to classify the amendment a Major Category 1 review (a through k, below). The ACUC DOHS member/alternate has the prerogative to require the amendment be classified as a Major, Category 1 if the amendment involves previously unapproved materials or methods based on the quantity of material or circumstances of use or other considerations at his/her professional discretion.
   c. Minor (Category 3) amendments are those not deemed Major or Significant, such as changes in trained personnel performing animal activities; typographical errors; grammar corrections; updating contact information. These are then reviewed and approved by the delegated reviewer(s) and reported to the ACUC at the next convened meeting.

Category 1: Major amendments require FCR (convened ACUC meeting) or DMR (Designated Member Review per DCR ACUC Policy 01, Review Methods).

a) Changes from non-survival to survival surgery; *
b) Changes resulting in potential greater pain and/or distress, or a greater degree of invasiveness; *
c) Changes in housing and/or use of animals to a location that is not currently part of the animal program overseen by the NIAID DCR ACUC;
d) Any increase in the number of nonhuman primates or companion species (excluding rodents); *
e) Increase of greater than or equal to 5% of USDA regulated species (of original ASP approved total);
f) Increase of greater than or equal to 10% of non-USDA regulated species (of original ASP approved total);
g) Changes in species; *

h) Changes in Study Objectives; *
i) Changes requesting unapproved AVMA euthanasia agents;
j) Changes in Principal Investigator (PI); and
k) Changes that could potentially impact personnel safety.

*Should modifications of this type involve nonhuman primates (NHPs) the amendment may require additional review by the Scientific Merit Review Panel (SMRP). (See Policy 13 for full details.)

Category 2: Significant change amendments may be reviewed upon meeting criteria as specified in Category 2.1 or 2.2 of this policy.

Category 2.1: Significant change amendments may be reviewed conditionally upon the attending veterinarian or veterinary alternate providing verification and certification that the Significant change proposal has appropriately addressed this NIAID DCR ACUC policy and all applicable ARAC Guidelines, NIH Policy, AWA Regulations, ACLAM Guidelines for Veterinary Care, and *The Guide for the Care and Use of Laboratory Animals*, 8th Edition are met.

In addition to appropriate coverage by this NIAID DCR ACUC policy, the attending veterinarian/ alternate will certify the appropriateness of the conditional review of the proposed Significant change for the animals covered by the approved ASP, to which the change is proposed.

Significant change amendments appropriate for conditional review via attending veterinarian / alternate in consultation with the NIAID DCR ACUC Chair or Vice-Chair include:

a. Changes in materials administered to animals:
   i. Anesthesia, Analgesia, or Sedation, and
   ii. Experimental Substances
b. Changes in method of euthanasia
c. Duration, frequency, or number of procedures performed on an animal.

The NIAID DCR ACUC policy authorizes the attending veterinarian/alternate to request any amendment be classified as a Major, Category 1 (i.e., FCR or DMR) review for any reason, and specify that the attending veterinarian/alternate must refer any amendment that he or she determines do not meet the parameters of the ACUC reviewed and approved policies.

Notes:

a. Changes in materials administered to animals:
   i. Anesthesia, Analgesia, or Sedation:
   The NIAID DCR ACUC policies for anesthesia, analgesia, and sedation are as follows: Veterinary medical and surgical management of animals requires that choices for anesthesia and analgesia be available to obtain the desired response. A variety of modern anesthetic/analgesic regimens are available for research animal use, alone, or in combination. Ideally, the ASP will include multiple options for anesthesia, analgesia, and sedation consistent with the veterinary medical needs and scientific requirements of the study. The choice of anesthetic, analgesic, and sedative among the options listed in the ASP will be at the professional discretion of the attending veterinarian/alternate.

   ii. Experimental Substances.
   The NIAID DCR ACUC policy defines Experimental Substances as falling into two classifications:

   1) Reagents, which are typically those compounds routinely and commonly used to modulate the animal's physiology, the animal's microbiota, or the animal's biological responses (for example, to a challenge stimulus) in a scientifically predictable and rational manner. While experimental groups may be defined by the presence or absence of the administration of a particular reagent, the response to the reagent is not the scientific objective of the experiment. Rather, the scientific objective of the experiment is to observe the effect of the modulation due to the reagent on the

animal's response to a challenge stimulus. Examples include antibiotics, antigens and adjuvants, immunomodulators, monoclonal antibodies, etc.

Significant change amendments involving the administration of reagents, as defined in this policy, may be handled conditionally by the attending or alternate veterinarian in consultation with the NIAID DCR ACUC Chair or Vice Chair as necessary. In cases where there may be known and accountable occupational health considerations involved with the significant change request, a DOHS member or alternate will review the amendment for additional safety precautions.

2) Experimental compounds, for which there may be little or no preliminary information from previous experimental use (reported in the scientific literature) from which to predict an effect on the experimental system. Examples include novel compounds, derived from natural sources or chemically synthesized, to be tested for therapeutic or other pharmacologic activity. Such experimental compounds might not come with maximum-tolerated dose or toxicology data, and might not be sufficiently structurally related to other, known activity compounds to deduce a likely mechanism of action. In such cases, the initial use of such experimental compounds should be on a trial or pilot scale, and that the dosing of such compounds should be tested sequentially, either increasing from a very low dose, or performed in an up/down evaluation process from a reasonable initial dose. In all cases of use of experimental compounds, the test animals should be monitored carefully for the appearance of clinical signs of toxicity. Should clinical signs of toxicity be observed, the animals should be quickly euthanized for pathological examination, or the treatment discontinued, at the discretion of the facility's attending veterinarian/designee.

b. Changes in method of euthanasia:

If the new method of euthanasia proposed is approved in the *AVMA Guidelines for the Euthanasia of Animals*, the amendment may be reviewed by the attending veterinarian/alternate. The veterinarian will review the amendment to verify that the proposed method is AVMA approved, and appropriate for the animals (all, or a particular subset, such as animals of a specific age or species) on the study. The amendment may be conditionally approved under Category 2.

If the new method of euthanasia proposed is not included among those approved in the AVMA Guidelines for the Euthanasia of Animals, then the amendment must be reviewed as Category 1.

c. Changes in:

i. Duration:
Amendments involving increases in the duration of procedures performed on animals will be reviewed by the veterinarians. Amendments involving decreases in the duration of procedures performed on animals may be reviewed as a Minor, Category 3.

ii. Frequency:
Amendments involving increases in the frequency of procedures performed on animals will be reviewed by the veterinarians. Amendments involving decreases in the frequency of procedures performed on animals may be reviewed as a Minor, Category 3.

iii. Number of procedures performed on an animal:
Amendments involving increases in the numbers of procedures performed on animals will be reviewed by the veterinarians. Amendments involving decreases in the numbers of procedures performed on animals may be reviewed as a Minor, Category 3.

The consultation between the NIAID DCR ACUC Chair or Vice Chair and the veterinarian must be documented. This is accomplished using digital signatures within the EDRMS NIAID DCR ACUC electronic system. The approved amendment is stored in the EDRMS NIAID DCR ACUC Repository within the respective ASP folder. The PI and CM staff are notified and ACUC is informed of changes made through this process at the next convened meeting.

This process does not preclude routine veterinary intervention for individual animals but would apply if an intervention may result in a change that is applied to animals going forward.

Category 2.2: Significant change amendments that may be reviewed conditional upon determination that the amendment is in accordance with this NIAID DCR ACUC policy:

a. Increase of originally approved animals less than or equal to 10% of non-USDA regulated species,
b. Increase of originally approved animals less than or equal to 5% of USDA regulated species.
c. Any increase of originally approved nonhuman primates or companion animals (excluding rodents) must be reviewed IAW Category 1.

No additional consultation is required. The approved amendment is stored in the EDRMS NIAID DCR ACUC Repository within the respective ASP folder. The PI and CM staff are notified and ACUC is informed of changes made through this process at the next convened meeting.

Category 3: Amendments that may be administratively reviewed unconditionally (i.e., without ACUC-approved policies, veterinary consultations, or notifications):

a. Correction of typographical errors;
b. Correction of grammar;
c. Contact information updates; and
d. Change in personnel other than the PI.

Notes: The administrative review will ensure that all personnel are appropriately identified; adequately trained and qualified; enrolled in occupational health and safety programs; and meet other criteria as required by the ACUC. The approved amendment is stored in the EDRMS NIAID DCR ACUC Repository within the respective ASP folder. The PI and CM staff are notified and ACUC is informed of changes made through this process at the next convened meeting.

This NIAID DCR ACUC policy (exclusive of guidance documents, standard operating procedures, and drug formularies) must be reviewed by the ACUC no less than once every three years to ensure it remains appropriate and accurate. PI's must familiarize themselves with the NIAID DCR ACUC Policies and how they are applied.

After the NIAID DCR ACUC reviews and approves the submitted change by either FCR or DMR, the approved amendment is stored in the EDRMS IRF ACUC Repository. The PI and Comparative Medicine (CM) staff are notified of the approved amendment, which is then recorded in the next convened NIAID DCR ACUC meeting minutes.

References:

1. National Institutes of Health. Guidance on significant changes to animal activities. NOT-OD-14-126. (National Institutes of Health, Washington, DC, 26 August 2014).

2. Institution for Laboratory Animal Research. Guide for the Care and Use of Laboratory Animals 8th ed. (National Academies Press, Washington, DC, 2011).