



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 17, 2019

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

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 instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of California Davis, following up on an initial telephone report on January 8, 2019. According to the information provided, OLAW understands that surgery was performed on a nonhuman primate which had lost more than 15% body weight, which was contrary to what had been approved in the protocol. The animal had been carefully monitored by numerous subject matter experts and was determined to be healthy but the conduct of the surgery on an animal with this percentage of weight loss constituted a protocol deviation.

The corrective actions consisted of implementing use of a mathematical algorithm to calculate body weight loss and to send this information to personnel involved. Veterinary staff will be consulted prior to the conduct of any proposed surgeries.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to prevent recurrence of this problem. OLAW concurs with the actions taken by the institution 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
Robert Gibbens, D.V.M., USDA-APHIS-AC

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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 protocol deviation report for R01 MH107333

Dear Dr. Wolf:

In accordance with Assurance D16-00521 # (A3433-01) and PHS Policy IV.F.3., UC Davis is bringing to your attention a protocol deviation and the corrective action taken to mitigate future such occurrences. This situation was previously reported over the phone by our IACUC Director, Donna Routley.

A single animal weight loss exemption was approved by the IACUC, which specified that surgical procedures would only occur when the individual NHP animal's weight loss did not exceed 15%. For one animal, this exemption was not followed and the approved surgery was performed. Although the animal had been monitored closely by the CNPRC SRA's, AHT, researchers, primate medicine, and the veterinarians for weight loss and overall health and appetite, as a group they did not establish a clear decision tree for the one person responsible for evaluating the percentage of weight loss to determine if procedures could be performed. While this represents a protocol deviation, we note that prior to the surgery the animal underwent a physical and had a body condition score of 2.5. From a health perspective the animal was deemed suitable for surgery.

It is UC Davis' expectation that the Principal Investigator is responsible for ensuring procedures described in animal care and use protocols and any approved amendments or exemptions to IACUC policy are adhered to. The IACUC was satisfied with the proposed plan moving forward to use a mathematical algorithm "Project Weight Loss" to calculate and automatically email to stakeholders

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

April 1, 2019

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the percentage of body weight loss for individual project animals. Additionally, moving forward, the veterinary staff will be consulted about 1-2 weeks prior to any surgical procedures that is scheduled to occur under this protocol.

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

Sincerely,

[REDACTED] (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

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

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 # (A343301). 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
(b)(6)(office)
dmroutley@ucdavis.edu



Initial Report of Noncompliance

By: am

Date: 1/8/19

Time: 10:00

Name of Person reporting: Donna Routley

Telephone #: (b)(6)

Fax #:

Email:

Name of Institution: U of California - Davis

Assurance number: A3433

Did incident involve PHS funded activity? Yes

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

Monkey approved for surgery. Had to be a specific weight but was used on surgery before gaining weight.

Species involved: Rhesus

Personnel involved:

Dates and times:

Animal deaths:

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

Retrain staff. Monkey survived surgery but not doing well. Euthanized monkey.

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____