



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

April 25, 2019

Re: Animal Welfare Assurance
A3433-01 [OLAW Case 2U]

Dr. Prasat Mohapatra
Vice Chancellor for Research
University of California, Davis
1850 Research Park Drive
Davis, California 95618

Dear Dr. Mohapatra,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 1, 2019 letter reporting an adverse event involving research mice at the University of California- Davis. According to the information provided, OLAW understands that tail necrosis occurred in several mice due to extravasation of a cancer drug.

The immediate action taken upon discovery consisted of contacting the veterinary staff and euthanizing the mice. The protocol was amended to include the possibility of tail necrosis and consultation with the veterinary staff should this occur. The student responsible was retrained, a senior laboratory member will assist, and only lateral tail veins will be used.

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 institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals.

Sincerely,

(b) (6)

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

cc: IACUC Chair

A3433-24

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April 1, 2019

AXEL WOLFF, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare
National Institutes of Health
RKL1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

RE: Institutional Report - D16-00521 # (A3433-01)
Follow-up to adverse effect report for R43 GM 1265599-01A1

Dear Dr. Wolf:

In accordance with Assurance D16-00521 # (A3433-01) and PHS Policy IV.F.3., UC Davis is bringing to your attention an adverse effect and the corrective action that occurred to mitigate future occurrences. This situation was previously reported and discussed with you over the phone with our IACUC Director, Donna Routley.

Extravasation of cancer therapeutics occurred during intended intravascular dosing, resulting in tail necrosis to a subset of affected mice. Campus Veterinary Services (CVS) veterinarians were notified and the animals euthanized. An amendment to the Animal Care and Use protocol was submitted to include tail necrosis as a potential risk of the therapeutic agents should extravasation occur during intravascular dosing, with immediate consultation with CVS should this occur again.

Also as recommended, the student, who was less experienced in tail vein injection, received additional hand-on training for intravenous injections in mice from the IACUC staff training coordinator. Additional recommendations will be followed in future experiments, including the involvement of a senior staff member who is proficient in the technique and only using the lateral tail veins for injections.

Axel Wolff, M.S., D.V.M

April 1, 2019

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If you have any questions, please do not hesitate to contact our IACUC Director at (b) (6) or by email at dmroutley@ucdavis.edu.

Sincerely,

(b) (6)

Prasant Mohapatra
Vice Chancellor for Research

/pk

c: IACUC
AAALAC

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, April 10, 2019 12:17 PM
To: Donna Routley; OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Institutional Reports - D16-00521 # (A3433-01)

Thank you for providing these reports Ms. Routley. We will send official responses 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: Donna Routley [mailto:dmroutley@ucdavis.edu]
Sent: Monday, April 01, 2019 6:28 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Institutional Reports - D16-00521 # (A3433-01)

Hello,

Please find the attached five signed reports from UC Davis, assurance D16-00521 # (A3433-01). These had previously been reported to OLAW. For the instances involving USDA covered species, each incident was self-reported to USDA. These reports have been copied to AAALAC.

Please let me know if you have any questions.

Kind regards,
Donna Routley

Donna Routley, RVT, RLATg, CPIA
Director, IACUC
Office of Research
University of California Davis
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dmroutley@ucdavis.edu