



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

January 4, 2023

Re: Animal Welfare Assurance
#A3225-01 (OLAW Case 1A)

Dr. Matthew Christian
Associate Vice President for Research
Saint Louis University
3700 West Pine Mall,
Fusz Memorial Hall, (b) (4)
St. Louis, MO 63108

Dear Dr. Christian,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 19, 2022 response to my December 14, 2022 request for additional information regarding an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Saint Louis University. According to the information provided, OLAW understands the following:

- 1) Toe clipping was the method of identification used in mice.
- 2) The age of the mice ranged from three months to over one year.
- 3) The institution prohibits toe clipping as a form of identification in rodents of any age.
- 4) In the case under discussion, no anesthesia/analgesia was used during toe clipping.
- 5) Any mice showing signs of pain were euthanized by the veterinary staff.
- 6) A veterinarian did examine the mice and as noted, three mice that were seen limping were euthanized.
- 7) The amended protocol was approved by the Institutional Animal Care and Use Committee (IACUC).
- 8) Approved methods of rodent identification for this study include cage card, ear tag, and ear punch.
- 9) Copies of the protocol have been posted in the laboratory, approved procedures have been discussed with the laboratory staff, and the laboratory staff was trained in identification methods by the veterinarians. The IACUC is providing updated guidance on animal identification to all animal users.

Based on its assessment of this additional information, 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. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

(b) (6)

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

cc: IACUC Chair



**SAINT LOUIS
UNIVERSITY**

— EST. 1818 —

**ASSOCIATE VICE
PRESIDENT FOR
RESEARCH**

3700 West Pine Mall
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December 19, 2022
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare

National Institutes of Health
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

Institution: Saint Louis University
Animal Assurance Number: D16-00141
AAALACi Accredited July 19, 2021 (Continued Full Accreditation)
Institutional Official: Matthew Christian
OLAW Case A3225-1A

Potential or actual effect on PHS supported activities: This research was supported by PHS funds (Grant number: 1R21AG067441-01).

Dear Dr. Wolff,

This information is being provided in response to the letter on December 14, 2022, requesting more information regarding the facts in this case. Each of those requests are addressed below:

Additional Incident Information:

- 1) Confirm that the identification method referred to in the final report is the same as described in the preliminary report, namely toe clipping.**
 - a. Toe clipping is the method of identification referred to in the final report.
- 2) What age were the mice which had been subjected to toe clipping?**
 - a. The age of the mice ranged from 3 months to over 12 months of age.
- 3) Is toe clipping allowed at the institution and if so, under what circumstances?**

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- a. Toe clipping as a form of identification of rodents at any age is prohibited at Saint Louis University.
- 4) Was anesthesia or analgesia used?**
 - a. No anesthesia or analgesia was used in this procedure.
- 5) Did the mice show signs of pain and if so, were any actions taken?**
 - a. Three animals that showed signs of pain and distress (limping) were euthanized by veterinary staff.
- 6) When veterinary staff was alerted, did they examine the mice and was any medical intervention necessary, such as hemostasis, pain relief, or surgery?**
 - a. The animals were found and evaluated by a veterinarian. Hemostasis was already achieved when the mice were observed.
- 7) Was the amendment to the protocol approved by the Institutional Animal Care and Use Committee?**
 - a. The amendment of the animal use protocol was approved on December 19, 2022.
- 8) What methods of identification are now approved to be used in this study?**
 - a. Cage card, ear tag, and ear punch are approved for use in this study.
- 9) Provide any additional relevant information and the status of the proposed corrective actions.**
 - a. The PI has posted copies of the protocol in the laboratory and discussed the procedures with laboratory staff members. The veterinary staff met with laboratory members on December 15, 2022, and re-trained them in IACUC-approved animal identification methods. The IACUC is updating the guidance to researchers to clarify acceptable methods of identification for animals.

Please let us know if you have any questions or if additional information is required.

Sincerely,

(b) (6)

Matthew Christian
Associate Vice President, Research
Saint Louis University

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McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, December 20, 2022 2:45 PM
To: Matthew Christian
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: OLAW Case A3225-1A

Good afternoon Dr. Christian,

Thank you for sending us this additional information. We will review it and send an official response soon.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

From: Matthew Christian <matthew.christian@slu.edu>
Sent: Tuesday, December 20, 2022 2:41 PM
To: McCoy, Devora (NIH/OD) [E] <devora.mccoy@nih.gov>
Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; John Chrivia <john.chrivia@health.slu.edu>; (b) (6)
Subject: [EXTERNAL] Re: OLAW Case A3225-1A

Good afternoon Ms. McCoy,

Thank you again for your response. I have attached SLU's responses to Dr. Wolff's request for additional information. Please let me know if you need anything additional.

Matthew

Matthew Christian
Deputy Vice President for Research
(b) (6)
SLU Impact Report



From: McCoy, Devora (NIH/OD) [E] <devora.mccoy@nih.gov>

Date: Wednesday, December 14, 2022 at 10:40 AM

To: Matthew Christian <matthew.christian@slu.edu>

Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>, John Chrivia <john.chrivia@health.slu.edu>, (b) (6)

Subject: [External] OLAW Case A3225-1A

Good morning Dr. Christian,

Attached please find Dr. Wolff's response to OLAW Case A3225-1A. Please note that additional information is being requested by January 15, 2023. If you have any questions, feel free to contact us by phone or by e-mail.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

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December 14, 2022

Re: Animal Welfare Assurance
#A3225-01 (OLAW Case 1A)

Dr. Matthew Christian
Associate Vice President for Research
Saint Louis University
3700 West Pine Mall,
Fusz Memorial Hall, (b) (4)
St. Louis, MO 63108

Dear Dr. Christian,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 1, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Saint Louis University, following up on an initial telephone report on November 10, 2022. According to the information provided, OLAW understands that eleven mice were subjected to toe clipping for identification, although this method had not been described in the approved protocol.

The corrective actions consisted of the veterinary staff directing the Principal Investigator to stop using the unapproved procedure, to post copies of the protocol in the laboratory and counsel staff on the content, and to amend the protocol to include all identification methods. The laboratory staff was counseled on only performing procedures as described in the approved protocol and the staff will be trained on any new identification methods approved.

While OLAW concurs with the proposed corrective actions, more information is needed regarding the facts in this case. Please address the following:

- 1) Confirm that the identification method referred to in the final report is the same as described in the preliminary report, namely toe clipping.
- 2) What age were the mice which had been subjected to toe clipping?
- 3) Is toe clipping allowed at the institution and if so, under what circumstances?
- 4) Was anesthesia or analgesia used?
- 5) Did the mice show signs of pain and if so, were any actions taken?
- 6) When veterinary staff was alerted, did they examine the mice and was any medical intervention necessary, such as hemostasis, pain relief, or surgery?
- 7) Was the amendment to the protocol approved by the Institutional Animal Care and Use Committee?
- 8) What methods of identification are now approved to be used in this study?
- 9) Provide any additional relevant information and the status of the proposed corrective actions.

Please provide the requested information by **January 15, 2023**.

Sincerely,

(b) (6)

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

cc: IACUC Chair

McCoy, Devora (NIH/OD) [E]

From: McCoy, Devora (NIH/OD) [E]
Sent: Wednesday, December 14, 2022 11:40 AM
To: mchristian@slu.edu
Cc: OLAW Division of Compliance Oversight (NIH/OD); john.chrivia@health.slu.edu;
(b) (6)
Subject: OLAW Case A3225-1A
Attachments: A3225-1A.pdf

Good morning Dr. Christian,

Attached please find Dr. Wolff's response to OLAW Case A3225-1A. Please note that additional information is being requested by January 15, 2023. If you have any questions, feel free to contact us by phone or by e-mail.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390



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December 1, 2022
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare

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Bethesda, MD 20892-7982
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FAX: 301-402-2803
E-mail: olawdco@mail.nih.gov

Institution: Saint Louis University
Animal Assurance Number: D16-00141
AAALACi Accredited July 19, 2021 (Continued Full Accreditation)
Institutional Official: Matthew Christian
Date of Incident: **Oct 17th, 2022**

Potential or actual effect on PHS supported activities: This research was supported by PHS funds (Grant number: 1R21AG067441-01).

The PHS supported activities were not materially altered by the non-compliance described.

Incident Description:

- **On Oct 17, 2022**, post-approval monitoring alerted veterinary staff that 11 mice had undergone an animal identification method not described in the PI's animal use protocol.
- **On Oct 17, 2022**, the veterinarian emailed the IACUC Chair and Attending Veterinarian to report this incident.

Investigation:

- **On Oct 25, 2022**, the IACUC Chair and PI met to discuss the incident. The PI indicated a new staff member instituted use of an identification method employed in their previous laboratory rather than the method described in the PI's animal use protocols.
- **On November 10, 2022**, the Chairman of the Saint Louis University IACUC contacted OLAW by phone to make an initial report of the incident.
- **On Nov 18, 2022**, this incident of noncompliance was discussed at

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the regularly scheduled IACUC meeting. Short term and long-term corrective actions were approved by the IACUC.

- **On Nov 28, 2022**, the IACUC chairman sent the PI a letter detailing the IACUC's conclusion that the incident was noncompliant with activities described in the PI's animal use protocol. The letter also described the corrective action plan approved by the IACUC to ensure future compliance by the PI.
- **On Nov 29, 2022**, in a return letter the PI agreed to work with the IACUC and complete the outlined corrective action plan.

Corrective Actions taken by the Institution to address the situation:

Short term:

- **On Oct 17, 2022**, veterinary staff directed PI to cease performing the animal identification method not described in the associated animal protocols.
- The PI was directed to post all animal use protocols and discuss details of protocol procedures with laboratory members.
- The PI was directed to amend the protocols to include all methods of animal identification that will be used.

Long Term:

- The PI and veterinary staff will also meet with laboratory members to reinforce the importance of following the methods described in the animal use protocols. The veterinary staff will include a discussion of methods of animal identification described in the PI's animal use protocols and provide additional training in these methods to all staff members. The meeting must be completed by **Jan 30, 2023**

Submitted by:

(b) (6)

Matthew Christian
Associate Vice President, Research
Saint Louis University

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McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, December 9, 2022 11:28 AM
To: Matthew Christian
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Incident report for Saint Louis University (D16-00141)

Good morning Matthew,

Thank you for sending us this report and we will send an official response soon.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

From: Matthew Christian <matthew.christian@slu.edu>
Sent: Friday, December 9, 2022 10:15 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: [EXTERNAL] Incident report for Saint Louis University (D16-00141)

Please see the attached incident report

Matthew

Matthew Christian
Deputy Vice President for Research
(b) (6)
SLU Impact Report



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A3225-1A



Initial Report of Noncompliance

By: (b) (6)

Date: 11/10/22

Time: 11:30

Name of Person reporting: John Chervia IACUC chair
Telephone #: (b) (6)
Fax #:
Email:

Name of Institution: St. Louis U
Assurance number: A3225 D16-00141

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

What happened?
Work conducted w/ out IACUC approval: Tcc clipping for ID

Species involved:
Personnel involved:
Dates and times:
Animal deaths:

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

Projected submission to OLAW of final report from Institutional Official:

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Case #