



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

June 23, 2021

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

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

Dear Dr. Kuhlman,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 8, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Battelle Memorial Institute - Columbus. This Office was not able to locate a preliminary report submitted by the institution.

According to the information provided, this Office understands that the Battelle Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: the conduct of animal-related activities without prior IACUC review and approval. The final report states a protocol was undergoing veterinary pre-review at the same time 35 rabbits were sedated for subcutaneous identification chip implantation. It was determined the incident occurred due to a communication error regarding which protocol the rabbits were transferred, a holding protocol or a study protocol. It further stated the holding protocol had an allowance for subcutaneous identification chip implantation, but the animals were intended to have chip implantation on the study protocol. In response to the incident, approval of the protocol with modifications occurred at a full committee review on May 19, 2021.

It is noted that this project is supported by PHS funds. Based on its assessment of this explanation, OLAW understands that the Battelle Memorial Institute - Columbus has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy.

We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

Jacquelyn T.
Tubbs -S

Digitally signed by Jacquelyn T.
Tubbs -S
Date: 2021.06.23 12:48:10 -04'00'

Jacquelyn Tubbs, DVM, DACLAM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact
Robert M. Gibbens, DVM, Director, Animal Welfare Operations



June 8, 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:

An incident recently occurred at Battelle (Assurance Number D16-00021 [A3034-01]) which we deemed reportable and for which we submitted a preliminary report on May 26, 2021. This document is our final report relative to this incident which was determined to be noncompliance with PHS Policy.

The incident involved an animal-related activity that occurred without IACUC approval. The protocol was undergoing veterinary pre-review at the time that 35 rabbits were sedated for subcutaneous identification chip implantation. All animals recovered uneventfully. The root cause was determined to be a communication error as to which protocol the rabbits were transferred, a holding protocol or a study protocol. The holding protocol had an allowance for subcutaneous identification chip implantation. The rabbits were intended to have chip implantation on the study protocol.

Corrective actions included approval of the protocol with modifications at a full committee review on 5/19/21. This issue was also discussed with the study director.

The contract number is CON00026323. This incident was reported to the funding component. OLAW's Guidance on Confirming Appropriate Charges to NIH Awards during Periods of Noncompliance for Activities Involving Animals is being utilized relative to unallowable costs.

Please feel free to contact me at any time if you require additional information.

Sincerely,

(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: Wednesday, June 9, 2021 7:32 AM
To: Kuhlman, Michael (US)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Final Report

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: Tuesday, June 8, 2021 11:28 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: [REDACTED] (b) (6)

[REDACTED] (b) (6)
Subject: Final Report

Dear OLAW,

Attached is Battelle's final report regarding the incident brought to your attention in our preliminary report dated May 26, 2021. Please feel free to contact me if you have any questions.

Best regards,

Michael R. Kuhlman, Ph.D.
Institutional Official

[REDACTED] (b) (6)
kuhlmanm@battelle.org<mailto:kuhlmanm@battelle.org>

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