



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, (b)(6)
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

25-F-2984

March 4, 2025

Re: Animal Welfare Assurance
A3448-01 (OLAW Case 2H)

(b)(6) DDS, Ph.D.
Assistant Vice President for
Technology Research and Innovation
Uniformed Services University of Health Sciences
4301 Jones Bridge Rd
Bethesda, MD 20982

Dear Dr. (b)(6)

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 26, 2025, letter reporting an incident of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Uniformed Services University of the Health Sciences (USU), following up on an initial November 1, 2024, notification by email.

According to the information provided, this office understands that the USU Animal Care and Use Committee (ACUC) determined that an incident of noncompliance occurred with respect to failure to adhere to IACUC approved protocols and failure to adhere to institutional policies (i.e., overnight satellite housing). The preliminary report states that during a room inspection, multiple protocol deviations were discovered on a protocol involving rats (i.e., unauthorized animal housing, lack of analgesic per veterinary consultation, animals exceeding humane endpoints, etc.). The final report further states that the Principal Investigator (PI) provided corrective actions to the IACUC.

Per the final report, the IACUC reviewed this incident at its November 20, 2024, December 18, 2024, January 15, 2025, and February 19, 2025, meetings and approved the corrective actions. In summary, a lab meeting was held to emphasize the need to verify the provision of food to all animals. Lab staff will assist with animal care and critical recovery observations. A suggestion was made to use additional rooms to improve post-exposure monitoring. Protocol modifications to increase the body weight loss to 30% as a criterion for euthanasia and to administer Ethiqua-XR as needed was approved. Daily logbook recordings of weight logs, procedure notes and other pertinent information was implemented. Additionally, the IACUC recommended compliance training for all USU personnel and a future Post-Approval Monitoring (PAM) session.

Per the final report, recommendations were made, during a PAM session on February 10, 2025, to include discontinuing the practice of recapping needles, and a protocol modification to increase the dose for aged rats. With this, the IACUC determined the corrective action plan was adequate, and required no further action.

It is noted that this study is supported by PHS funding. Based on its assessment of this explanation, OLAW understands that the USU Animal Care and Use Committee has implemented measures to correct and prevent recurrence 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 action by this Office.

Sincerely,

Angelina M.

Williams -S

Angelina Williams, DVM, MPH, DACLAM

Animal Welfare Program Specialist

Division of Compliance Oversight

Office of Laboratory Animal Welfare

Digitally signed by Angelina M.
Williams -S
Date: 2025.03.04 11:15:52 -05'00'

cc: IACUC contact



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



February 26, 2025

(b)(6) DVM, DACLAM

Director, Division of Compliance Oversight

Office of Laboratory Animal Welfare

National Institutes of Health

RKLI, (b)(6)

6705 Rockledge Drive

Bethesda MD 20892-7982

Dear Dr. (b)(6)

Final Incident Report

Case A3448-2H

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

This is the final report for case A3448-2H at the Uniformed Services University of the Health Sciences (USU) (OLAW Assured Facility Number D16-00258/A3448-01). This affected a protocol funded by NIH Grant number G170UW.

On October 30, 2024, the IACUC office was notified of multiple protocol noncompliances on a protocol involving rats that were discovered on October 23, 2024. During room inspections by a veterinarian, the following noncompliances were discovered:

- an animal was found overnight with no food except a food gel container
- monitoring in a satellite/study location (procedure room) at inappropriate time points
- animals kept overnight in an unauthorized location and inappropriate housing
- animals getting Ethiqua without veterinary consultation and not in the IACUC-approved protocol
- animals not euthanized at the protocol's approved early endpoint (20% of body weight loss)

The Principal Investigator (PI) provided the following corrective actions for each item:

- an animal was found overnight with no food except a food gel container
 - A meeting was held with all animal caregivers on the laboratory team and it was emphasized the need to verify all animals have enough food in the hoppers
- monitoring in a satellite/study location (procedure room) at inappropriate time points

- additional laboratory staff will be allocated to assist with animal care and observations during the critical phase of recovery
- animals kept overnight in an unauthorized location and inappropriate housing
 - additional Department of Laboratory Animal Resources (DLAR) rooms have been suggested that will allow for better monitoring of the animals post-exposure to the protocol-approved nerve agents
- animals getting Ethiqs without veterinary consultation and not in the IACUC-approved protocol
 - A minor modification was submitted and approved to administer Ethiqs-XR for animals as needed
- animals not euthanized at the protocol's approved early endpoint (20% of body weight loss)
 - A minor modification was submitted and approved to increase the body weight loss to 30% for euthanasia as long as no pain or distress is noted

In addition, though the logbook recording weight logs, procedure notes, animal condition and medical interventions existed, a logbook recording every animal check and daily visits was implemented.

The incident was reviewed at the November 20, 2024 meeting and the IACUC recommended that all USU personnel on the protocol retake the Common Compliance Issues course in the AALAS learning library, and that a future Post-Approval Monitoring (PAM) session be scheduled. All personnel completed the retraining as instructed.

A PAM session was conducted on February 10, 2025, to monitor euthanasia and perfusion procedures. Two minor recommendations were made:

- Staff should follow procedures on no recapping of sharps
 - Lab members were instructed by the PI to ensure no recapping in the future after use
- Research team should consult with the veterinarians and prepare a modification for escalating Euthasol for animals in advanced age/weight
 - Modification was submitted and approved to increase the maximum dose to 300mg/kg for aged rats, older than 12 months and heavier than 600g.

The IACUC reviewed the incident at the November 20, 2024, December 18, 2024, January 15, 2025, and February 19, 2025, meetings. All corrective actions were determined to be sufficient and complete; no further actions were recommended.

The IACUC now considers this incident closed.

Sincerely,

(b)(6)

Assistant Vice President for Technology Research and Innovation
IACUC Institutional Official

Cc: ACURO

Ware, Teagan (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, February 27, 2025 8:37 AM
To: IACUC
Cc: [REDACTED] (b)(6) OLAW
Division of Compliance Oversight (NIH/OD)
Subject: RE: [EXTERNAL] Final Report - USUHS - D16-00285 (A3448-01) 27 February 2025

Good morning,

Thank you for providing this final report for OLAW case **A3448-2H**. We will send an official response soon.

Best,
Teagan

Teagan Ware, MS, PMP
Animal Welfare Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Phone: 301-435-2390
Email: teagan.ware@nih.gov

~~**Disclaimer:** Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected, or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.~~

From: IACUC <iacuc@usuhs.edu>
Sent: Thursday, February 27, 2025 8:28 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; usarmy.detrick.medcom-usamrmc.other.acuro@health.mil
Cc: iacuc <iacuc@usuhs.edu> [REDACTED] (b)(6)

Subject: [EXTERNAL] Final Report - USUHS - D16-00285 (A3448-01) 27 February 2025

Dear Dr. [REDACTED] (b)(6)

Please see the attached final report for case **A3448-2H** regarding a noncompliance at the Uniformed Services University.

If you have any additional questions or require further information, please feel free to contact us.

USU IACUC
[REDACTED] (b)(6)
iacuc@usuhs.edu

Ware, Teagan (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, February 11, 2025 12:32 PM
To: 'IACUC'
Cc: (b)(6) OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: [EXTERNAL] Preliminary Report - USUHS - D16-00285 (A3448-01) November 01 2024

Good afternoon,

Thank you for providing this update. We will add this note to the case file and will look forward to receiving the final report.

Best,
Teagan

Teagan Ware, MS, PMP
Animal Welfare Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Phone: 301-435-2390
Email: teagan.ware@nih.gov

~~**Disclaimer:** Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected, or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.~~

From: IACUC <iacuc@usuhs.edu>
Sent: Tuesday, February 11, 2025 11:57 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; iacuc <iacuc@usuhs.edu>
Cc: (b)(6)
Subject: Re: [EXTERNAL] Preliminary Report - USUHS - D16-00285 (A3448-01) November 01 2024

Good morning,

Thank you for your inquiry. This incident remains open at this time due to the ongoing investigation. We will send a final report once the investigation has concluded.

Please let us know if you have any further questions.

Thank you,

USU IACUC
(b)(6)
iacuc@usuhs.edu

On Tue, Feb 11, 2025 at 11:47 AM 'OLAW Division of Compliance Oversight (NIH/OD)' via iacuc@usuhs.edu <iacuc@usuhs.edu> wrote:

Good morning,

I am reaching out regarding open OLAW case **A3448-2H**. This case was preliminarily reported on November 1, 2024, per the email chain below. Could you please provide an update on this matter at your earliest convenience?

Thank you!

Best,

Teagan

Teagan Ware, MS, PMP

Animal Welfare Program Analyst

Division of Compliance Oversight

Office of Laboratory Animal Welfare

National Institutes of Health

Phone: 301-435-2390

Email: teagan.ware@nih.gov

Disclaimer: Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected, or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

A3448-2H

The IACUC was notified on October 30, 2024 regarding multiple protocol noncompliances on a protocol involving rats that occurred on October 23, 2024 on a protocol funded by NIH Grant number G170UW. During a room inspection by a veterinarian, the following noncompliances were discovered: an animal found overnight with no food except a food gel container, monitoring in a satellite / study location (procedure room) at inappropriate time points, animals kept overnight in an unauthorized location and in inappropriate housing, animals getting Ethiqs without veterinary consultation not IAW approved protocol, animals not euthanized at protocol's approved early end point (20% body weight loss).

The incident will be discussed at the November 20, 2024 full committee meeting.

A final detailed report on the incident will be sent by the IO once the investigation and any further subsequent actions are concluded. Please contact us if you have any questions or concerns.

IACUC Office

(b)(6)

iacuc@usuhs.edu

Uniformed Services University of the Health Sciences

OLAW Assured Facility Number D16-00285 (A344801)

cc:

Dr. (b)(6) IACUC Chair

Ware, Teagan (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, November 1, 2024 3:32 PM
To: 'IACUC'
Cc: [REDACTED] (b)(6) OLAW Division of
Compliance Oversight (NIH/OD)
Subject: RE: [EXTERNAL] Preliminary Report - USUHS - D16-00285 (A3448-01) November 01
2024

Good afternoon,

Thank you for providing this preliminary report, which has been assigned as OLAW case **A3448-2H**. Please reference this case ID when providing updates or submitting the final report for this incident.

Best,
Teagan

Teagan Ware, MS, PMP
Animal Welfare Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Phone: 301-435-2390
Email: teagan.ware@nih.gov

~~**Disclaimer:** Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected, or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.~~

From: IACUC <iacuc@usuhs.edu>
Sent: Friday, November 1, 2024 3:25 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; usarmy.detrick.medcom-usamrmc.other.acuro@health.mil

Cc: [REDACTED] (b)(6)

[REDACTED] (b)(6)

Subject: [EXTERNAL] Preliminary Report - USUHS - D16-00285 (A3448-01) November 01 2024

Dear Dr. [REDACTED] (b)(6)

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.

USU IACUC
[REDACTED] (b)(6)
iacuc@usuhs.edu