



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 24, 2020

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

Dr. Michael Kuhlman
Chief Scientist
Battelle Memorial Institute – Columbus
550 King Avenue
Columbus, OH 43201

Dear Dr. Kuhlman,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your September 21, 2020 letter reporting a non-compliance with the PHS Policy on the Humane Care and Use of Laboratory Animals at the Battelle Biomedical Research Center. Your letter supplements the information provided in your initial email report to our office on September 14, 2020. According to the information provided it is understood that three pigs underwent CSF collection without this procedure being approved on the training protocol. These collections were performed by a clinical veterinarian using appropriate procedures, anesthetics, and analgesics. The animals recovered uneventfully, and no animal health issues were noted. The activity was not PHS-sponsored.

The following actions are to correct, and to prevent the recurrence of, such an incident:

The veterinarian was formally counseled by the IACUC Chair to submit an IACUC amendment for training on new procedures and the consequences of failing to do so.

The training protocols will be revised and will contain lists of skills that may be practiced such that a separate IACUC request for each procedure is not required.

OLAW believes that the corrective and preventive measures put in place by the Battelle Biomedical Research Center are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals. Although this activity was not PHS funded, the application of the expectations of the PHS Policy across the animal care and use program reduces any potential appearance of a double standard. We appreciate being informed of these matters and find no cause for further action by this office.

Sincerely,

Brent C. Morse -S

Digitally signed by Brent C.

Morse -S

Date: 2020.09.24 14:52:17 -04'00'

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact

September 21, 2020

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 a training activity not reviewed and approved by the IACUC. This incident was first reported on September 14, 2020 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. This situation was not related to a PHS-funded activity.

The reportable event involved collection of cerebrospinal fluid (CSF) from three training colony pigs without specific IACUC approval under our active Veterinary Skills Training protocol. Since CSF collection is not specifically listed in our Veterinary Skills Training protocol, an amendment to the protocol specifying this procedure would have been necessary to maintain compliance. These collections were performed by a clinical veterinarian using appropriate procedures, anesthetics, and analgesics. There is an SOP in place describing the procedure. The training was performed in support of a study that required CSF collections in pigs. The animals recovered uneventfully, and no animal health issues were noted.

The following corrective actions were implemented after the incident:

- The veterinarian was required to submit a detailed description of the procedure that was performed plus the anesthesia and analgesia records. These documents were reviewed by the Attending Veterinarian and two additional veterinarians and found to be acceptable.
- On August 31, 2020, the veterinarian was formally counseled by the IACUC Chair to submit an IACUC amendment for training on new procedures and the consequences of failing to do so.
- Continuation of the ongoing initiative to revise the training protocols. Specifically, the revised protocols will contain lists of skills that may be practiced such that a separate IACUC request for each procedure is not required. Training skills not listed would require IACUC review and approval prior to initiation.

The IACUC full committee review occurred on August 12, 2020. The corrective and preventive actions were reviewed and accepted by the IACUC.

On September 16, 2020, revised protocols were distributed for review as part of the Holding and Training Protocol Consolidation effort.

The IACUC determined that this was an isolated incident and not a programmatic failure.

Battelle is committed to protecting the welfare of animals used in research and appreciates the guidance provided by OLAW in this regard. Should you have any questions regarding this report, please let me know.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Michael R. Kuhlman, Ph.D.

Institutional Official

Battelle

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kuhlmannm@battelle.org

Battelle

505 King Ave.

Columbus, OH 43201

<http://www.battelle.org>

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, September 23, 2020 7:42 AM
To: Kuhlman, Michael R
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Revised Battelle final report

Thank you for this report, Dr. Kuhlman. I will substitute this revised version.
Axel Wolff

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

From: Kuhlman, Michael R <KUHLMANM@battelle.org>
Sent: Monday, September 21, 2020 5:56 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: [REDACTED] (b) (6)
Subject: Revised Battelle final report

Dear Dr. Wolff,

Attached please find a slightly revised version of Battelle's final report regarding the noncompliance event addressed in my email of September 14.

Please feel free to contact us with any questions.

V/r,

Michael R. Kuhlman, Ph.D.
Chief Scientist
Office: [REDACTED] (b) (6) Mobile: [REDACTED] (b) (6) | Fax: [REDACTED] (b) (6)
kuhlmanm@battelle.org<mailto:kuhlmanm@battelle.org>

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Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, September 16, 2020 7:28 AM
To: Kuhlman, Michael R
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Reportable Event Preliminary Notice

Thank you for this preliminary report, Dr. Kuhlman. We will start 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 R <KUHLMANM@battelle.org>
Sent: Monday, September 14, 2020 12:39 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
Subject: Reportable Event Preliminary Notice

Dear Division of Compliance Oversight:

An event recently occurred at Battelle which our IACUC deemed reportable to OLAW. The following is a summary of the event:

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

Funding component and if contacted: Not applicable

Description of the incident: The reportable event involved collection of cerebrospinal fluid (CSF) from three training colony pigs without specific IACUC approval under our active Veterinary Skills Training protocol approved by IACUC. Since CSF collection is not specifically listed in our Veterinary Skills Training protocol, an amendment to the protocol specifying this procedure would have been necessary to maintain compliance. These collections were performed by a clinical veterinarian using appropriate procedures, anesthetics, and analgesics. There was an SOP in place describing the procedure. The training was performed in support of a study that required CSF collections in pigs. The animals recovered uneventfully, and no animal health issues were noted.

Description of actions taken: The veterinarian was required to provide a detailed description of the procedure that was performed plus the anesthesia and analgesia records. The veterinarian was counseled by the IACUC chair to submit an IACUC amendment for training on new procedures. The IACUC reviewed this at a full committee review.

Description of corrective plans: There is an ongoing initiative (prior to this incident) to revise the training protocols specifically to add lists of skills that may be practiced such that a separate IACUC request for each procedure is not required. Novel procedures would still need to be submitted for IACUC review.

A signed copy of the final report will be provided no later than September 22, 2020.

Please contact me if you require additional information.

Michael R. Kuhlman, Ph.D.

Institutional Official

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