

SEMIANNUAL REPORT

ANIMAL CARE AND USE
PROGRAM REVIEW AND FACILITY INSPECTION
OF THE

Eunice Kennedy Shriver
National Institute of Child Health and Human Development

April 2020

Section A – Site Visits & Program Review

- 1) Inspections of the **NICHD** 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. | AF | 3 March 2020 | Woodward, Pfeifer |
| | AF | 11 March 2020 | Woodward, Pfeifer, Redacted by agreement. |
| | SF | 11 March 2020 | Woodward, Pfeifer, Redacted by agreement. |
| | SF | 28 February 2020 | Woodward, Pfeifer |
| | AF | 3 March 2020 | Woodward, Pfeifer |
| | SF | 3 March 2020 | Woodward, Pfeifer |

- 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 th Edition (Guide) |
| X | AAALAC Program Description |
| X | OACU " Animal Program Semiannual Assessment Checklist " (1 page summary) |
| X | OACU/OLAW " Semiannual Program Review & Facility Inspection Checklist " (24 pages) |
| X | Other documents/resources (please specify): NIH ARAC Guidelines |
| | |

Incremental Program Review
Dates and Topics: N/A

- 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: |
| | |

Section B – Regulatory Compliance:

Except as noted in Sections E, 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:

MPF Federal, LLC. and SoBran, Inc. have been awarded the new animal care contract for the Rodent Facilities.

Charles River Laboratories has again been awarded the new animal care contract for the Aquatics Facilities.

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) |
|--|------------------------|-----------------------------|
| IC Animal Program Manager - Aquatics | Redacted by [REDACTED] | Departed |
| IC Animal Program Manager - Rodents | Redacted by agreement. | Departed |
| IC Animal Program Manager – Aquatics | Redacted by agreement. | Joined |
| IC Animal Program Manager – Rodents | Redacted by agreement. | Joined |

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) |
|---|-----------------------------------|---|
| Cage Size Allowance/Multiple Litters per Cage | 57 | Veterinary |
| | | |

2. Exceptions to the AWAR:

| Species | # Animals Affected (this Period) | 9CFR title/section | Description and Rationale |
|---------|----------------------------------|--------------------|---------------------------|
| N/A | | | |
| | | | |

Section E – Previous Deficiencies & Plans:

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

Section F – Current Deficiencies & Plans:

Deficiencies found over the past 6 months during NICHD program review, facility inspections, and laboratory inspections, are as follows:

| | Deficiency | ¹ M/S | Location | Correction Plan | Responsible Party | Scheduled Completion Date | ² Status: C/P |
|---|---|------------------|------------------------|---|------------------------|---------------------------|--------------------------|
| 1 | (b) (5) | | | | | | |
| 2 | | | | | | | |
| 3 | | | | | | | |
| 4 | | | | | | | |
| 5 | Updated Euthanasia SOP not posted by euthanasia chamber | M | Redacted by agreement. | Post updated SOP which follows 2020 AVMA Guidelines | Redacted by agreement. | 03/03/20 | C |
| 6 | Chemical container tag dated August 2019, beyond 60-day limit | M | | Replace container or confirm that chemical wasn't added | | 03/03/20 | C |
| 7 | Flammable cabinet signage fading & poorly readable | M | | Replace signage on cabinet | | 03/10/20 | C |
| 8 | (b) (5) | | | | | | |
| 9 | Excessive rat caging being stored inside animal room | M | Redacted by agreement. | Remove excess caging to prevent contamination | Redacted by agreement. | 03/05/20 | C |

¹M=minor; S=significant

²C=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: [] None

| SA 1 st noted | Description of event | Current Status |
|--------------------------|--|---------------------------------------|
| Fall 2019 | Above average animal deaths reported in Aquatics Facility | OLAW memo received, Resolved 2/7/2020 |
| 1/4/2020 | Mouse caught paw in cracked cage back panel resulting in death | Report sent to Gottesman 2/20/2020 |
| 1/4/2020 | Technician did not follow veterinary directive to euthanize mouse, found dead the next morning | Report sent to Gottesman 2/20/2020 |

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. | 2/25/20 | Redacted by agreement. |
| | 2/26/20 | |
| | 2/6/2020 | |

Section I – Minority Report

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

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

IC Name: National Institute of Child Health and Human Development

Semiannual Report Submission Date: April 30, 2020

| | | | | | | |
|--------------------------------|---------|--|--|--|--|--|
| Spring Program Review Date(s): | 4/15/20 | | | | | |
|--------------------------------|---------|--|--|--|--|--|

| | | | | | | |
|------------------------------|--|--|--|--|--|--|
| 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. | 3/3/2020 | | AF 27131 | Mouse | Rat | 3 | 1 23,655 | 2 142 | 3 |
| | | | | 4 | 5 | 6 | 4 | 5 | 6 |
| | 3/11/2020 | | AF 9369 | 1 Zebrafish | 2 | 3 | 1 175,109 | 2 | 3 |
| | | | | 4 | 5 | 6 | 4 | 5 | 6 |
| | 3/11/2020 | | SF 70 | 1 Zebrafish | 2 | 3 | 1 2,190 | 2 | 3 |
| | | | | 4 | 5 | 6 | 4 | 5 | 6 |
| | 2/28/2020 | | SF 36 | 1 Z.fish larvae | 2 | 3 | 1 2,020 | 2 | 3 |
| | | | | 4 | 5 | 6 | 4 | 5 | 6 |
| | 3/3/2020 | | AF 1985 | 1 Mouse | 2 Cavefish | 3 X. laevis | 1 1,957 | 2 286 | 3 512 |
| | | | | 4 | 5 | 6 | 4 | 5 | 6 |

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CONTINUATION PAGE

| | Facility Insp. Date(s) Spring / Fall | | | Species Housed | | | Average Daily Inventory | | |
|------------------------|---|--|-----------|----------------------------|---|---|-------------------------|---|---|
| | | | | 1 | 2 | 3 | 1 | 2 | 3 |
| Redacted by agreement. | 3/3/2020 | | SF 242.05 | ¹ X. tropicalis | | | 1 951 | | |
| | | | | 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 |
| | | | | 1 | 2 | 3 | 1 | 2 | 3 |
| | | | | 4 | 5 | 6 | 4 | 5 | 6 |

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.

Cage size Allowance/Multiple Litters per Cage: The IC ACUC has approved a “Fourteen Heads – Fourteen Days” policy as an engineering standard. On day fourteen postpartum the maximum number of animals permitted per cage is fourteen. This includes the three adults (one male, two females) and up to eleven pups whose birth dates are not more than 7 days apart. Separation of the litter on day fifteen, rather than at an earlier date is facilitated by the fact that by fourteen days postpartum most pups are supplementing their milk diet with solid food. Therefore, if one of the dams is a poor milk producer, the negative impact of separating the litter and placing some of the pups solely with the poorly lactating female is minimized. (reference: *Guide*, p. 56-57)

Veterinary Verification & Consultation:

If your IC has a VVC policy, please include a copy with your semiannual report submission.

Please see the attachment.

Animal Adoption:

If applicable, please provide the number of animals adopted from your IC by species.

If your IC has an adoption policy, please include a copy with your semiannual report submission.

N/A

Category 2.1: Conditional Administrative Review Process (Veterinary Verification and Consultation) VVC

These changes may be approved by the Animal Program Director (or by an NICHD facility veterinarian) in consultation with the principal investigator when the changes are within the scope of the following:

- Changes in [anesthesia](#), [analgesia](#), [sedation](#) when consistent with NICHD Policy “Appropriate Analgesic Drug Substitution for Rodents”.
- Changes in [method of euthanasia](#) which are not expected to increase pain or distress or impact the approved personnel safety considerations and when consistent with the following:
 - [Guidelines for the Euthanasia of Rodent Fetuses and Neonates](#)
 - [Guidelines for Euthanasia of Rodents Using Carbon Dioxide](#)
 - [Guidelines for Use of Zebrafish in the NIH Intramural Research Program](#)
- Changes in [substances](#) that are the [same class of compounds](#) currently approved in the ASP and which are not expected to increase pain or distress, impact the approved endpoint criteria, or impact the approved personnel safety considerations.
- Changes diluents than those currently approved in the ASP but which are not expected to change the objectives of the study, increase pain or distress, impact the approved endpoint criteria, or impact the approved personnel safety considerations. Specifically, these include PBS, normal saline, water, corn oil, sesame oil, DMSO, and ethanol.
- Use of Trio or Harem breeding when the procedures are consistent with NICHD SOP 2.220 (Breeding and Weaning Rodents)
- Change in [duration](#), [frequency](#), [type or number of procedures](#) performed on an animal that are not expected to increase pain or distress, impact the approved endpoint criteria, or impact the approved personnel safety considerations. The following procedures are allowed:
 - Blood sampling method, volume, & frequency consistent with ARAC guidelines http://oacu.od.nih.gov/ARAC/documents/Rodent_Bleeding.pdf
 - Food/water control consistent with ARAC guidelines http://oacu.od.nih.gov/ARAC/documents/Diet_Control.pdf
 - Genotyping method consistent with NICHD **6B Facility SOP 3.113**
 - Behavior test methods and duration consistent with **NICHD SOP “Behavioral tests in rodents.**

Procedure:

- PIs will submit amendments through the ACUC coordinator. If the PI requests that the amendment be reviewed and acted on prior to the next scheduled ACUC meeting, the coordinator can forward the amendments to the APD or one of the facility veterinarians. If approved, the amendment will be returned to the ACUC coordinator for processing.
- The relevant facility and the PI will be notified by email and receive a signed copy of the amendment. The approved amendment will also be listed on the agenda for the next ACUC meeting and posted on the ACUC members web page for review and possible discussion at the ACUC meeting

NICHD ACUC Member Signatures:

Karl E. Pfeifer -S Digitally signed by Karl E. Pfeifer -S
Date: 2020.04.15 11:15:44 -04'00'

Karl Pfeifer, Chair, ACUC

Redacted by agreement, Alternate Scientist/chair (Pfeifer)

Ruth Woodward, Attending Veterinarian, APD

Redacted by agreement.

(Revised – 03/2020)

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Redacted by agreement, Alternate Scientist/chair (Pfeifer)

Ruth A. Woodward
Herbert -S
Digitally signed by Ruth A.
Woodward Herbert -S
Date: 2020.04.15 11:20:11
-04'00'

Ruth Woodward, Attending Veterinarian, APD

Redacted by agreement.

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(Revised – 03/2020)

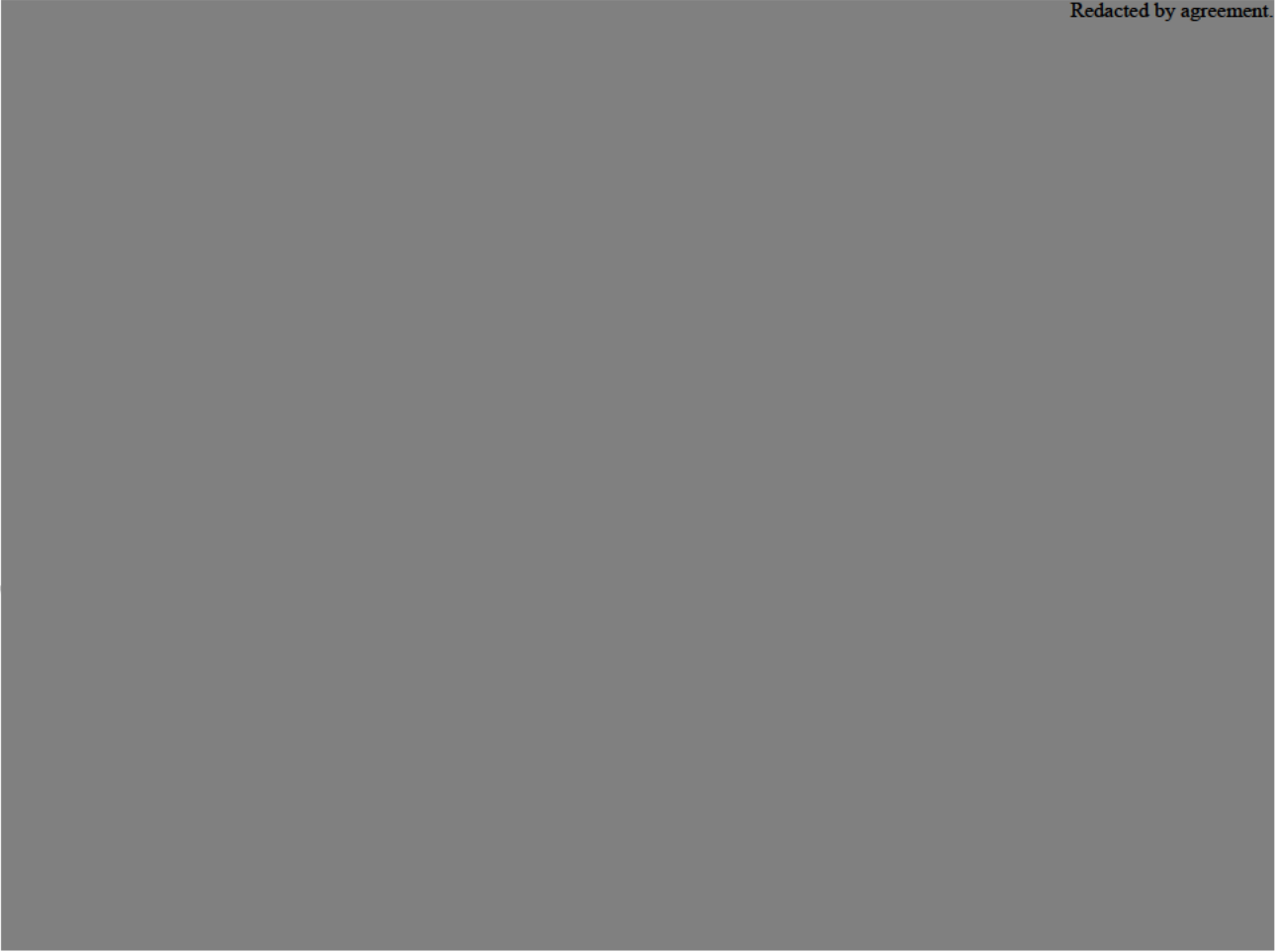
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