



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) 402-7065

January 6, 2020

Re: Animal Welfare Assurance
A3448-01 [OLAW Case 1C]

Bruce Doll, DDS, Ph.D., MBA
Assistant Vice President for Technology
Research and Innovation
IACUC Institutional Official
Uniformed Services University of the Health Sciences
4301 Jones Bridge Road
Bethesda, MD 20814

Dear Dr. Doll,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your 06 December 2019 letter reporting a noncompliance with the PHS Policy on the Humane Care and Use of Laboratory Animals at the Uniformed Services University of the Health Sciences. Your letter supplements information provided in the initial email report received on May 13, 2019. According to the information provided, OLAW understands that on 09 May 2019 your institution became aware that a PI had used two female rats for a procedure when the protocol was only approved for male rats. Subsequent to investigation it became apparent that this mistake occurred due to several causes including mislabeling of cage cards and a system that tracks only cages and not individual animals. A lack of hands-on training, including gender identification, also could have added to the errors. It was not noted if this activity was PHS or NSF-funded.

The corrective actions consisted of the IACUC recommending tracking animals (where and when possible) to the maximum extent to minimize human errors and their recurrence. The IACUC also recommends implementation of overall across the board and consistent training to ensure all the research staff involved are adequately trained to carry out the process/procedures of the protocol. The PI agreed to all recommendations put forth by the IACUC. All personnel working on the protocol have been trained and can adequately carry out all processes and procedures in the protocol.

OLAW believes that the corrective and preventive measures put in place by the Uniformed Services University of the Health Sciences are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals for institutional self-monitoring and self-reporting. As noted in previous reports, please indicate in future reports if the activity was/was not PHS or NSF-funded. OLAW appreciates being informed of this issue and finds no cause for further action.

Sincerely,

(b) (6)

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

cc: IACUC Contact

Obtained by Rise for Animals. Uploaded 08/24/2020

Retrieved from Animal Research Laboratory Overview (ARLO)



UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES

OFFICE OF THE VICE PRESIDENT FOR RESEARCH

4301 JONES BRIDGE ROAD

BETHESDA, MARYLAND 20814-4799

www.usuhs.edu



06 December 2019

Brent C. Morse, DVM, DACLAM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
RKL1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda MD 20892-7982

Final Incident Report

OLAW Assured Facility Number D16-00258 (A3448-01)

Dear Dr. Morse,

This is a final report on an incident at Uniformed Services University of the Health Sciences (USU) OLAW Assured Facility Number D16-00285 (A3448-01) that was initially reported to the Office of Laboratory Animal Welfare (OLAW) on 9 May 2019.

The USU IACUC was first notified on Thursday 09 May of an event in which a PI used female rats for a procedure when their protocol was only approved for male rats.

Protocol procedures began with 6 rats. Two of the rats had been transferred to their protocol from a surgical training protocol. These two rats were induced under anesthesia with inhalational isoflurane, were given weight based dosing of buprenorphine SR, and underwent a pneumatic blast. After the blast, these animals were allowed to recover from anesthesia while under continuous monitoring by a designated team member. The rats recovered without issues and returned to their previous pre-procedure activity level.

During the recovery period, the protocol team noted that two rats were in fact female, despite the cage card designation. The protocol is only approved for male SD rats. The staff member immediately stopped any further procedures. After investigating the cage cards, the rats were originally listed as females on their original cage card and upon transfer to a LAM training protocol, the rat cage card listed them as males. These rats were transferred another two times to different protocols before being transferred to the PIs, all while being listed as male.

Protocol staff immediately alerted a LAM veterinarian of the issue and then spoke with the LAM Director as well, regarding the mislabeling of the rats. IACUC staff was informed that a LAM veterinarian would perform an investigation into their own procedures and documentation SOPs.

Overall, the subcommittee found that there were a series of minor human errors that resulted the gender mistake for this specific instance.

The significant problem discovered in this investigation relates to animals tracking and the process that entails following that. In the current system set up, the investigation identified that cages were tracked vs. specific animals being tracked, which in the sub-committee opinion was the source of errors and duplication of same as the process continued under various protocols and internal transfers. The error at this stage (labelling or sexing) could have been identified if the system was based on tracking animals vs. tracking cages in which animals could change. Since the current system transfers are by cage, the committee could only see what cages are transferred, and can only assume they are looking at the correct animals in the cages being transferred.

The subcommittee also feels that lack of hands-on training could be a contributing issue. In speaking with some laboratories, we found inadequate and lack of basic hands on-skills, such as handling animals, identifying the gender, injections etc. that some laboratories personnel were suffering which could have also contributed to the errors.

The IACUC made the following recommendations:

1. The sub-committee recommends tracking animals (where and when) possible to the maximum extent to minimize human errors and their recurrence.
2. The sub-committee recommends an implementation of overall across the board and consistent training to ensure all the research staff involved are adequately trained to carry out the process/procedures of the protocol.

The PI agreed to all recommendations put forth by the IACUC. All personnel working on the protocol have been trained and can adequately carry out all processes and procedures in the protocol.

The IACUC now considers this incident closed.

Sincerely,

(b) (6)

Bruce Doll, DDS, Ph.D., MBA
Assistant Vice President for Technological Research and Innovation
Office of the Vice President for Research
Institutional Official

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, December 06, 2019 2:22 PM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b) (6) iacuc@usuhs.edu; (b) (6)
Subject: RE: FW: Preliminary Report - USUHS - D16-00285 (A3448-01) 9 May 2019

Thank you for providing this final report (b) (6) We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

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From: (b) (6)
Sent: Friday, December 06, 2019 1:09 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) iacuc@usuhs.edu; (b) (6)
Subject: Re: FW: Preliminary Report - USUHS - D16-00285 (A3448-01) 9 May 2019

Hi Dr. Morse,

Please see the attached final report signed by the Institutional Official. Feel free to contact us if you have any comments or concerns.

Thank you so much,
(b) (6)

On Thu, Dec 5, 2019 at 2:51 PM (b) (6) wrote:

Hi Dr. Morse,

We are waiting on the IO to sign the final report. It should be sent to you tomorrow or Monday.

Thank you for your patience,
(b) (6)

From: OLAW Division of Compliance Oversight (NIH/OD) [mailto:olawdco@od.nih.gov]

Sent: Thursday, December 5, 2019 1:47 PM

To: (b) (6)

Subject: RE: Preliminary Report - USUHS - D16-00285 (A3448-01) 9 May 2019

Hello (b) (6)

OLAW has no record of receiving a final or interim report regarding this incident. Please advise.
Thank you.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM

Director

Division of Compliance Oversight

Office of Laboratory Animal Welfare

National Institutes of Health

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From: (b) (6)

Sent: Monday, May 13, 2019 1:25 PM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Cc: USARMY Ft Detrick MEDCOM USAMRMC Other ACURO <usarmy.detrack.medcom-usamrmc.other.acuro@mail.mil>; dha.ncr.reg-support.mbx.r2o2@mail.mil; (b) (6)

iacuc@usuhs.edu; Bruce Doll <bruce.doll@usuhs.edu>; (b) (6)

Subject: Preliminary Report - USUHS - D16-00285 (A3448-01) 9 May 2019

Dear Dr. Morse,

Please find the attached initial incident report regarding a rat protocol at the Uniformed Services University. A final report will be submitted by the IO once the investigation has concluded.

Thank you for your review.

(b) (6)



(b) (6)



(b) (6)



Morse, Brent (NIH/OD) [E]

A3448-1C

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, May 13, 2019 4:09 PM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: USARMY Ft Detrick MEDCOM USAMRMC Other ACURO; (b) (6)
iacuc@usuhs.edu; Bruce Doll; (b) (6)
Subject: RE: Preliminary Report - USUHS - D16-00285 (A3448-01) 9 May 2019

Thank you for providing this prompt preliminary report (b) (6). We will open a case file and await the final report.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

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From: (b) (6)
Sent: Monday, May 13, 2019 1:25 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: USARMY Ft Detrick MEDCOM USAMRMC Other ACURO <usarmy.detrack.medcom-usamrmc.other.acuro@mail.mil>; dha.ncr.reg-support.mbx.r2o2@mail.mil; (b) (6) iacuc@usuhs.edu; Bruce Doll <bruce.doll@usuhs.edu>; (b) (6)
Subject: Preliminary Report - USUHS - D16-00285 (A3448-01) 9 May 2019

Dear Dr. Morse,

Please find the attached initial incident report regarding a rat protocol at the Uniformed Services University. A final report will be submitted by the IO once the investigation has concluded.

Thank you for your review.

(b) (6)

May 13, 2019

On 5/9/2019, the IACUC office was notified of an event in which a PI used female rats for a procedure when their protocol is approved for only male rats.

Protocol procedures began with 6 rats, two of the rats had been transferred to their protocol from a surgical training protocol. These two rats were induced under anesthesia with inhalational isoflurane, were given weight based dosing of buprenorphine SR, and underwent a pneumatic blast. After the blast, these animals were allowed to recover from anesthesia while under continuous monitoring by a designated team member. The rats recovered without issues and returned to their previous pre-procedure activity level.

During the recovery period, the protocol team noted that two rats were in fact female, despite the cage card designation. The protocol is only approved for male SD rats. The staff member immediately stopped any further procedures. After investigating the cage cards, the rats were originally listed as females on their original cage card and upon transfer to a LAM training protocol, the rat cage card listed them as males. These rats were transferred another two times to different protocols before being transferred to the PIs, all while being listed as male.

Protocol staff immediately alerted a LAM veterinarian of the issue and then spoke with the LAM Director as well, regarding the mislabeling of the rats. IACUC staff has been informed that a LAM veterinarian will perform an investigation into their own procedures and documentation SOPs.

These rats underwent isoflurane, a weight-based. Pre-procedure dose of buprenorphine SR, and a pneumatic blast. They did not undergo any subsequent procedure and they appear healthy and well appearing with normal activity.

A final report on the incident will be sent to OLAW when the incident has been resolved. Please contact us if you have any questions or concerns.

Contact person making report:

(b) (6)