



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

May 26, 2020

Re: Animal Welfare Assurance
A3270-01 [OLAW Case 1L]

Dr. Laurie Locascio
Vice President for Research
University of Maryland – College Park
(b) (4) Lee Building – 7809 Regents Drive
College Park, MD 20742

Dear Dr. Locascio,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 14, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Maryland – College Park. We received the initial report via a phone call on December 9, 2019. According to the information provided, OLAW understands that on November 18, 2019 it was reported that five dairy cattle on a mastitis study had experienced unexpectedly severe degree of infection. Two of the five animals were subsequently euthanized. Samples of the original inoculum and milk samples from the infected cows were sent for analysis. Results suggested contamination of the inoculum during administration. No PHS funds supported this work.

Corrective actions: The impacted cattle were immediately treated under the standard farm mastitis SOP and three subsequently improved. The PI, veterinary staff and laboratory staff conducted a review of procedures and laboratory staff were retrained. The IACUC mandated that the PAM officer and a veterinarian observe any subsequent inoculation procedures, however the study has not continued due to restrictions in research activities associated with the COVID-19 stay-at-home order.

The consideration of this matter by the University of Maryland – College Park was consistent with the philosophy of institutional self-regulation. Similarly, the actions taken to correct and prevent recurrence of the issue were appropriate. OLAW assumes that the remainder of the corrective actions will be implemented if the inoculation procedure is continued. We appreciate being informed of this matter and find no cause for further action by this office at this time.

Sincerely,

Brent C. Morse -S

Digitally signed by Brent C.
Morse -S
Date: 2020.05.26 08:48:16 -04'00'

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

cc: IACUC Contact



DIVISION OF RESEARCH

OFFICE OF THE VICE PRESIDENT FOR RESEARCH

A3270-1L
2133 Lee Building
College Park, Maryland 20742-5125
301.405.4175 TEL

May 14, 2020

Dr. Brent Morse, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892-7982

RE: Animal Welfare Assurance Number: D16-00172 (A3270-01)

Dear Dr. Morse,

The University of Maryland, College Park, has finalized an issue that was previously self-reported to OLAW on December 9, 2019. On November 18, 2019, the Post-approval Monitoring coordinator received notification that five dairy cattle on a mastitis study had experienced unexpectedly severe degree of infection. Two of the five animals were subsequently euthanized. This adverse event was considered by the UMD IACUC at its next regularly scheduled meeting, December 21st, where it was deemed a reportable adverse event, since the experimental outcome fell beyond the range of expected results as described in the protocol. No PHS funds supported this work.

Corrective actions: The impacted cattle were immediately treated under the standard farm mastitis SOP and three subsequently improved. As stated, two animals were unable to recover and were euthanized. The PI, veterinary staff and laboratory staff conducted a review of procedures and sent samples of the original inoculum and as well as milk samples from the infected cows for analysis. Results suggested contamination of the inoculum during administration, and laboratory staff were retrained on procedures. The IACUC mandated that the PAM officer and a veterinarian observe any subsequent inoculation procedures, however the study has not continued due to restrictions in research activities associated with the COVID-19 stay-at-home order.

Sincerely,

(b) (6)

Laurie E. Locascio
Vice President for Research and
Institutional Official

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, May 20, 2020 7:12 AM
To: Pamela Jean Lanford
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: UMD D16-00172

Thank you. We will respond soon.
Axel Wolff

From: Pamela Jean Lanford <planford@umd.edu>
Sent: Monday, May 18, 2020 10:51 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Laurie Ellen Locascio <lel@umd.edu>; (b) (6)
Subject: UMD D16-00172

Dear Dr. Morse,

Please find attached a letter from the University of Maryland, College Park Institutional Official, Dr. Laurie Locascio, finalizing an animal care issue previously self-reported to the Office of Laboratory Animal Welfare on December 9th, 2019.

Please let us know if you have questions or concerns.

Sincerely,

Pam Lanford

Pamela Lanford PhD, MS, CPIA
Director of Animal Research Support & Administrator, IACUC
Past Chair, University Senate
(b) (4) James Clark Hall
8278 Paint Branch Drive
University of Maryland
College Park, MD 20742
t: (b) (6)
pronouns: she/her/hers

Morse, Brent (NIH/OD) [E]

From: Pamela Jean Lanford <planford@umd.edu>
Sent: Wednesday, April 29, 2020 10:10 AM
To: Morse, Brent (NIH/OD) [E]
Subject: Re: Open OLAW cases

Follow Up Flag: Follow up
Flag Status: Flagged

Thank you very much for this email, Dr. Morse. Many apologies for the delays on these letters. We will make sure that they are completed as soon as possible.

Sincerely, Pam Lanford

Pamela Lanford PhD, MS, CPIA
Director of Animal Research Support & Administrator, IACUC
Chair, University Senate
(b) (4) James Clark Hall
8278 Paint Branch Drive
University of Maryland
College Park, MD 20742
t: (b) (6)
pronouns: she/her/hers

On Wed, Apr 29, 2020 at 10:00 AM Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov> wrote:

Hello Dr. Lanford,

I hope you and your family are well. This is just a reminder that OLAW has three open compliance cases from U.MD - College Park. One is recent but two are getting old. Those two are OLAW Case A3270-1K reported to OLAW October 1, 2019 (cold room used as housing area without approval) and case -1L reported on December 9, 2019 (8 cows inoculated and 2 euthanized). OLAW understands that these are challenging times, but if you are able to provide interim or final reports, we can update our files. If not, please respond with a request for an extension for the investigation for these cases. An email is fine. Thank you for your cooperation.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM

Director

Division of Compliance Oversight



Initial Report of Noncompliance

By: (b) (6)

Date: 12/9/19

Time: 10:00

Name of Person reporting: Pam Lanford, PhD
 Telephone #:
 Fax #:
 Email:

Name of Institution: U. MD - Coll. Park
 Assurance number: A3270

Did incident involve PHS funded activity? No

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

8 cows inoculated on Weds.
 Infection was greater than expected. 2
 cows euthanized, others
 on treatment.

Species involved: Cattle

Personnel involved: Researcher

Dates and times: 11/18/19

Animal deaths:

Yes, 2 euthanized

Projected plan and schedule for correction/prevention (if known):

cows cultured. Also source culture sent
 for analysis

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____