



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

September 21, 2021

Re: Animal Welfare Assurance
A3034-01 [OLAW Case Y]

Dr. Michael R. Kuhlman
Institutional Official
Battelle Memorial Institute - Richland
550 King Avenue
Columbus, OH 43201

Dear Dr. Kuhlman,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your September 16, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Battelle Memorial Institute, following up on an initial report on September 7, 2021. According to the information provided, OLAW understands that a mouse was not euthanized upon reaching the approved humane endpoint, based on percentage of weight loss.

The corrective actions consisted of counseling the animal technician responsible, as well as other staff, on adhering to the protocol. Although there is a data collection system in place which issues notifications regarding euthanasia criteria, it cannot be modified. Therefore a paper backup system may be used to prompt endpoint actions or weight loss data may be exported to a spreadsheet for use by the technicians. The contract was not charged for any unauthorized animal activities and the funding component was notified of the incident.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to 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

September 16, 2021

Axel Wolff, MS, DVM
Deputy Director
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892

Dear Dr. Wolff:

Battelle, in accordance with Assurance D16-00021 (A3034-01) and PHS Policy, provides this report of noncompliance regarding an adverse event. This incident was first reported on September 8, 2021 via email to OLAW's Division of Compliance Oversight. This document is our final report relative to this incident which we identified as noncompliant with PHS Policy.

One mouse on an IACUC-approved protocol was not euthanized when it reached the protocol-specified endpoint (failure to adhere to the IACUC-approved protocol). The following corrective and preventive actions were implemented after the incident:

- On 8/5/21 the involved animal technician was interviewed, and on 8/24/21, additional staff members were counselled to check their work closely.
- The data collection system was reviewed relative to the preset "flags" intended to prompt the animal technician if euthanasia criteria were met.
- The IACUC reviewed this occurrence at a convened meeting on 8/19/21 and additionally on 9/16/21. The IACUC reviewed and accepted the corrective action plan as described below.

Currently, the data collection system is unable to be modified to better capture protocol-specific data endpoints that would be useful in alerting staff to these animals. Discussions about adding and/or modifying additional parameters have occurred with the software company and modifications or additions are not possible. In the meantime, data capture on paper or with a paper back up for endpoints is also under discussion. Additionally, staff are performing a test run on exporting data captured in Provantis to an excel spreadsheet set with conditional formatting to alarm when an animal has met the protocol-specified weight loss criteria. This process has been used previously on unrelated studies.

The contract number is HHSN273201700005C. There were no unallowable costs charged. This incident was reported to the funding component.

Should you have any questions regarding this report, please let me know.

Thank you.

(b) (6)

Michael R. Kuhlman, Ph.D.
Institutional Official
Battelle

(b) (6)

kuhlmanm@battelle.org

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, September 17, 2021 8:08 AM
To: Kuhlman, Michael (US)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Final Report of Incident

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

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

-----Original Message-----

From: Kuhlman, Michael (US) <KUHLMANM@battelle.org>
Sent: Thursday, September 16, 2021 5:07 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Final Report of Incident

Dear Division of Compliance Oversight:

Attached is Battelle's final report regarding the incident reported initially on September 7.

Please do not hesitate to contact me with any questions.

V/r,

Michael R. Kuhlman, Ph.D.
Institutional Official

(b) (6)

kuhlmanm@battelle.org<mailto:kuhlmanm@battelle.org>

Battelle
505 King Ave.
Columbus, OH 43201
<http://www.battelle.org><<http://www.battelle.org/>>

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, September 8, 2021 7:07 AM
To: Kuhlman, Michael (US)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Reportable Incident preliminary report

Thank you for this preliminary report, Dr. Kuhlman. We will open a new case file and look forward to receiving the final report after the IACUC has completed its investigation.

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

-----Original Message-----

From: Kuhlman, Michael (US) <KUHLMANM@battelle.org>
 Sent: Tuesday, September 7, 2021 10:03 AM
 To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
 Subject: Reportable Incident preliminary report

Director, Division of Compliance Oversight Office of Laboratory Animal Welfare National Institutes of Health Rockledge
 1, Suite 360, MSC 7982
 6705 Rockledge Drive
 Bethesda, MD 20892-7982

Dear Division of Compliance Oversight:

A situation recently occurred at Battelle which we deemed reportable. We instituted immediate corrective actions, the details of which are provided below.

Animal Welfare Assurance number: D16-00021 (A3034-01)

Funding component and if contacted: NTP; notified August 27, 2021.

Description of the incident:

One mouse on an IACUC-approved protocol was not euthanized when it reached the protocol-specified endpoint (% weight loss).

Description of actions taken:

- * The animal technician was interviewed.
- * The data collection system was reviewed relative to the preset "flags" intended to prompt the animal technician if euthanasia criteria were met.
- * The IACUC reviewed this at a convened meeting on August 19, 2021.

Corrective plans included:

- * Currently, the data collection system is unable to be modified to better capture protocol-specific data endpoints that would be useful in alerting staff to these animals. Discussions about adding and/or modifying additional parameters are ongoing.
- * In the meantime, data capture on paper or with a paper back up for endpoints is also being discussed.

* Finally, the staff members have been counselled to check their work more closely.
A signed copy of the final report will be provided no later than 9/17/21.

Please contact me if you require additional information.

V/r,

Michael R. Kuhlman, Ph.D.
Institutional Official

(b) (6)

kuhlmanm@battelle.org<mailto:kuhlmanm@battelle.org>

Battelle
505 King Ave.
Columbus, OH 43201
<http://www.battelle.org><<http://www.battelle.org>>