

SEMIANNUAL REPORT

ANIMAL CARE AND USE  
PROGRAM REVIEW AND FACILITY INSPECTION  
OF THE

NHGRI

April 2020

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

- 1) Inspections of the **NHGRI** 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
Redacted by agreement Two Incubators	SF	4/17/20	Clark
Redacted by agreement Two Incubators	SF	4/17/20	Clark
Redacted by agreement Incubator	SF	4/15/20	Redacted by agreement
Redacted by agreement Incubator	SF	4/22/20	Redacted by agreement
Redacted by agreement	SF/Surg	4/6/20	Clark, Redacted by agreement
Redacted by agreement Two Incubators	SF	4/17/20	Clark
Redacted by agreement Incubator	SF	4/17/20	Clark

- 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
	OACU “Animal Program Semiannual Assessment Checklist” (1 page summary)
	OACU/OLAW “Semiannual Program Review & Facility Inspection Checklist” (24 pages)
	Other documents/resources (please specify)
X	NHGRI Disaster Plan
X	OACU “Animal Program Semiannual Assessment Checklist” tailored to include NHGRI-specific information

A comprehensive summary review was performed at the 4/27/20 ACUC Meeting.

**Additional Topic Review Dates and Topics:**

Spring Program Review Date(s) & Topics	12/6/19 Reviewed the ARAC Guidelines for ACUC Oversight of Animal Activities in Shared and Central Facilities	1/29/20 Assessing Pain and Distress in Animal Research Models	2/26/20 2020 AVMA Guidelines on Euthanasia	3/25/20 Veterinary Verification and Consultation (VVC)	4/27/20 Compassion Fatigue
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4) The program review was conducted in the following manner:

	<b>Program Review Process</b>
X	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
	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:**

Redacted by agreement replaced Redacted by agreement as the nonscientific ACUC member.

Redacted by agreement replaced Redacted by agreement as our ACUC OACU observer.

ACUC Guideline 01.1 “Guidelines for the Euthanasia of Mice” was updated to include the revised euthanasia methods consistent with the 2020 AVMA Guidelines on Euthanasia.

ACUC Guideline 01.2 “Guidelines for the Euthanasia of Zebrafish” was updated to

include the revised euthanasia methods consistent with the 2020 AVMA Guidelines on Euthanasia.

ACUC Guideline 02.2 “Animal Study Proposal Amendment Guideline” was revised to add “Unconditional Administrative Process” for minor changes such as the addition or removal of personnel, grammar/spelling corrections or changes in check boxes that were incorrectly selected. Only one ACUC designee has to sign these amendments. The Designated Member Review (DMR) was expanded to include review/approval of any significant amendment. The Veterinary Verification and Consultation (VVC) policy was revised in response to OLAW concerns and ACUC approved references were added.

The NHGRI Disaster Plan and NHGRI Pandemic Plan were merged into one document and new procedures for continuity plans for ACUC function/operation were added. Procedures for identifying critical animals for research was also added.

Room Redacted by agreement is no longer being used for housing NHGRI Transgenic Mouse Core mice.

Laboratory Redacted by agreement is no longer being used by NHGRI investigators.

Laboratory Redacted by agreement is no longer being used being used by NHGRI investigators.

## 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)
Skin biopsies without surgical prep	Chapter 4 – Veterinary Care, Aseptic Technique Section, page 118	Scientific

## 2. Exceptions to the AWAR:

None

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

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

	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	Strong rat smell in lab adjacent to rat room	M	10/2/19	Redacted by agreement	NEI Redacted by agreement	NEI response delayed by COVID-19. Discussed either air flow adjustments or relocating the rat room	8/31/20

<sup>1</sup>M=minor; S=Significant**Section F – Current Deficiencies & Plans:**

Deficiencies found *over the past 6 months* during NHGRI 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	(b)(5)						
2	Expired Blue Water	M	Redacted by agreement	Discard	Redacted by agreement	4/22/20	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: **[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	4/15/20	Redacted by agreement
	4/22/20	
	4/21/20	Redacted by agreement (approved as qualified ad hoc inspector)
	4/17/20	Clark
	Lab only – Visited in the Fall	N/A
	4/7/20	Redacted by agreement
	2/24/20-3/4/20	Redacted by agreement (approved as qualified ad hoc inspectors)
	4/6/20	Clark, Redacted by agreement
	Labs only – Visited in the Fall	N/A
	N/A	No animals in the last 6 months
	4/23/20	Redacted by agreement (approved as qualified ad hoc inspector)
	4/17/20	Clark
	N/A	No animals in last 6 months
	2/27/20	Redacted by agreement (approved as qualified ad hoc inspectors)

**Section I – Minority Report**

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

**NHGRI ACUC Member Signatures:**

Bodine, David  
(NIH/NHGRI) [E]

Digitally signed by Bodine,  
David (NIH/NHGRI) [E]  
Date: 2020.04.28 07:41:18  
-04'00'

David Bodine, Chair, ACUC

Clark, Tannia  
(NIH/NHGRI)  
[E]

Digitally signed by  
Clark, Tannia (NIH/  
NHGRI) [E]  
Date: 2020.04.29  
08:58:12 -04'00'

Tannia Clark

Redacted by agreement

Redacted by agreement

(Revised – 03/2020)



**ANIMAL PROGRAM SEMIANNUAL ASSESSMENT CHECKLIST**  
(Based on 2011 Guide)

	PROGRAM AREA	Guide Page	Comments
<b>I</b>	<b>Animal Care &amp; Use Program</b>		
A	Program Management & Responsibility	13-24	Who has the primary oversight for the animal program? The Institutional Official (IO), the Attending Veterinarian (AV), and the ACUC
	Key Management Personnel – IO, Attending Vet, ACUC	13-15	Who is the IO? Michael Gottesman What are the responsibilities of the veterinarian? The veterinarian is responsible for the health and well-being of all laboratory animals used at the institution.
	Collaborations – Review of Inter Agency Agreements (IAAs), Memorandums Of Understanding (MOUs), Contracts (Preventative Maintenance, 3040-3)	15	In cases of such collaboration involving animal use, the participating institutions should have a formal written understanding (e.g., a contract, memorandum of understanding, or agreement) that addresses the responsibility for offsite animal care and use, animal ownership, and IACUC review and oversight
	Training & Education – Vets/Professional Staff, Animal Care, Researchers, ACUC	15-17	How does NHGRI assure adequate training of personnel? Individual training at time of adding to protocol, monthly classes, OACU classes, etc.
	Occupational Health & Safety – Control & Prevention, Hazard ID & Risk Assessment, Facilities, Equipment & Monitoring, Training, Hygiene, Research Hazards, Protection, Medical Evaluation (LAAPP, PM 3044-2, Visitors)	17-23	An effective OHSP requires coordination between the research program (as represented by the investigator), the animal care and use Program (as represented by the AV, IO, and IACUC), the environmental health and safety program, occupational health services, and administration (e.g., human resources, finance, and facility maintenance personnel). What procedures are in place for assuring safety when working with hazardous agents? Safety officer on the ACUC, established SOPs, DOHS and OLAM training.
	Personnel Security	23	While contingency plans normally address natural disasters, they should also take into account the threats that criminal activities such as personnel harassment and assault, facility trespassing, arson, and vandalism pose to laboratory animals, research personnel, equipment and facilities, and biomedical research at the institution
	Investigating & Reporting Animal Concerns (ARAC C2)	23-24	What mechanisms are in place for reporting animal welfare concerns? “Gottesman letter”, Gottesman, Director OACU, ombudsman, ACUC chair, veterinarian
<b>B</b>	<b>Program Oversight</b>		
	Animal Care and Use Committee - Role, Constitution, & Function (ARAC C1,C5)	24-25	Each member has a specific area of review they are responsible for – what are they? Dr. Bodine assures that the literature search is appropriate; Redacted by agreement assures that the proposed animal experiments are appropriate models for human disease; Redacted by agreement assures the appropriateness of the animal model especially as it relates to developmental models; Redacted by agreement assures appropriateness of selected strains and nomenclature; Redacted by agreement is pivotal in the pre-review process and assures that animals are correctly classified and justified in the appropriate pain or distress category; Dr. Clark assures that the members understand all veterinary medical aspects of the protocol. Redacted by agreement assures that the numbers of animals are suitably justified and that statistics are applied when appropriate. Redacted by agreement assures that all aspects of the protocol regarding safety (e.g., hazardous, biological, and chemical agents) are in compliance with federal and NIH guidelines/regulations.

			Redacted by agreement represents the general community interests in the proper care and use of animals Redacted by agreement represents the non-scientist view. Assures section D is understandable to the layman
	Facility Inspections & Animal Program Review	25	At least annually – a change from the old Guide where it was every 6 months +/- 30 days – cannot float year to year.
	<u>Animal Study Proposal Review</u> - de novo, Annual Reviews, <u>Amendments</u> , Full Committee Review (FCR), Designated Member Review (DMR)	25-33	How many people must be present to conduct committee business? A quorum. What is a quorum? One-half of the membership plus one. What three documents does the committee use to assist in the review of ASPs? The Guide, AWRs, PHS Policy
	Use-Benefit Analysis	27	The IACUC is obliged to weigh the objectives of the study against potential animal welfare concerns. By considering opportunities for refinement, the use of appropriate nonanimal alternatives, and the use of fewer animals, both the institution and the principal investigator (PI) can begin to address their shared obligations for humane animal care and use.
	<u>Protocol Endpoints</u>	27-28	What is the difference between a humane and experimental endpoint? The humane endpoint is the point at which pain or distress in an experimental animal is prevented, terminated, or relieved. The use of humane endpoints contributes to refinement by providing an alternative to experimental endpoints that may result in unrelieved or severe animal pain and distress, including death. Studies that require special consideration include those that involve tumor models, infectious diseases, vaccine challenge, pain modeling, trauma, production of monoclonal antibodies, assessment of toxicologic effects, organ or system failure, and models of cardio-vascular shock.
	Unexpected Outcomes	28-29	Example – unpredicted phenotype
	Physical Restraint (Prolonged)	29-30	Does NHGRI have any ASPs with prolonged restraint? NO
	Multiple Survival Surgery Procedures	30	Define "major" surgery. Penetrates and exposes a body cavity or produces substantial impairment of physical or physiologic function or involves extensive tissue dissect/transection. Are multiple survival surgeries allowed on the same animal? Yes with scientific justification. When are they NOT allowed? For cost savings alone. NHGRI does not have any multiple major survival surgeries.
	<u>Food &amp; Fluid Regulation</u>	30-31	Does NHGRI have food/fluid restriction protocols? YES – food: Redacted by agreement (Zebrafish), Redacted by (Zebrafish)
	<u>Non-Pharmaceutical Grade Compounds</u>	31-32	Should be used, when available, for all animal-related procedures (USDA Policy #3). The use of non-pharmaceutical-grade chemicals should be described and justified in the animal use protocol and be approved by the ACUC.
	<u>Post-approval Monitoring</u>	33	How does NHGRI do PAM (post-approval monitoring)? Training. Surgery "red" cards. PI cards. Irene. Communication. Rounds.
C	Disaster Planning & Emergency Preparedness	35	Cryopreservation, Pandemic Response to include continuity plans for ACUC function/operation.
II	<b>ENVIRONMENT, HOUSING &amp; MANAGEMENT</b>		
A	<b>Terrestrial Animal Environment</b> Temp, Humidity, Ventilation, Air Quality, Illumination, Noise & Vibration	42-50	Temperature range for mice? 64-79F (usually 72 +/- 2) Relative humidity? 30-70%
B	<b>Terrestrial Housing</b> – Primary Enclosure, Enrichment, Outdoor Housing, Naturalistic Environments, Space	50-63	What are the requirements of the primary enclosure? Must allow for the normal physiologic and behavioral needs, allow conspecific social interaction, allow animals to remain clean and dry, adequate ventilation, access to food and water, secure environment, free of sharp edges, allow observation.



			Is rust/oxidized equipment allowed in the animal facility? If it does not threaten the health or safety of the animals. What are important considerations of the social environment? Social species should be housed together whenever possible. Environmental enrichment should be considered.
C	Habituation, & Training), Husbandry (Food & Water), Bedding/Nesting Materials, Sanitation (Bedding Change, Waste Disposal, & Effectiveness), Pest Control, Emergency, Weekend, & Holiday Care, Population Management ( <u>Identification</u> , <u>Recordkeeping</u> , <u>Breeding</u> , <u>Nomenclature</u> , & <u>Genetics</u> )	63-77	What are the components of adequate veterinary medical care? Preventive medicine, surveillance, diagnosis, treatment and control of disease (incl. zoonoses), management of protocol-associated disease, disability, or other sequelae, anesthesia and analgesia, surgery and postsurgical care, assessment of animal well-being, euthanasia Is floor feeding allowed? Not as a general rule, must have scientific or veterinary justification. Does NHGRI have floor-feeding protocols? YES
D	<b>Aquatic Animal Environment</b> - Water Quality, Support System, Temperature, Humidity, Ventilation, Illumination, Noise & Vibration	77-82	Temperature range for ZF? 82 +/- 2F
E	<b>Aquatic Housing</b> – Primary Enclosure, Enrichment, Social Housing, Outdoor Housing, Naturalistic Environments, Space	82-83	Zebrafish are a shoaling species, the NHGRI default policy is housing in groups
F	<b>Aquatic Management</b> - Behavior & Social Management, Husbandry (Food, Water, Substrate, Sanitation (Micro & Macroenvironment), Waste Disposal, Pest Control, Emergency, Weekend, & Holiday Care, Population Management ( <u>Identification</u> , <u>Recordkeeping</u> )	84-86	Identification for fish? Are based on genotype and are maintained on a tank level via a tank tape label.
<b>III VETERINARY CARE</b>			
A	<b>Animal Procurement &amp; Transportation</b> (ARAC <u>A1a</u> , <u>A1b</u> , <u>CC Policy</u> )	106-107	Can animals be used immediately upon arrival? Yes but guide, and NHGRI ACUC guideline, recommends against. They should be given a rest period (NHGRI requires 48 hours) for “physiologic, psychological, and nutritional stabilization.
B	<b>Preventive Medicine</b> - <i>Biosecurity</i> , <i>Quarantine</i> , Stabilization, <u>Separation of Species</u> , & Disease Surveillance, Diagnosis, Treatment, Control (PM 3043-1, PM3044-1, ARAC D3)	109-113	What methods does NHGRI use for the prevention and control of disease? Rederivation, sentinel monitoring. What are some important zoonotic diseases from mice and ZF? LCMV, Hantaan, Salmonella, Mycobacterium
C	<b>Clinical Care &amp; Management</b> - Medical Management, Emergency Care, & <u>Recordkeeping</u>	113-115	Are individual research, clinical and/or surgical records required for rodents? No. NHGRI requires surgery records (red cards available) Are individual research, clinical records required for zebrafish? No. NHGRI requires research records at tank level.
D	<b>Surgery</b> - Training, Planning, Facilities, Procedures, Aseptic Technique, Intra-Op Monitoring, Post-Op Care	115-120	Should antibiotics be routinely given post-surgically? No, the use of antibiotics should never be considered as a replacement for aseptic procedure. Is alcohol an appropriate agent for the sterilization of surgical instruments? Alcohol is neither a sterilant nor a high-level disinfectant.
E	<b>Pain &amp; Distress</b> (ARAC <u>B12</u> , <u>Pain &amp; Distress Memo</u> )	120-121	What is pain? A complex experience that results from stimuli that damage or have the potential to damage tissue; such stimuli prompt withdrawal and evasive action. What is distress? An aversive state in which an animal fails to cope or adjust to various stressors with which it is presented. May not produce an immediate and observable pathologic or behavioral alteration.
F	<b>Anesthesia &amp; Analgesia</b> (PM 1345)	121-123	Do we have any protocols that allow the use of paralytics (i.e., neuromuscular blocking agents, pancuronium)? No
G	<b>Euthanasia</b> (ARAC <u>B4</u> , <u>B5</u> )	123-124	What documents outlines the recommendations for euthanasia? The AVMA Guidelines for Euthanasia (2020).

			What are important criteria for performing euthanasia? Personnel must be trained, distress to the animals must be minimized, euthanasia should be in the home cage whenever possible, other animals should not be present.
IV	<b>PHYSICAL PLANT</b>		
A	<b>Functional Areas</b> – Housing, Care, Sanitation, Receipt, Quarantine, <u>Separation of Species</u> , Storage	135-136	Receipt of animals from “unapproved” source. Mice are rederived, ZF embryos are “bleached” before 36hpf. Are mice and rats allowed in the same room? Yes, individually ventilated cages, changed in hood. Example: room 10C127C
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	What is the maximum recommended noise level in an animal facility? 85 decibels What are some of the effects of persistent exposure to high noise levels? Eosinopenia, increased adrenal weights, reduced fertility, increased blood pressure. How wide should the corridor be? 6-8 feet. Should doors open into or out of the animal room? Into How large should the doors be? 42 x 84 inches. Suggested light level? 30 ft. candles (325 lux) about 1 m off the floor. Exceptions? Albino animals. What is the recommended air changes/hour? 10-15
	Safety Devices - Showers, Eyewashes, Escape for Cage/Rack Washers, Autoclaves	143	Do you know where the safety shower and eyewash is? Do you have all the Material Safety Data Sheets for your protocol?
C	<b>Special Facilities</b> - Surgery, Barriers, Imaging, Irradiators, Hazard Containment, Behavior Studies, Aquatics	143-150	Is a dedicated surgery area required for rodents? No but should be sanitizable and out of the way of traffic.
D	<b>Security &amp; Access Control</b>	151	Important for the prevention of domestic terrorism and the control of access by people who are not trained.

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

**IC Name:** National Human Genome Research Institute

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

Spring Program Review Date(s):	4/27/20					
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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	4/17/20		3	1 Zebrafish	2	3	1 1,300	2	3
				4	5	6	4	5	6
	4/17/20		9	1 Zebrafish	2	3	1 1,917	2	3
				4	5	6	4	5	6
	4/15/20		3	1 Zebrafish	2	3	1 30	2	3
				4	5	6	4	5	6
	4/22/20		3	1 Zebrafish	2	3	1 42	2	3
				4	5	6	4	5	6
	4/6/20		12	1 Mice	2	3	1 4	2	3
				4	5	6	4	5	6

**NATIONAL INSTITUTES OF HEALTH**  
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**CONTINUATION PAGE**

Bldg/Area/Rm	Facility Insp. Date(s) Spring / Fall		AF/SF; Gross Sq. Ft.	Species Housed			Average Daily Inventory		
Redacted by agreement	4/17/20		4	1 Zebrafish	2	3	1 230	2	3
				4	5	6	4	5	6
	4/17/20		4	1 Zebrafish	2	3	1 383	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