



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
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Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
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July 13, 2022

Re: Animal Welfare Assurance
#A3621-01 (OLAW Case H)

Thenkurussi Kesavadas, Ph.D.
Vice President for Research and Economic Development
State University of New York at Albany
1400 Washington Ave, UNH 307
Albany, NY 12222

Dear Dr. Kesavadas,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 2, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University at Albany, State University of New York. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the University at Albany Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to failure to adhere to the IACUC-approved protocol. The final report states on March 28, 2022, a laboratory member notified Laboratory Animal Resources (LAR) that impacted bowels were suspected in two rats used in an experiment. It is stated the impaction was discovered during a terminal procedure in one animal, while the other impaction was revealed during necropsy of the second animal. In response to the notification, a Post-Approval Monitoring (PAM) assessment was performed the following day.

During the PAM assessment, lab personnel confirmed no changes had been made to the approved protocol procedures. Surgical logs indicated chewable Rimadyl had been provided to animals post-operatively, as opposed to subcutaneous injections of the drug at the time of surgery. The PAM assessment noted a peri-operative complication and that nonsurgical animals appeared unaffected. It was also noted that neither the Consulting Veterinarian nor LAR had been provided with the euthanized animals to assess or to perform necropsies. Necropsies were performed by the lab, and LAR recommended surgeries cease until further evaluation could occur.

On April 6, 2022, during a semiannual facility inspection, surgery logs were reviewed, and the logs did not include the anesthetics or analgesics administered to animals undergoing surgical procedures. Lab personnel stated chewable Rimadyl was provided to animals 15min prior to surgery. It was concluded that partially eaten Rimadyl tablets by rats and administration 15min prior to surgery did not result in adequate analgesia for the animals. The Principal Investigator (PI) was awaiting a shipment of injectable Rimadyl, which led to a discussion with the Consulting Veterinarian regarding the use of chewable Rimadyl. The PI assumed the conversation with the Consulting Veterinarian was equivalent to approval for use of chewable Rimadyl. There was no record of a request for protocol modification to add chewable Rimadyl to the protocol. Ultimately, the PI obtained injectable Rimadyl and has been using it as approved in the protocol.

In response to the incident, the following corrective actions were implemented:

- Correspondence from the IACUC sent to Principal Investigator included a reminder that he is required to ensure that his lab personnel are knowledgeable of and comply with the approved protocol and approved procedures and only the IACUC approved analgesia method may be used.

He was also reminded that use of an alternative or additional analgesic or route of administration, requires a protocol modification request to the IACUC. A consultation with the veterinarian alone is not sufficient.

- The IACUC further determined that any future noncompliance by the Investigator/Investigator's lab with the surgical protocol will result in withholding of/suspension of approval for his lab to perform surgeries.
- The IACUC will formally direct an investigator to cease surgeries immediately until the IACUC has had an opportunity to review the situation and determine an appropriate resolution.
- The IACUC also reaffirmed that when a health issue occurs in animals, the investigator must contact the Consulting Veterinarian or LAR to conduct the necropsy or other animal health investigation. Neither investigators nor their lab personnel are to conduct necropsies. A guidance email has been sent to all animal users with this information.

It is understood that this research is supported by PHS funding. Based on its assessment of this explanation, OLAW understands that the University at Albany, State University of New York 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: 2022.07.13
09:02:35 -04'00'

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

cc: IACUC Contact

McCoy, Devora (NIH/OD) [E]

From: McCoy, Devora (NIH/OD) [E]
Sent: Wednesday, July 13, 2022 12:03 PM
To: tkesavadas@albany.edu
Cc: OLAW Division of Compliance Oversight (NIH/OD); (b) (6)
Subject: OLAW Case A3621-H
Attachments: SIGNED Compliance Case University at Albany, State University of New York H.pdf

Good afternoon Dr. Kesavadas,

Attached please find Dr. Tubbs' final response to OLAW Case A3621-H. If you have any questions, feel free to contact us by phone or by e-mail.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390



A3621-H

June 2, 2022

Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982
E-mail: olawdco@mail.nih.gov

Dear Director:

PHS Policy, IV.F.3, requires that:

"The IACUC, through the Institutional Official (IO), shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:

- a) any serious or continuing noncompliance with this Policy;
- b) any serious deviation from the provisions of the *Guide [for the Care and Use of Laboratory Animals]* ; or
- c) any suspension of an activity by the IACUC."

In accordance with requirement, the University at Albany Institutional Animal Care and Use (IACUC) through the IO, makes this report of a serious deviation from the provisions of the Guide.

Animal Welfare Assurance number:	D16-00376 (A3621-01) - State University of New York - University at Albany
Relevant Grant or Contract Number:	# 5 R01AG050598-02
Relevant Grant or Contract Title:	Mechanisms Transducing Insulin and Insulin Resistance in the Hippocampus
Sponsor:	NIH - National Institute on Aging
IACUC Protocol Number:	20-009
Principal Investigator:	Ewan McNay, PhD, Associate Professor, University at Albany

Background/Description of Incident

A report of concern was made by a member of the McNay laboratory via email to Laboratory Animal Resources on 3/28/2022. The email indicated that a lab member had observed two instances of suspected impacted bowels in rats used in experiment.

- 1) In first instance:

"... the impaction was discovered during transcardial perfusion during a scheduled euthanasia. Otherwise, there were no other signs of illness."

- 2) In the second instance:

[The animal], "...seemed to have rapid onset of illness symptoms...Later that afternoon, [lab staff] was able to perform a necropsy on the rat where [lab staff] found a very obvious impacted descending colon with what appeared to be a partial tear in the region of her rectum."

Upon receipt of the email, Laboratory Animal Resources (LAR) Facilities Manager and the Veterinary Technician responded to the email and provided a Post Approval Monitoring (PAM) assessment to IACUC and Consulting Veterinarian on 3/29/22.

PAM Assessment

LAR visited the lab and met with Lab personnel. The Lab personnel indicated that there had been no changes made to the approved protocol procedures. However, the surgical logs appeared to indicate that only chewable Rimadyl was being provided to animals post operatively, as opposed to subcutaneous administration at the time of surgery. Lab personnel also indicated that there appeared to be partially eaten Rimadyl tablets in cages. No other analgesics were being deployed/referenced. Non-surgical rats did not appear to be affected and the PAM assessment pointed to a peri-operative complication. Also noted was fact that neither the Consulting Veterinarian nor the LAR had been provided with the euthanized animals to assess/perform necropsies. These had been done by McNay Lab Personnel. LAR recommended that surgeries cease until further evaluation could be done.

Follow up evaluation of the matter was done on April 6, 2022, during the semi-annual IACUC facilities inspection. The Consulting Veterinarian and inspection team reviewed the surgery logs and spoke with McNay Lab personnel. The inspection team confirmed that the surgical logs did not include data as to the anesthetics or analgesics being administered to animals undergoing protocol surgeries. During discussion with the personnel, they indicated that the chewable Rimadyl was being provided to the animals approximately fifteen minutes prior to surgery.

The Consulting Veterinarian concluded that the partially eaten Rimadyl tablets suggested that the rats were not consistently receiving appropriate analgesia and advised that chewable Rimadyl provided only 15 minutes prior to surgery was not effective administration and timing for adequate analgesia for the rats. He further indicated that, though it was possible that some inanimate objects (like cardboard) may have caused or contributed to the deaths, it would not be possible to draw final conclusions since neither the Veterinarian nor LAR were able to perform the necropsies.

The Principal Investigator was promptly contacted by the Institutional Animal Care and Use Committee (IACUC) with the findings and observations. The Principal Investigator responded that, during a period when he was awaiting shipment of injectable Carprofen, he had consulted with the Consulting Veterinarian regarding use of a chewable version instead. Per that consultation, the Consulting Veterinarian indicated to the Investigator that the use of chewable could be acceptable. However, there is no record of an IACUC protocol modification request to implement the change was ever submitted to the IACUC (required before implementation of the change.) Thus, the modification was never reviewed or approved by the IACUC. The Principal Investigator mistakenly believed that the conversation with the Consulting Veterinarian deemed approval to make the change without submission of a modification request. The Principal Investigator indicated that he subsequently has obtained the injectable Carprofen and has been using it as described in the approved protocol.

Findings

- 1- There was only one drug and method of analgesia in the approved IACUC protocol – the injectable Carprofen. However, the oral Rimadyl was used without prior IACUC approval.
- 2- Lab personnel were not aware that they were not following the approved protocol procedures (i.e., using injectable vs. oral analgesia.)
- 3- Once the injectable Carprofen was available, Lab personnel were not adequately apprised by the Principal Investigator to use only the injectable Carprofen as analgesia since the chewable Rimadyl was only a temporary measure while awaiting for supply of injectable Carprofen.

Corrective Plan

At the next IACUC meeting (held on 5/18/22) the matter was discussed.

Please note: Dr. Ewan McNay is the Chair of the University at Albany IACUC. Dr. McNay did not participate in the review, discussion, actions of the IACUC regarding this matter. Dr. McNay recused himself throughout the process.

After being fully apprised of the foregoing by the Consulting Veterinarian and Laboratory Animal Facilities Manager, the IACUC determined that the incident would warrant reporting to Office of Laboratory Animal Welfare as a serious deviation from the provisions of the *Guide*. The IACUC also determined that this was an isolated incident and not a programmatic failure.

To address the incident the following actions would be taken:

- 1- A correspondence from the IACUC was sent to Principal Investigator advising him of the findings which included reminder that he is required to ensure that his Lab personnel are knowledgeable of and comply with the approved protocol and approved procedures and that only the IACUC approved analgesia method may be used. He was also reminded that use of an alternative or additional analgesic or route of administration, requires a protocol modification request to the IACUC. A consultation with the veterinarian alone, is not sufficient.
- 2- The IACUC further determined that any future noncompliance by the Investigator/Investigator's lab with the surgical protocol will result in withholding of/suspension of approval for his Lab to perform surgeries.
- 3- Going forward, in such situations, the IACUC will formally direct an Investigator to cease surgeries immediately until the IACUC has had opportunity to review the situation and determine appropriate resolution.
- 4- The IACUC also reaffirmed that when a health issue occurs in animals, the investigator must contact the Consulting Veterinarian or LAR to conduct the necropsy or other animal health investigation. Neither Investigators nor their lab personnel are to conduct necropsies. A guidance email has been sent to all animal users with this information.

The University at Albany is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact (b) (6)

(b) (6) or me at tkesavadas@albany.edu or (b) (6)

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Thenkurussi "Kesh" Kesavadas, PhD
Vice President for Research and Economic Development
Institutional Official
University at Albany

CC: Ewan McNay, PhD
Douglas Cohn, DVM, Consulting Veterinarian

(b) (6)

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, June 3, 2022 7:56 AM
To: Research Compliance Officer
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: IACUC Report to OLAW - University at Albany

Thank you for sending this report. We will respond shortly.

Best,

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

From: Research Compliance Officer <RCO@albany.edu>
Sent: Thursday, June 2, 2022 3:12 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) Kesavadas, Thenkurussi <tkesavadas@albany.edu>; Douglas Cohn <veterinaire@nycap.rr.com>; McNay, Ewan <emcnay@albany.edu>; Institutional Animal Care and Use Committee <IACUC@albany.edu>
Subject: [EXTERNAL] IACUC Report to OLAW - University at Albany

Dear Director:

PHS Policy, IV.F.3, requires that: "The IACUC, through the Institutional Official (IO), shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:

- a) any serious or continuing noncompliance with this Policy;
- b) any serious deviation from the provisions of the Guide [for the Care and Use of Laboratory Animals] ; or
- c) any suspension of an activity by the IACUC."

In accordance with requirement, the University at Albany Institutional Animal Care and Use (IACUC) through the IO, makes the attached report of a serious deviation from the provisions of the Guide.

The University at Albany is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard.

The details of the report, actions, and corrective plan are contained in the attached document.

Please do not hesitate to let us know if you require any additional information or have any questions.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

