



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

March 7, 2022

Re: Animal Welfare Assurance
A3034-01 [OLAW Case 1A]

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 February 24, 2022 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 February 1, 2022. According to the information provided it is understood that a technician administered an expired solution of Telazol to one primate. The animal was appropriately anesthetized. The Telazol functioned as expected and there were no adverse effects noted. Once discovered that the solution was expired, the bottle was placed in the expired/empty bin in the lock box. The associated project is PHS-funded. The funding component was notified. No unallowable costs were charged. There was no impact or effect on PHS-supported activities.

Corrective and preventive actions:

- More visible, clearer labeling of Telazol bottles with the expiration date once reconstituted.
- More frequent inventory of s commonly accessed designated satellite storage areas. These are now inventoried monthly by the controlled Substance Management Coordinator; the most recent inventory was conducted on 2/17/2022.
- Retraining staff to verify expiration dates of items when being retrieved from locked storage and before administration. Retraining occurred on 1/06/2022.
- Utilizing drugs for sedation with a longer shelf life. Other options (e.g. ketamine) are already listed in the current Anesthesia and Analgesia for Selected Species guideline document.

OLAW believes that the corrective and preventive measures put in place by Battelle Biomedical Research Center are consistent with the provisions of the PHS policy on Humane Care and Use of Laboratory Animals. We appreciate being informed and find no cause for further action by this office.

Sincerely,

Brent C. Morse -S

Digitally signed by Brent C.

Morse -S

Date: 2022.03.08 10:11:49 -05'00'

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

cc: IACUC contact
Dr. Robert M. Gibbens, USDA, APHIS, AC

February 24, 2022

Dear Division of Compliance Oversight:

An incident recently occurred at Battelle which we deemed reportable and for which we previously submitted a preliminary report. This document is our final report relative to this incident.

Assurance number:

D16-00021 (A3034-01)

Reporting requirement:

This incident involved a deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals*.

Preliminary report:

On February 1, 2022, Institutional Official Dr. Michael Kuhlman submitted the preliminary report to OLAW's Division of Compliance Oversight.

Explanation of incident:

Technician "A" retrieved reconstituted Telazol from locked storage in a designated satellite (auxiliary) storage location and provided it to Technician "B". Technician B was already in the animal room at that time preparing for the study activities. The Telazol usage form remained in the anteroom to prevent contamination of paperwork with test material. Technician B administered the Telazol to one primate and the animal was appropriately anesthetized. The Telazol functioned as expected and there were no adverse effects noted. When Technician A took the Telazol back to the anteroom to fill out the usage form, it was noted that it was past the expiration date for the reconstituted material. The source material was not expired. The bottle was placed in the expired/empty bin in the lock box.

Corrective actions:

Although this was an isolated incident, safeguards were put in place to prevent a repeat of this occurrence. Several corrective and preventive actions were implemented as reviewed and agreed upon by the IACUC at the December monthly meeting.

Corrective actions included:

- More visible, clearer labeling of Telazol bottles with the expiration date once reconstituted.

- More frequent inventory of items in less commonly accessed designated satellite storage areas. These areas are now inventoried monthly by the Controlled Substance Management Coordinator; the most recent inventory was conducted on 02/17/2022.
- Retraining staff to verify expiration dates of items when being retrieved from locked storage and before administration. Retraining occurred on 01/06/2022.
- Utilizing drugs for sedation with a longer shelf life. Other options (e.g., ketamine) are already listed in the current Anesthesia and Analgesia for Selected Species guideline document.
- Stating more options for sedation in the protocol. During veterinary preview of new IACUC submissions, the listed sedatives will be reviewed and options recommended if appropriate for that particular study.

Grant/contract number:

The contract number is HHSN272201800023C.

Impact on PHS-supported activities:

There was no impact or effect on PHS-supported activities.

Compliance with terms and conditions:

The funding component was notified. No unallowable costs were charged.

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

Sincerely,

Michael R. Kuhlman, Ph.D.

Institutional Official

Battelle

(o) [REDACTED] (b) (6)

(c) [REDACTED]

kuhlmanm@battelle.org

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, February 25, 2022 7:28 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: Thursday, February 24, 2022 3:07 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: [EXTERNAL] Final Report

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Dear OLAW,

Attached is the B06021 final report from Battelle. Please feel free to contact us with any questions.

V/r,

Michael R. Kuhlman, Ph.D.

Institutional Official

Office: (b) (6) | Mobile: (b) (6) | Fax: (b) (6)
kuhlmanm@battelle.org<mailto:kuhlmanm@battelle.org>

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



February 24, 2022

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Explanation of incident:

Technician "A" retrieved reconstituted Telazol from locked storage in a designated satellite (auxiliary) storage location and provided it to Technician "B". Technician B was already in the animal room at that time preparing for the study activities. The Telazol usage form remained in the anteroom to prevent contamination of paperwork with test material. Technician B administered the Telazol to one primate and the animal was appropriately anesthetized. The Telazol functioned as expected and there were no adverse effects noted. When Technician A took the Telazol back to the anteroom to fill out the usage form, it was noted that it was past the expiration date for the reconstituted material. The source material was not expired. The bottle was placed in the expired/empty bin in the lock box.

Corrective actions:

Although this was an isolated incident, safeguards were put in place to prevent a repeat of this occurrence. Several corrective and preventive actions were implemented as reviewed and agreed upon by the IACUC at the December monthly meeting.

Corrective actions included:

- More visible, clearer labeling of Telazol bottles with the expiration date once reconstituted.
- More frequent inventory of items in less commonly accessed designated satellite storage areas. These areas are now inventoried monthly by the Controlled Substance Management Coordinator; the most recent inventory was conducted on 02/17/2022.
- Retraining staff to verify expiration dates of items when being retrieved from locked storage and before administration. Retraining occurred on 01/06/2022.
- Utilizing drugs for sedation with a longer shelf life. Other options (e.g., ketamine) are already listed in the current Anesthesia and Analgesia for Selected Species guideline document.
- Stating more options for sedation in the protocol. During veterinary preview of new IACUC submissions, the listed sedatives will be reviewed and options recommended if appropriate for that particular study.

Grant/contract number:

The contract number is HHSN272201800023C.

Impact on PHS-supported activities:

There was no impact or effect on PHS-supported activities.

Compliance with terms and conditions:

The funding component was notified. No unallowable costs were charged.

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

(o) (b) (6)
(c)

kuhlmanm@battelle.org

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, February 28, 2022 7:13 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: Friday, February 25, 2022 3:20 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: [EXTERNAL] Re: Final Report

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Dear OLAW,

I was reminded that you may need the report in the attached format for your files.

V/r,

Michael R. Kuhlman, Ph.D.
Institutional Official
Office: (b) (6) | Mobile: (b) (6) | Fax: (b) (6)
kuhlmanm@battelle.org<mailto:kuhlmanm@battelle.org>

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

From: Kuhlman, Michael (US)
Sent: Thursday, February 24, 2022 15:07
To: olawdco@mail.nih.gov

Subject: Final Report

Dear OLAW,

Attached is the B06021 final report from Battelle. Please feel free to contact us with any questions.

V/r,

Michael R. Kuhlman, Ph.D.

Institutional Official

Office: (b) (6) | Mobile: (b) (6) | Fax: (b) (6)
kuhlmanm@battelle.org<mailto:kuhlmanm@battelle.org>

Battelle

505 King Ave.

Columbus, OH 43201

<http://www.battelle.org><<http://www.battelle.org/>>

Dear Division of Compliance Oversight:

An incident recently occurred at Battelle which we deemed reportable. We instituted prompt corrective actions, the details of which are provided below.

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

Funding component and if contacted: NIAID, yes.

Description of the incident:

Technician "A" retrieved reconstituted Telazol from locked storage in a designated satellite (auxiliary) storage location and provided it to Technician "B." Technician B was already in the animal room at that time preparing for the study activities. The Telazol usage form remained in the anteroom. Technician B administered the Telazol to one primate and when Technician A took the Telazol back to the anteroom to fill out the usage form noted that it was past the expiration date for the reconstituted material. The source material was not expired. The Telazol functioned as expected and there were no adverse effects noted. The bottle was placed in the expired/empty bin in the lock box.

The IACUC was notified and discussed this incident on 12/16/21, including the corrective actions below.

Corrective actions are in the process of being finalized. They include:

- More visible, clearer labeling of Telazol bottles with the expiration date once reconstituted. Other considerations include color-coded bottles, study-specific bottles, second person verification of forms and bottles
- More frequent inventory of items in less commonly accessed designated satellite storage areas
- Retraining staff to verify expiration dates of items when being retrieved from locked storage and before administration
- Utilizing drugs for sedation with a longer shelf life
- Stating more options for sedation in the protocol

A signed copy of the final report will be provided no later than 02/25/22.

Please contact me if you require additional information.

V/r

Michael R. Kuhlman, Ph.D.

Institutional Official

Battelle

(o)  (b) (6)

(c) 

kuhlmanm@battelle.org

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, February 2, 2022 7:44 AM
To: Kuhlman, Michael (US)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Preliminary report

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

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

From: Kuhlman, Michael (US) <KUHLMANM@battelle.org>
Sent: Tuesday, February 1, 2022 3:43 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: [REDACTED] (b) (6)
[REDACTED] (b) (6)
Subject: [EXTERNAL] Preliminary report

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Dear Division of Compliance Oversight:

An incident recently occurred at Battelle which we deemed reportable. We instituted prompt corrective actions, the details of which are provided in the attached.

This preliminary report has been delayed in submission because I was on vacation, and did not see the notifying email sent to me in a timely manner.

Please feel free to contact me with any questions.

V/r

Michael R. Kuhlman, Ph.D.

Institutional Official

Office: [REDACTED] (b) (6) | Mobile: [REDACTED] (b) (6)

kuhlmanm@battelle.org

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