

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

October 21, 2021

Re: Animal Welfare Assurance #A3290-01 (OLAW Case 2F)

Todd R. Evans, Ph.D.
Associate Dean for Research, WCM
Weill Medical College of Cornell University
1300 York Avenue, LC-708
New York, NY 10065

Dear Dr. Evans,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 8, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Weill Medical College of Cornell University. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the Weill Medical College of Cornell University Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: failure to adhere to the IACUC-approved protocol and failure to adhere to veterinary directives. The final report states an investigator was issued a request to euthanize two mice which had exceeded endpoints described in the approved protocol. When the mice were still present after the euthanasia deadline, one mouse was euthanized by the veterinarian. It is stated the second mouse was being treated parenterally by the investigator with a non-sterile drug but was later euthanized. It is understood the drug was described in the protocol for oral use only.

The IACUC sent correspondence to the Principal Investigator (PI) emphasizing the need to respond in a timely manner to euthanasia requests, to not exceed endpoints and to administer drugs only by approved routes as stated in the protocol. In response to the incident, corrective actions included the following:

- The PI addressed these issues with his lab members and submitted an amendment that included additional routes for administration for the drug that was improperly injected.
- The IACUC will also meet with the PI to discuss endpoints for the study that address the need to
 prevent suffering but allow the PI to treat animals that appear sick that may recover with
 intervention.

A second incident involved a dead mouse discovered in a cage as it was being processed in cagewash following decontamination cycle in an autoclave. Per the report, it was not possible to determine whether the animal was deceased prior to autoclaving or to trace the animal back to its originating cage. In response, the employee responsible for changing cages in this specific area received disciplinary action and retraining.

It is noted that the first incident involved a research project supported by PHS funding. Based on its assessment of this explanation, OLAW understands that the Weill Medical College of Cornell University has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy.

Page 2 - Dr. Evans OLAW Case A3290-2F October 21, 2021

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

Sincerely,

Jacquelyn T.

Digitally signed by Jacquelyn T. Tubbs -S Date: 2021.10.21 15:00:17 -04'00'

Tubbs -S

Jacquelyn Tubbs, DVM, DACLAM Animal Welfare Program Specialist

Division of Compliance Oversight

Office of Laboratory Animal Welfare

cc: IACUC Contact



Institutional Animal Care and Use Committee 1300 York Avenue, Box 5 New York, NY 10065

Telephone: 646-962-2981/2 Email: iacucadmin@med.cornell.edu

445 East 69th Street, Olin Hall Rm-423 New York, NY 10065

October 8, 2021

Brent Morse, DVM
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

Re: Assurance # D16-00186

Dear Dr. Morse:

We are writing to report incidents of non-compliance that occurred within the animal care and use program at Weill Cornell Medical College. The incidents were presented to and discussed by the IACUC during the month of September and October. The incident and resolution are as follows:

An investigator was sent a request to euthanize two mice which had exceeded the endpoints described in their approved protocol. When the mice exceeded the euthanasia deadline set by the veterinary staff, one of the mice was euthanized by the veterinarian. The other mouse was being treated parenterally by the investigator with a non-sterile drug required to prevent morbidity associated with the phenotype but was later euthanized. While the drug is described in the approved protocol, it was for oral use. The IACUC sent correspondence to the PI emphasizing the need to respond in a timely manner to euthanasia requests, to not exceed the endpoints, and to administer drugs only by approved routes as described in the protocol. The PI addressed these issues with his lab members and submitted an amendment that included additional routes for administration for the drug that was improperly injected. The IACUC will also meet with the PI to discuss endpoints for the study that address the need to prevent suffering but allow the PI to treat animals that appear sick that may recover with intervention. (National Institute on Alcohol Abuse & Alcoholism 1 R01 AA027327-01A1; National Institute of Allergy & Infectious Diseases 1 R01 AI143295-01A1 & National Heart, Lung, & Blood Institute 2 R01 HL131093-05)

A dead mouse was found in a cage as it was being processed in cagewash
following a decontamination cycle in an autoclave as the cage had originated in
our ABSL-3 facility. It was not possible to identify whether the mouse was dead
prior to autoclaving or to trace the animal back to its originating cage. The
employee responsible for changing cages in this area received disciplinary action
and retraining.

We believe that these issues have been adequately addressed and that the procedures implemented should prevent recurrence. Should you have any questions or concerns, please contact me at (b) (6) or the IACUC Chairman, Dr. Andrew Nicholson, at (b) (6)





Todd R. Evans, Ph.D.
Institutional Official
Associate Dean for Research
Weill Cornell Medicine

Wolff, Axel (NIH/OD) [E]

From:

OLAW Division of Compliance Oversight (NIH/OD)

Sent:

Tuesday, October 12, 2021 4:45 AM

To:

(b)(6)

Cc: Subject: OLAW Division of Compliance Oversight (NIH/OD) RE: WCM IACUC Incident Report (#D16-00186)

Thank you for this report,

(b) (6) We will send a response soon.

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

From:

(b)(6)

Sent: Friday, October 8, 2021 12:51 PM

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

Cc: Andrew C. Nicholson <nicholso@med.cornell.edu>; Todd R. Evans <tre2003@med.cornell.edu>

Subject: WCM IACUC Incident Report (#D16-00186)

Importance: High

Dear OLAW:

Please find a WCM IACUC incident report attached and let me know if any further clarifications are required.

Best regards, (b) (6)

(b) (6)



Weill Cornell Medicine