



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

Memorandum

Date: November 6, 2019

From: NIOSH/HELD Animal Care and Use Committee

Subject: Semiannual Program Review and Facilities Inspection Report (May 2019 – Oct 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 May 2019 – 31 October 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.

Animal Welfare Assurance for Domestic Institutions Renewal

The PHS Assurance Renewal for CDC-Morgantown Program D16-00687 (old A4367-01) was submitted to OLAW, Division of Assurances on 30 August 2019.

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

- New policies drafted and approved by the IACUC:
 - CDC-Morgantown IACUC Policy P-007 on the Reporting and Investigation of Animal Welfare Concerns. Approved 16 May 2019.
 - CDC-Morgantown IACUC Policy P-008 on Post-Approval Monitoring. Approved 19 September 2019.
 - CDC-Morgantown IACUC Policy P-009 on USDA Pain Categories. Approved 24 October 2019.

ACUC Roster Changes

No roster changes during this semi-annual program review and inspection period.

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 in 12-hour intervals to collect urine. Animals have sufficient space to stand up, turn around and lie down. Food and water are 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, #19-005 and #19-016 (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 (Usually less than 2 hours).

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 (Usually less than 1 hour).

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 rarely see lesions due to the wire. Exposures may last anywhere from 16 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 October 24, 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 current ACUC Policies: 1) CDC-Morgantown IACUC Policy P-001 on the Social Housing of Mice and Rats, 2) CDC-Morgantown IACUC Policy P-003 on Euthanasia, 3) CDC Morgantown IACUC Policy P-004 on Conflict of Interest, 4) CDC-Morgantown IACUC Policy P-005 on the Satellite Animal Facility and 6) CDC-Morgantown IACUC Policy P-006 on the Review of Protocols and Modifications to Protocols. P-003 and P-005 are under revision to improve and describe current IACUC/ACUP procedures.

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 October 24, 2019. Updates to the Animal Welfare posters were not required as all information remained current. The ACUC provided "Expired- Not for use in animals" stickers during the inspection to make on the spot corrections during the inspection. The inspection forms for the laboratories and animal facility were revised to capture the animal activities performed in laboratories and specific room types (breeding rooms, animal housing rooms, inhalation rooms, cage washing, etc.) in the animal facility. The inspection forms for the laboratories and animal facility were sent to the investigators, Attending Veterinarian and Animal Facility Manager one week in advance of the scheduled inspections and requested that the forms be filled out and returned to the IACUC prior to the lab inspection. The IACUC inspection team reviewed the forms prior to visiting the labs and followed up on the information provided by the investigators. A Division (HELD) SOP (SOP-OD-00346) for the handling and use of controlled substances (Schedule I and II) was developed as a guidance on division (and DEA) requirements. The IACUC inspection team discussed/ confirmed that PIs were aware of the SOP during the inspection.

The Fall Semi-annual Inspections were conducted on the following dates –

Animal Facilities – October 3, 2019.

Investigator laboratories where animals are used – October 7 – 9, 2019.

Significant Deficiency

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

Minor Deficiency

Animal Facility –

- One bottle of expired antibiotic found in animal facility pharmacy cabinet and one bottle found in one animal housing room were removed from animal facility and the deficiency corrected, 3 October 2019.
- Expired disinfectant removed/ replaced in several rooms. The deficiency was corrected, 7 October 2019.
- Monthly eyewash inspection logs out of date in several rooms. This deficiency was corrected by the Animal Facility technicians, 21 October 2019.

Research Laboratories –

- The most common deficiency found in several laboratories was that the ACUC notebooks were not up to date and did not contain all current protocols and the Animal Emergency Response Plan Appendix 3 did not have the signatures of all the protocol associates identified in the protocols in the book. The deficiencies in recordkeeping were corrected by the PIs and confirmed by the IACUC Administrator by 17 October 2019.
- One lab stored the key to their controlled substance locked drawer in open view; the key was moved to a concealed location. The deficiency was corrected, 8 October 2019.

Reports to OLAW

OLAW Case W- human error in administration of agent to animals, 28 June 2019.

OLAW Case X- improper euthanasia method to ensure death of animal, 16 September 20019

Cage containing mice discovered without water bottle- reported to IO, 10 September 2019; IO sent report to OLAW, 2 October 2019 (Case number to be assigned).

Minority Views

There are no minority views to report.

Signatures

Signatures of the ACUC members are provided below.

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Names of Voting IACUC Members

(b)(6)

[illegible]

Semiannual Report for May 2019 – October 2019

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CC;

ACUC file

Don Beezhold

~~Steve Monroe~~

Richard Probst