



Memorandum

Date: May 6, 2019

From: NIOSH/HELD Animal Care and Use Committee

Subject: Semiannual Program Review and Facilities Inspection Report (Nov 2018 – April 2019)

To: Steve Monroe, Ph.D., Associate Director for Laboratory Science and Safety and IACUC Institutional Official (CDC/OD/OADLSS)
Through: Don Beezhold, Ph.D., Director, CDC/NIOSH/HELD *DHB*

This is the semiannual report for the NIOSH (CDC-Morgantown) Institutional Animal Care and Use Committee (IACUC) for the period of 1 November 2018 – 30 April 2019 as required by the PHS Policy on Humane Care and Use of Laboratory Animals and as a condition of this institution's Animal Welfare Assurance D16-00687 (Old Assurance# A4367-01) on file with the Office of Laboratory Animal Welfare (OLAW) and USDA Animal Welfare Regulations, 9 CFR Chapter I, subchapter A, as applicable (NIOSH is covered under the CDC-Atlanta USDA Registration #57-F-0004). The ACUC utilizes the Guide for Care and Use of Laboratory Animals (Guide), 8th edition, the Animal Welfare Regulations (9 CFR Chapter I) and OLAW policies as the basis for program evaluation.

AAALAC Accreditation Status

Full Accreditation Status. Program Description will be due December 1, 2019, with a site visit scheduled the Winter Trimester (Jan - Mar 2020).

Programmatic Changes since last report

- The IACUC implemented an animal facility support meeting to review an animal special care or special instructions request form. The form is attached to an email to the PI when a new protocol is approved. The Attending Veterinarian, Animal Facility Manager and IACUC Administrator will meet with the PI and protocol associates to review the form and discuss other potential areas to support execution of the protocol.
- Change in protocol and modifications to protocol review process: Modifications to approved protocols (amendments) will use the PHS OLAW notice #NOT-OD-14-126, Guidance on Significant Changes to Animal Activities, to define the type of change/ modification requested and determine how the documents are reviewed. As defined by these regulations, the changes are either significant or administrative. The IACUC Chair will determine if the requested modification is

significant or administrative. Significant modifications can be reviewed by designated member review (DMR) or Veterinarian Verification and Consultation (VVC). The IACUC Chair makes this determination. Modifications to protocols with USDA Pain Category E animals are now reviewed by DMR. During the DMR process, any member of the IACUC can call for full committee review (FCR). The IACUC revised the P-0006 IACUC (CDC-Morgantown) Policy – Review of Protocols and Modifications to Protocols. The revised policy expands the IACUC- reviewed and approved list of significant changes that can be reviewed and approved by Veterinarian Verification and Consultation (VVC) and is documented in the Animal Care and Use Protocol.

ACUC Roster Changes

IACUC Chair (b)(6) rotated off of the committee and (b)(6) a current voting member was appointed as the new Chair (b)(6) appointment was dated March 1, 2019.

Scientist member rotating off of the committee – (b)(6)

Scientist members moving from alternate to full membership – (b)(6)

Scientist member new appointments (b)(6) (alternate) and (b)(6) (alternate)

Organizational name changes for (b)(6) (Engineering and Control Technology Branch renamed Physical Effects Research Branch); (b)(6) (Office and Administrative Management Services renamed Office of Facilities Management)

USDA Covered Species – None were housed during this period.

ACUC Approved Departures from the Guide

Animal Protocol #17-007 (Non-standard Housing) The studies require short term (up to 3 days) housing of rats in wire floored rat metabolism cages to collect urine. Animals have sufficient space to stand up, turn around and lie down. Food and water is still available ad libitum and the ACUC has approved for a minimum time period. Rats are housed in bedded cages of appropriate size when not in the metabolism cage.

Animal Protocol #18-008 and #19-005 (Use of Prolonged Restraint). Mouse and rat nose-only inhalation studies utilize rigid tubes for whole body prolonged restraint. Animals are acclimated to tubes prior to experiment and exposures/restraint time is limited to only what is scientifically necessary to provide exposure.

Animal Protocol #18-011 and #19-004 (Use of Prolonged Restraint). Rats will be placed in Broome restrainers for prolonged whole body restraint for exposure and physiological testing. The animals are acclimated to the Broome restrainers prior to the experiments.

Confinement versus Restraint

There are many mice and rat inhalation studies where animals are dosed with particles via whole body exposure. The animals are confined but are able to turn around and lie down in wire cage batteries. The animals frequently sleep during the procedure and no lesions are found due to the wire. Exposures may last anywhere from 1-6 hours per day on multiple days. The ACUC has determined that this is not restraint.

Program Review

The Semiannual Program Review was conducted during the ACUC meeting April 18, 2019 with a quorum present. The ACUC utilized the OLAW checklist to perform program review. As part of the Semiannual Program Review, the IACUC reviewed the ACUC Charter, Semiannual Annual laboratory and animal facility inspection forms and the animal facility room entry sequence list. Modifications/ updates will be made to all of these documents to improve and describe current IACUC/ ACUP procedures. Discussed the review and revision of Animal Facility Working Standards begun by the animal facility staff, AV, and IACUC Administrator; intent is to update animal facility procedures currently in use into a re-formatted Working Standards Form.

Facility Inspections

The findings from the Semiannual Inspections of the Animal Facility and laboratories where animals are used were discussed and categorized at a convened meeting on April 18, 2018. Updated Animal Welfare posters were distributed. The ACUC provided "Expired- Not for use in animals" stickers during the inspection to make on the spot corrections during the inspection.

Inspections were conducted on the following dates -

Investigator laboratories where animals are used – April 1 – 3, 2019.

Animal Facilities – April 1 and 4, 2019.

Significant Deficiency

No significant deficiencies were identified during this semi-annual program review and inspection period.

Minor Deficiency

Animal Facility –

- Insect traps were missing from storage rooms located outside of the Animal Facility; this was attributed to current facility renovations. This deficiency was corrected by the Animal Facility technicians, 2 April 2019.
- Monthly eyewash inspection logs out of date. This deficiency was corrected by the Animal Facility technicians, 8 April 2019.
- One room in Inhalation Facility was cluttered with equipment and not an ideal environment for moving animals on carts within the room. The clutter was removed by the Inhalation Facility technicians and this deficiency was corrected, 17 April 2019.

Research Laboratories –

- A single bottle of expired sterile normal saline was found in one lab. An “Expired- Not for use in animals” sticker was placed on the bottle and the deficiency corrected, 8 April 2019.
- One lab was extremely cluttered with equipment and not an ideal environment for performing animal procedures. The PI consulted with the AV to 1) clear and sanitize lab counter space used for animal procedures, and 2) ensure appropriate space for ingress and egress of personnel between countertop stations used for animal procedures. This deficiency was corrected, 18 April 2019.
- Several laboratories did not have their ACUC lab notebooks up to date: 1) missing approved protocols and 2) missing protocol information and protocol associates’ signatures on Animal Emergency Response Plan Appendix 3. These deficiencies were corrected by the PIs and confirmed by the IACUC Administrator, 11 April 2019.

Reports to OLAW

No reports were filed to OLAW during the period of November 2018 – April 2019.

Minority Views

There are no minority views to report.

Signatures

Signatures of the ACUC members are provided below.

(b)(6)	(b)(6)
Names of Voting IACUC Members	Signatures

(b)(6) Semiannual Report for November 2018 – April 2019

cc: ACUC file

(b)(6) Office