



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
6705 Rockledge Drive – MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

April 19, 2018

Re: Animal Welfare Assurance
#A3348-01 (OLAW Case 1V)

Thomas F. Murray, Ph.D.
Institutional Official and Provost
Creighton University
2500 California Plaza
Omaha, NE 68178

Dear Dr. Murray,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 16, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Creighton University, following up on an initial telephone report on April 2, 2018. According to the information provided, OLAW understands that surgical glue had been used to close an incision site on a microswine, although the approved protocol only listed sutures. No adverse effects occurred due to use of the glue.

The corrective action consisted of the Attending Veterinarian counseling the Principal Investigator to only conduct animal procedures as approved in the protocol and to consult the veterinarian regarding a proposed deviation.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to prevent recurrence of this incident. 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

(b) (6)
Robert Gibbens, D.V.M., USDA-APHIS-AC

Creighton UNIVERSITY

Office of the Provost
Research Compliance

April 16, 2018

Dr. Alex Wolff
Office of Laboratory Animal Welfare
National Institutes of Health
Division of Compliance Oversight
6705 Rockledge Drive
RKL1, Suite 1050, MSC 7982
Bethesda, Maryland 20892-7982

Re: Creighton's Institutional Animal Care and Use Committee (IACUC) Animal Incident Report,
Assurance Number A3348-01/D16-00226

Dear Dr. Wolff:

Creighton University is submitting a finalized report regarding a protocol violation that was initially reported to you via phone on April 2, 2018 by the Research Compliance Auditor.

Background Information/Protocol Violation Issue:

Prior to archiving a study, a review of the medical records was conducted by the Attending Veterinarian. During this review, it was discovered that dermaglue was used to close a surgical wound in one microswine. A review of the approved protocol verified that sutures were the only approved closure method listed in the protocol. Although the deviation resulted in no ill effects to the animal's well-being, the use of dermaglue is considered a failure to adhere to the approved IACUC protocol as written.

Corrective Action Plan Taken:

Considering this was a new investigator with no additional ongoing IACUC studies and that the deviation did not jeopardize the well-being of the animal, no corrective action was implemented:

- Nevertheless, the Attending Veterinarian did inform the PI of this noncompliance and reiterated that all procedures must be completed as detailed in the approved protocol and any deviation requires immediate veterinary approval.

Reporting:

The following agencies/organizations will be contacted regarding this noncompliance:

- Although this is an USDA covered species, the nature of this noncompliance does not meet the requirements set forth by the the United States Department of Agriculture (USDA), and therefore does not require reporting to this organization.

- The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) will be informed of this noncompliance.
- No additional reporting is required as this protocol was not Public Health Service (PHS) funded.

Please feel free to contact Dr. Thomas F. Murray, Provost and Institutional Official, at (b) (6) or Dr. Joseph A. Knezetic, Director of Research Compliance, at (b) (6) if you have any further questions.

Sincerely,

(b) (6)

Thomas F. Murray Ph.D.
Institutional Official and
Provost

(b) (6)

Joseph A. Knezetic, Ph.D.
Director of Research Compliance

CC: IACUC Chair
Animal Resource Facility Director
Research Compliance Office

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, April 19, 2018 1:12 PM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Creighton University Incident Report - Assurance # A3348-01

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

From: (b) (6)@creighton.edu]
Sent: Thursday, April 19, 2018 12:18 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Murray, Thomas F <tfmurray@creighton.edu>; Knezetic, Joseph A <joe@creighton.edu>; (b) (6)
(b) (6)@creighton.edu>; (b) (6)@creighton.edu>
Subject: Creighton University Incident Report - Assurance # A3348-01

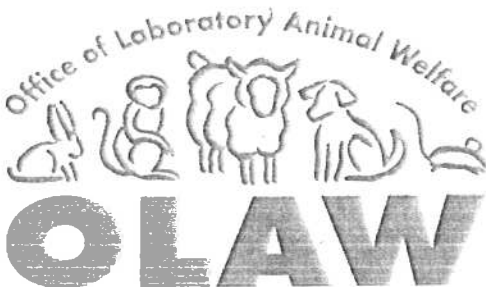
Hello,

Attached please find attached the written report as follow-up to an initial report made via phone on April 2, 2018 regarding a reportable incident.

Best Regards,

(b) (6)





Initial Report of Noncompliance

By: *aw*Date: *4/2/18*Time: *10:10*

Name of Person reporting: [REDACTED] (b) (6)

Telephone #: [REDACTED] (b) (6)

Fax #:

Email:

Name of Institution: *Creighton U*Assurance number: *A3348*Did incident involve PHS funded activity? *NO*

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

*1 pig had surgical site closed with glue when
protocol said suture used*

Species involved: *Microswine*

Personnel involved:

Dates and times:

Animal deaths:

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

Retrain

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____