



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
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
Rockledge One, Suite 360
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

March 12, 2019

Re: Animal Welfare Assurance
A3350-01 [OLAW Case V]

Dr. Richard S. Larson
Executive Vice Chancellor
University of New Mexico Health Sciences Center
MSC 4640 1 University of New Mexico
Albuquerque, NM 87131-5126

Dear Dr. Larson,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 13, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of New Mexico, following up on an initial telephone report on February 12, 2019. According to the information provided, OLAW understands that five mice were subjected to a cardiac perfusion although this procedure was not described in the approved protocol. Furthermore, the mice were inadequately anesthetized before the procedure was started.

The corrective actions consisted of amending the protocol to include perfusions, having the Principal Investigator (PI) ensure that laboratory staff is aware of the procedures approved in the protocol, retraining the PI and staff on the appropriate conduct of anesthesia, and placing the laboratory under enhanced post-approval monitoring.

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



Office of Animal Care Compliance

February 13, 2018

Division of Compliance Oversight
Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH)
Rockledge 1, Suite 360, MSC 7982, 6705 Rockledge Drive
Bethesda, MD 20892-7982
Phone: 301-594-2061
FAX: 301-402-2803
E-mail: olawdco@mail.nih.gov

Attn: Dr. Neera Gopee, DVM, PhD, Veterinary Medical Officer

RE: Assurance # D16-00228 (A3350-01) – Failure to ensure adequate anesthesia and performing a procedure that is not listed on an approved protocol (protocol deviation)

As per our telephonic report to Dr. Neera Gopee on February 12, 2019, a graduate student rotating through a Principle Investigator's (PI's) lab observed that a visiting MD from another country, who is currently working towards a PhD degree, performed heart perfusions on five mice. Although the PI laboratory associates thought this procedure was approved, the protocol was only approved for tissue harvest after euthanasia. In addition, the protocol associate failed to ensure an adequate plane of anesthesia before starting the procedure as evidenced by some movement and vocalizations from some of the mice. Upon review with the PI, it was determined that there had been problems with overdosing of mice and subsequently they reduced the initial dose to prevent premature death. Repeated anesthesia doses were administered during the procedure when animals were lightly anesthetized, but unfortunately not before mice were exposed to unnecessary pain or distress.

This incident was discussed in the February 7th, 2019 convened Health Sciences Center (HSC) Institutional Animal Care and Use Committee (IACUC) meeting and a sub-committee of the IACUC (Chair and Vice-Chair), Attending Veterinarian (AV), Animal Resource Facility (ARF) Supervisor, and the Office of Animal Care Compliance (OACC) staff to include the Senior Operations Manager and Compliance Specialist met with the PI on February 8th, 2019 to discuss the incident and action items to remediate the incident. In addition, the same group will meet with the PI and all the lab members on February 22, 2019 to further discuss ongoing remediation process for the incident.



Action items for remediation of the incident:

1. The PI will immediately amend the IACUC protocol to include perfusions as "Non-survival Surgery" in addition to tissue harvest after euthanasia.
2. The PI will ensure that all lab members know which specific procedures are approved in the IACUC protocol.
3. The ARF Supervisor and veterinarian will retrain the PI and all lab personnel on anesthesia methods and dosing.
4. The ARF, IACUC, and/or OACC will complete Post-approval Monitoring (PAM) prior to the lab personnel conduction any additional animal procedures. PAM will continue quarterly for the next calendar year in order to ensure both adherence to the approved IACUC protocol and lab member proficiency with animal procedures.

Sincerely,

DocuSigned by:
(b) (6)
1FEC99E358B14B8...

Richard S. Larson, M.D., Ph.D.
Executive Vice Chancellor
Vice Chancellor for Research

Cc:
Kevin O'Hair, D.V.M., DACLAM, Attending Veterinarian
Laura Gonzalez Bosc, Ph.D., IACUC Chair

(b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, March 1, 2019 1:04 PM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Assurance # D16-00228 (A3350-01) - University of New Mexico Health Sciences Center

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, March 1, 2019 11:31 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Laura V Gonzalez Bosc <LGonzalezBosc@salud.unm.edu>; Kevin C O'Hair <KOHair@salud.unm.edu>; (b) (6)
(b) (6)
Subject: Assurance # D16-00228 (A3350-01) - University of New Mexico Health Sciences Center

Good morning, Dr. Gopee,

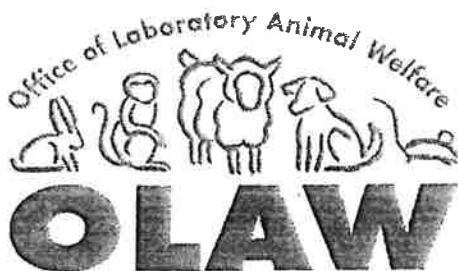
Please see the attached, signed final report as previously discussed.

Thank you!

(b) (6)

*****CONFIDENTIALITY STATEMENT – PLEASE READ*****

This email is an official communication intended for use by the designated recipient(s) only. This email (including any attachments) contains information which is confidential and/or legally privileged under federal/state laws and/or regulations as well as UNM policies. The authorized recipient(s) should keep this communication confidential and not forward it to any person without permission of the Committee in charge of handling this matter. Any use by parties other than the named recipient(s) is unauthorized and prohibited. If you receive this email in error, please call 505-272-0418, notify the sender by email, and delete this email including any attachments.



Initial Report of Noncompliance

By: Nerea GageDate: 2-12-19Time: 3:55 PMName of Person reporting: (b) (6)Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: University of New MexicoAssurance number: A3350-01Did incident involve PHS funded activity? Yes

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

Graduate student observed the procedure. an unapproved person performed it since that were not adequately anesthetized

Species involved: micPersonnel involved: Visiting Scientist

Dates and times:

Animal deaths:

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

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____