



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

February 26, 2020

Re: Animal Welfare Assurance
A3304-01 [OLAW Case 3Q]

Dana L. Director, Ph.D.
Vice President for Research Operations
And Student Affairs
Oregon Health and Science University
3181 SW Sam Jackson Park Rd.
Portland, OR 97239-3098

Dear Dr. Director,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 25, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Oregon Health & Science University, following up on an initial telephone report on January 31, 2020. According to the information provided, OLAW understands that 12 rhesus monkeys failed to receive the required second day dose of analgesia following a procedure. The animals had received a pre-procedural dose of analgesic, no adverse effects were subsequently noted in the animals, and the study was not impacted. The incident occurred due to an error in programming parameters in the software which generates the schedules for provision of medications based on the type of procedure performed.

The corrective actions consisted of adjusting and verifying the programming parameters, having the investigators compare the schedules developed by the software with what was approved by the Institutional Animal Care and Use Committee, checking this consistency before using new/modified procedures, and having two laboratory members create and verify the software output for any new procedures.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair
Robert Gibbens, D.V.M., USDA-APHIS-AC



February 25, 2020

Brent Morse, DVM, DACLAM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892

Dear Dr. Morse:

Oregon Health & Science University (OHSU), in accordance with Assurance D16-00195 (A3304-01) and PHS Policy IV.F.3., provides this report of a missed medication for a cohort of 12 non-human primates. This was first reported to you on January 31, 2020 via a telephone voice message from Vickie L. Jarrell, Ph.D., Director, Animal Care & Use Program.

The incident involved 12 Rhesus macaques assigned to one Animal Use Protocol (#0334) that underwent cerebral spinal fluid collection procedures for which carprofen was to be administered for 2 days post-procedurally. The animals received a pre-procedural dose of carprofen covering 24 hours of post-procedural analgesia. However, the medications were not administered on the second day following the procedure due to human error.

Post-procedural observations of the animals were conducted on day 2 and 3 by veterinary technicians of the centralized veterinary care unit who had no prior knowledge that pain medications had been omitted. The medical records reflect objective pain scores for all 12 animals at zero (scale of 0-5, with 0 = no signs of pain) on day 2 and day 3 following the procedures. All affected animals were bright, alert and responsive. The incident was reported to the IACUC on February 18, 2020. The committee concurred there were no adverse effects on the welfare of the animals.

After careful consideration, it was determined that this incident was due in part to an error in programming parameters in the software used to generate schedules of required medications associated with given procedures. CSF collections are typically conducted with other procedures to capitalize on single anesthetic events. In this instance, CSF samples were collected independently of other procedures. The coupling of CSF aspirations with other, more invasive procedures directs prescription of analgesics in excess of those for CSF collections alone. It was therefore

Research & Innovation Office

tel 503 494-1083

fax 503 494-1099

Dana Director, PhD
Vice President of Research
Administration & Senior Staff
Officer

director@ohsu.edu
www.ohsu.edu/research

Mail code: L335
3181 S.W. Sam Jackson Park Rd.
Portland, OR 97239-3098

determined that this incident was not reflective of a larger problem. The programming parameters were corrected and verified through extensive testing to prescribe post-operative analgesics for the CSF aspirations in accordance with IACUC approvals. The committee approved the following corrective action plan in response to this event:

- The research group will conduct a quality-control comparison of the output generated by the software program with analgesic schedules approved by the IACUC.
- The consistency of the software output with the analgesic schedules approved by the IACUC will be verified prior to use of the program for any new or modified procedures.
- Two research staff members will be involved in the creation of the programming parameters and verification of the output from the software program for any new procedures.

All other medications were administered appropriately and there were no impacts on research outcomes from this incident. We have determined that expenditures from NIH/NCI 1R01CA206404-01 in response to this error were of a minimal nature not requiring refunding of the grant.

OHSU is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact Dr. Jarrell (b) (6) or jarrellv@ohsu.edu).

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Dana L. Director, Ph.D.

Vice President of Research Administration & Senior Staff Officer
Institutional Official
Oregon Health & Science University

cc: Attending Veterinarian
IACUC Chair
Director, Animal Care & Use Program

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, February 26, 2020 7:10 AM
To: Vickie Jarrell
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: OHSU report of non-compliance missed analgesics

Thank you for this report, Dr. Jarrell. We will send a response soon.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: Vickie Jarrell <jarrellv@ohsu.edu>
Sent: Tuesday, February 25, 2020 2:14 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Dana Director <director@ohsu.edu>; (b) (6)
(b) (6)
Subject: OHSU report of non-compliance missed analgesics

Dear Dr. Morse:

Please find attached the final report of non-compliance from the Oregon Health & Science University, D16-00195 (A3304-01), regarding missed analgesic medications.

If you have questions or need additional information, please do not hesitate to contact me.

Respectfully,
Vickie Jarrell

Vickie Jarrell, PhD
Director, Animal Care and Use Program
OHSU Research Integrity
(b) (6)
jarrellv@ohsu.edu

A3304-3Q



Initial Report of Noncompliance

By: (b) (6)

Date: 1/31/20

Time: 3:00 via email

Name of Person reporting: Vicky Gerard
Telephone #: (b) (6)
Fax #: (b) (6)
Email:

Name of Institution: Oregon Health + Science U
Assurance number: A3304

Did incident involve PHS funded activity? _____
Funding component: _____
Was funding component contacted (if necessary): _____

What happened?
*12 monkeys didn't receive 2nd day dose of
anesthetic as described in protocol*

Species involved: *Rhesus*
Personnel involved:
Dates and times:
Animal deaths:

Projected plan and schedule for correction/prevention (if known): _____

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY
Case # _____