



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

July 25, 2019

Re: Animal Welfare Assurance  
#A3117-01 [OLAW Case Q]

Dr. Margaret Callahan  
Provost, Health Sciences Division  
Loyola University Chicago Health Sciences  
2160 S. First Ave., Bldg. 120, (b) (4)  
Maywood, IL 60153

Dear Dr. Callahan,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 22, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Loyola University Chicago Health Sciences Division. According to the information provided, OLAW understands that a variety of expired drugs were found in a laboratory and that expired anesthetics, analgesics, and antibiotics were being used in acute studies.

The corrective actions consisted of the Institutional Animal Care and Use Committee (IACUC) directing the laboratory staff to stop activities using the expired drugs and to discard them. An institutional policy was created that prohibits keeping expired agents in animal laboratories. The management responsibility of specific laboratories has been transferred to the Department of Comparative Medicine which will organize the areas and use a room log sheet to track items.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.  
Deputy Director  
Office of Laboratory Animal Welfare

cc: IACUC Chair

A3117-Q



**Health Sciences Division**

Cuneo Center • Health Sciences Campus  
2160 South First Avenue • Maywood, IL 60153  
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July 22, 2019

Axel Wolff, DVM  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Rockledge 1, Suite 360  
6705 Rockledge Drive  
Bethesda, MD 20892

Dear Dr. Wolff,

The Loyola University Chicago Health Science Division (LUC HSD), in accordance with Assurance Number: D16-00074, Legacy #A3117-01 and PHS Policy IV.F.3., provides this report of noncompliance regarding the result of the July 10, 2019 AAALAC International site visit.

The AAALAC International representatives noted that there were expired products in the physiology core lab (Bldg. 115, (b) (4) e.g. cetacaine, ampicillin, iodine solution, buprenorphine diluted with NaCl (diluent expired 2014). These items were identified as "Expired - For Acute Use Only", however anesthetics, analgesics and antibiotics cannot be used once they have expired.

On July 11, 2019, the IACUC informed the Department Chair, Principal Investigators and staff who use the laboratory that the room has been placed under IACUC administrative hold on all activities related to the use of expired agents, chemicals and procedures. Activities could resume once the expired items are disposed of properly, the laboratory is organized and the space is re-inspected and approved by the IACUC.

On July 12, 2019, the IACUC was informed that all expired items were disposed of properly. The IACUC performed an inspection on the laboratory on July 15, 2019 and found that the laboratory has complied with the directives and the IACUC administrative hold was lifted. Placing the laboratory on hold did not affect any activities supported by grants or related to PHS-supported activities.

To further address the situation, additional corrective actions were taken including the creation of a policy that expired items are no longer permitted in laboratories that use laboratory animals and that they must be disposed of properly and in a timely matter. On July 12, 2019, the LUC HSD Provost sent a memo to faculty and staff that the management of (b) (4) (Physiology Surgical Core) and (b) (4) (Imaging Facility) in the CTRE will be the responsibility of the Department of Comparative Medicine. Comparative Medicine will

work with the CCLC to clean and organize the space and incorporate an additional procedure room log sheet to ensure compliance.

LUC HSD 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 Jawed Fareed, PhD, IACUC Chair, via the IACUC Director, Tony Valero, [avalero@luc.edu](mailto:avalero@luc.edu).

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

A large rectangular area of the document is redacted with a solid grey box, obscuring the signature and any text that might have been present below the "Sincerely," line.

Margaret Faut Callahan, CRNA, PhD, FNAP, FAAN  
Interim Provost and Chief Academic Officer  
Senior Vice President, Strategy and Innovation  
Loyola University Chicago

## Morse, Brent (NIH/OD) [E]

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, July 24, 2019 2:57 PM  
**To:** Valero, Antonio; OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** Callahan, Margaret; (b) (6) Fareed, Jawed; (b) (6)  
**Subject:** RE: Reporting Noncompliance

Thank you for this report Dr. Valero. 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:** Valero, Antonio [mailto:avalero@luc.edu]  
**Sent:** Wednesday, July 24, 2019 12:12 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Callahan, Margaret <mcallahan3@luc.edu>; (b) (6)  
Fareed, Jawed <jfareed@luc.edu>; (b) (6)  
(b) (6)  
**Subject:** Reporting Noncompliance

Dear Dr. Wolff,

The Loyola University Chicago Health Science Division (LUC HSD), in accordance with Assurance Number: D16-00074, Legacy #A3117-01 and PHS Policy IV.F.3., provides the attached final report of noncompliance regarding the result of the July 10, 2019 AAALAC International site visit. If you have any questions or concerns, please let us know.

Kind regards,  
Tony V.

Tony Valero, DVM, LATG, CPIA  
IACUC Director  
Office of Research Services, Health Sciences Division  
Loyola University Chicago, Health Sciences Campus  
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