#### SEMIANNUAL REPORT

### ANIMAL CARE AND USE PROGRAM REVIEW AND FACILITY INSPECTION OF THE

#### <u>NHGRI</u>

October 2019

#### Section A - Site Visits & Program Review

 Inspections of the NHGRI animal facilities (AF), satellite holding facilities (SF), USDAdefined study areas for regulated species (SA) and areas where any surgical manipulations (Surg) are performed (as applicable) were conducted as indicated below:

| Location                 | Туре    | Date     | ACUC Members                 |
|--------------------------|---------|----------|------------------------------|
| Redacted by<br>agreement | SF      | 10/11/19 | Clark, Redacted by agreement |
| Two Incubators           |         |          |                              |
| Redacted by agreement    | SF      | 10/11/19 | Clark, Redacted by agreement |
| Two Incubators           |         |          |                              |
| Redacted by<br>agreement | SF      | 10/8/19  | Clark, Redacted by agreement |
| Incubator                |         |          | Redacted by agreement        |
| Redacted by agreement    | SF      | 10/4/19  | Clark Redacted by agreement  |
| Incubator                |         |          |                              |
| Redacted by agreement    | SF/Surg | 10/2/19  | Clark Redacted by agreement  |
|                          |         |          | Redacted by agreement        |
| Redacted by agreement    | SF      | 10/18/19 | Clark, Redacted by agreement |
| Two Incubators           |         |          | Redacted by agreement        |
| Redacted by agreement    | SF      | 10/18/19 | Clark, Redacted by agreement |
| Incubator                |         |          | 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 documents were used as the basis for review of the animal care and use program:

|   | Document/Resource:   |
|---|--|
| Χ | Guide for the Care & Use of Laboratory Animals, 8th Edition (Guide)              |
| Χ | 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)                                       |
| Χ | NHGRI Disaster Plan  |
| Χ | OACU "Animal Program Semiannual Assessment Checklist" tailored to include        |
|   | NHGRI-specific information   |

A comprehensive summary review was performed at the 10/30/19 ACUC Meeting.

Additional Topic Review Dates and Topics:

|                |              |             | 1            |            |              |  |
|----------------|--------------|-------------|--------------|------------|--------------|--|
| Fall Program   | 6/25/19      | 7/24/19     | 8/27/19      | 9/26/19    | 10/30/19     |  |
| Review Date(s) | Reviewing    | USDA Policy | ARAC         | FOIA       | ARAC         |  |
| & Topics       | protocols    | #3          | Guideline on | Compliance | Guidelines   |  |
|                | (De-novo and |             | Significant  |            | for ACUC     |  |
|                | annual)-     |             | Changes to   |            | Oversight of |  |
|                | discussion   |             | Animal Study |            | Satellite    |  |
|                | about each   |             | Proposals    |            | Facilities,  |  |
|                | committee    |             |              |            | Study Areas, |  |
|                | member's     |             |              |            | Laboratories |  |
|                | approach     |             |              |            | and other    |  |
|                |              |             |              |            | Animal       |  |
|                |              |             |              |            | Activity     |  |
|                |              |             |              |            | Areas        |  |
|                |              |             |              |            |              |  |

#### 4) The program review was conducted in the following manner:

|   | Program Review Process   |
|---|--|
| X | 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:  |

#### 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 Alternate DOHS |
|----------------------------|--|--------------------|
| ACUC represer              | ntative.                                     |                    |
| Roon Redacted by           | is no longer being used for temporary rodent | housing.           |
| Room Redacted by agree     | was added to a NHGRI protocol for behavi     | or testing.        |
| Room Redacted by agreement | was added to an NHGRI protocol for visual fu | nction testing.    |

A new annual review format was created and put into use in June 2019.

One incubator previously in Redacted by agreement was sent to surplus. It may be replaced at a later date.

New semiannual program review checklists were created for evaluating rodent housing rooms, zebrafish housing rooms and laboratories.

NHGRI ACUC Guideline 00.1 "Guideline and Procedures for Retro-orbital Bleeding in Mice" was retired and investigators will follow the NIH ARAC Survival Bleeding in Rodent Guideline. In lieu of this guideline, an SOP for retro-orbital bleeding was created.

NHGRI ACUC Guideline 00.2 "Guideline and Procedures for Genotyping Mice" was retired and investigators will follow the NIH ARAC Rodent Genotyping Guideline and the NHGRI SOP for tail biopsies.

NHGRI ACUC Guideline 01.3 "Identification Methods for Mice" was retired and was replaced by a SOP.

NHGRI ACUC Guideline 04.2 "Guideline and Procedures for Perfusion in Mice" was retired and was replaced by a SOP.

NHGRI ACUC Guideline 04.3 "Guideline and Procedures for Terminal Blood Collection in Mice" was retired.

### 2) Key Personnel Changes - ACUC Chair, ACUC Attending Vet, APD, or Program Manager:

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

3) Animal Facility/Area Changes:

| Facility Type (AF/SF) Location | Action (opened, closed, under renovation, etc.) |
|--------------------------------|---|
| SF Redacted by agreemen        | opened  |

#### <u>Section D – Guide Departures & USDA Exceptions:</u>

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<br>(scientific,<br>veterinary, or animal<br>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<br>and Plan  | <sup>1</sup> M/S | SA 1 <sup>st</sup> noted | Location   | Responsible<br>Party     | Status update  | Revised<br>completion date<br>mm/dd/yy |
|---|---|------------------|--------------------------|--|--------------------------|--|--|
| 1 | No emergency power source for the incubator                                   | M                | Redacted by agreement    | Install an emergency power outlet  | Redacted by<br>agreement | Due to power restrictions, unable to upgrade emergency power. In the event, of a power outage the embryos would be removed from the incubator (NHGRI Disaster Plan updated). | 7/24/19                                |
| 2 | Equipment stored in the fume hood blocks the air baffles                      | M                | Redacted by agreement    | Store equipment on a shelf elevated above the baffles or remove it from the hood | Redacted by agreement    | Completed  | 5/10/19                                |
| 3 | Flammable liquids stored in the chemical fume hood                            | M                | Redacted by agreement    | Store in a flammable storage cabinet   | Redacted by<br>agreement | Completed  | 5/10/19                                |
| 4 | No eye wash log   | М                | Redacted by<br>agreement | Initiate<br>eyewash<br>testing log   | Redacted by agreement    | Completed  | 10/31/19                               |
| 5 | Several rows of breeding<br>animals when protocol<br>allows for 4-6 litters   | М                | Redacted by<br>agreement | Reduce<br>breeding or<br>amend ASP   | Redacted by agreement    | Breeding numbers are in compliance   | 5/3/19                                 |
| 6 | Breeder pairs housed in divided cages   | М                | Redacted by<br>agreement | Provide justification for exception to the Guide or stop the practice            | Redacted by agreement    | Justification was provided   | 5/3/19                                 |
| 7 | No documentation that filters in the aerosolization chamber have been changed | M                | Redacted by agreement    | Provide<br>documentation<br>of filter<br>changes/<br>preventative<br>maintenance | Redacted by agreement    | Old chamber was<br>replaced with a<br>new chamber  | 10/22/19                               |
| 8 | Air Clean Hood needs to be certified  | М                | Redacted by<br>agreement | Make<br>arrangements<br>with DOHS for<br>certification                           | Redacted by<br>agreement | DOHS could not certify this equipment. Verified that it is only used for cell culture.   | 8/16/19                                |

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

#### <u>Section F – Current Deficiencies & Plans:</u>

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<br>Plan | Responsible<br>Party | Scheduled<br>Completion Date<br>(mm/dd/yy) | <sup>2</sup> Status:<br>C/P |
|---|------------|------------------|----------|--------------------|----------------------|--|-----------------------------|
| 1 | (b)(5)     |                  |          |                    |                      |  |                             |
| 2 |            |                  |          |                    |                      |  |                             |
| 3 |            |                  |          |                    |                      |  |                             |
| 4 |            |                  |          |                    |                      |  |                             |
| 5 |            |                  |          |                    |                      |  |                             |

<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 | 10/18/19 | Clark, Redacted by agreement   |
|                       | 10/8/19  | Clark, Redacted by agreement   |
|                       | 10/4/19  | Clark, agreement   |
|                       | 10/22/19 | Clark,   |
|                       | 10/2/19  | Clark, Redacted by agreement   |
|                       | 10/2/19  | Clark,   |
|                       | N/A      | No animals in last 6 months  |
|                       |          |  |
|                       | 10/2/19  | Clark Redacted by agreement  |
|                       | 10/2/19  | Clark, Redacted by agreement   |
|                       | 10/9/19  | Clark, Redacted by agreement (no animals in Redacted by agreement or |
|                       |          | Redacted by agreement in the last 6 months)                          |
|                       | 10/11/19 | Clark, Redacted by agreement   |
|                       | N/A      | No animals in last 6 months  |
|                       | 10/9/19  | Clark, Redacted by agreement   |

#### Section I - Minority Report

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

| Redacted by agreement                  | Elizar periodically digitalized but |  |
|--|-------------------------------------|--|
| edacted by agreement                   |                                     |  |
| David Bodine, Chair, ACUC Tannfa Clark |                                     |  |
|  | <u></u>                             |  |
| dacted by agreement                    |                                     |  |
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|  |                                     |  |

(Revised - 09/2019)

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

IC Name: National Human Genome Research Institute

Fall Semiannual Report Submission Date: October 31, 2019

| Spring Program Review Date(s): | 4/23/19  |  |  |  |
|--------------------------------|----------|--|--|--|
|                                | ı        |  |  |  |
| Fall Program Review Date(s):   | 10/30/19 |  |  |  |

| Bldg/Area/Rm          | Facility Insp. Date(s)<br>Spring / Fall |          | AF/SF;<br>Gross Sq. Ft. | Species Housed         |     |   | Average Daily Inventory |     |   |
|-----------------------|---|----------|-------------------------|------------------------|-----|---|-------------------------|-----|---|
| Redacted by agreement | 4/9/19                                  | 10/11/19 | 3                       | <sup>1</sup> Zebrafish | 5   | 6 | 1 120                   | 2   | 6 |
|                       | 4/9/19                                  | 10/11/19 | 9                       | <sup>1</sup> Zebrafish | 2 5 | 3 | 1 500                   | 2 5 | 3 |
|                       | N/A                                     | 10/8/19  | 3                       | 1 Zebrafish            | 5   | 3 | 1 50                    | 5   | 6 |
|                       | 4/5/19                                  | 10/8/19  | 3                       | 1 Zebrafish            | 5   | 6 | 1 250<br>4              | 5   | 6 |
|                       | 4/10/19                                 | 10/2/19  | 12                      | 1 Mice                 | 5   | 6 | 1 4                     | 5   | 6 |

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#### **CONTINUATION PAGE**

| Bldg/Area/Rm              | Facility Insp. Date(s)<br>Spring / Fall |          | AF/SF;<br>Gross Sq. Ft. | Species Housed         |   |   | Average Daily Inventory |   |   |
|---------------------------|---|----------|-------------------------|------------------------|---|---|-------------------------|---|---|
| Redacted by agreement 4/2 | 4/2/19                                  | 10/18/19 | 4                       | <sup>1</sup> Zebrafish | 2 | 3 | 1 200                   | 2 | 3 |
|                           |   |          |                         | 4                      | 5 | 6 | 4                       | 5 | 6 |
|                           | 4/2/19                                  | 10/18/19 | 4                       | <sup>1</sup> Zebrafish | 2 | 3 | 1 500                   | 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 |