



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

July 20, 2020

Re: Animal Welfare Assurance
A3414-01 [OLAW Case V]

Dr. Frank Calzonetti
The University of Toledo
Vice President for Research
3000 Arlington Avenue- CCE 2102
Toledo, OH 43614

Dear Dr. Calzonetti,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 15, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Toledo, following up on an initial telephone report on July 13, 2020. According to the information provided, OLAW understands that nine mice died of post-operative infections after receiving a contaminated diluted analgesic which had been improperly stored. In addition, a student in this laboratory failed to adequately monitor mice post-operatively and then falsified the records. The protocol is supported by grant #5R01HD081792.

The corrective actions consisted of the Institutional Animal Care and Use Committee (IACUC) suspending the protocol, requiring the investigator to develop a laboratory and protocol management plan, and requiring the investigator to hire a laboratory manager to oversee the laboratory. The Office of Research Integrity is involved regarding the records falsification.

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. Please also inform the NIH funding component about the suspension and ensure that the grant is not charged for any unauthorized animal activities. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

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

cc: IACUC Chair
Bryan Clark, NICHD Chief GMO



THE UNIVERSITY OF
TOLEDO

**Office of Research
and Sponsored Programs**

July 15, 2020

Axel Wolff, D.V.M.
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:

In accordance with Assurance A3414-01 and PHS Policy IV.F.3., The University of Toledo (UToledo) provides this report of continuing noncompliance, reported to the IACUC on July 15, 2020.

On June 18, 2020, it was discovered that nine mice died of post-operative infections over a two-month period. It was subsequently discovered these deaths were linked to the use of contaminated, diluted Meloxicam that had been stored by the laboratory at room temperature for an extended period of time.

This same laboratory failed to monitor mice post-operatively on three separate occasions in June and falsified post-operative records. The student involved is working with the Office of Research Integrity on this incident.

Due to the history of non-compliance in the protocol, the IACUC has voted to suspend the protocol effective immediately. The investigator must submit a formal management plan to the IACUC for the protocol and the laboratory. This management must include at least a part-time FTE Lab Manager to manage the laboratory and protocol. I have contacted the College Dean, who has promised to take action. Until this is accomplished, the protocol remains suspended.

NIH funds were used on this project.

UToledo is committed to protecting the welfare of animals used in research. Should you have any questions regarding this report, please contact Kathryn Eisenmann, Ph.D., IACUC Chair (Kathryn.Eisenmann@utoledo.edu).

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Frank J. Calzonetti, Ph.D.

CC: (b) (6)

Kathryn Eisenmann, Ph.D.

Frank J. Calzonetti, Ph.D.

Vice President for Research

The University of Toledo, 2801 W. Bancroft St., MS 218, Toledo, OH 43606

PH: 419-530-4749; Email: Frank.Calzonetti@UToledo.edu

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, July 20, 2020 7:24 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Non-Compliance and Suspension - Assurance A-3414-01

Thank you for this report, (b) (6) I will send a response shortly.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: (b) (6)
Sent: Friday, July 17, 2020 12:29 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Calzonetti, Frank <frank.calzonetti@utoledo.edu>; Eisenmann, Kathryn M. <Kathryn.Eisenmann@utoledo.edu>; (b) (6)
(b) (6) Alsol, Hazel (NIH/NICHD) [E] <hazel.alsol@nih.gov>; Ravindranath, Neelakanta
(NIH/NICHD) [E] <neelakanta.ravindranath@nih.gov>
Subject: RE: Non-Compliance and Suspension - Assurance A-3414-01

To Whom it May Concern:

Attached is a letter describing an incident of serious non-compliance that resulted in protocol suspension. It relates to NIH grant number 5R01HD081792. If you have any questions, please feel free to contact us.

Thank you,
(b) (6)

(b) (6)



Initial Report of Noncompliance

By: (b) (6)

Date: 7/13/20

Time: 3:00

Name of Person reporting: (b) (6)
 Telephone #: (b) (6)
 Fax #:
 Email:

Name of Institution: U of Toledo
 Assurance number: A3414

Did incident involve PHS funded activity? Yes
 Funding component: _____
 Was funding component contacted (if necessary): _____

What happened?

Mice were not monitored post-operatively. The grad student responsible lied to the AV. Student not found on access logs

Species involved: Mouse

Personnel involved:

Dates and times:

Animal deaths: No, no animal problems

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

*Remove facility access unless w/ PI, OR I involved,
 PI needs to hire new student.*

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____