

From: OLAW Division of Compliance Oversight (NIH/OD) olawdco@od.nih.gov
Subject: RE: Preliminary report of Non-compliance - Northern Arizona University A3908-01
Date: September 23, 2019 at 10:34 AM
To: David Michael Faguy David.Faguy@nau.edu



Thank you for this preliminary report Dr. Faguy. We will open a case file and wait on your final report.

Best regards,

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

*National Institutes of Health
6700B Rockledge Dr., Suite 2500
Bethesda, MD 20892*

[REDACTED]

[REDACTED]

From: David Michael Faguy <David.Faguy@nau.edu>
Sent: Monday, September 23, 2019 11:06 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Tad Theimer <Tad.Theimer@nau.edu>
Subject: Preliminary report of Non-compliance - Northern Arizona University A3908-01

Please find enclosed a preliminary report of non-compliance at Northern Arizona University. Please let us know if we can provide any further information before the final report.

Best regards,
David

David M. Faguy, Ph.D.
Assistant Vice President
Office of Research Compliance
(928) 523-6117
Peterson Hall, Rm 221
PO Box 4137, Flagstaff, AZ 86011



Office of Research Compliance

Rm 221 Peterson Hall,
805 S. Beaver St., PO Box 4137, Flagstaff, AZ 86011-4137
Ph: 928-523-6117
Fax: 928-523-1607

September 19, 2019

Brent Morse, DVM
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. Morse,

Northern Arizona University (Assurance A3908-01), in accordance with PHS Policy IV.F.3., provides this report of noncompliance regarding an incident in which procedures were performed that were not approved under Protocol 17-012 entitled "Coccidioides Exposure and Development of B Cell Chronic Lymphocytic Leukemia (B-CLL) in Eu-TCL-1 transgene-bearing mice". This protocol is not funded by federal sources.

On 30 August 2019, the NAU IACUC received an anonymous report that an investigator had:

- 1) removed tail tips from mice to collect blood while the animals were not anesthetized, and
- 2) placed mice in a glass water bottle containing bedding and then placed the water bottle in an incubator to "warm up" prior to blood collection. None of these procedures had been approved under the protocol and the investigator had been told previously by the institutional veterinarian that whole-body warming was stressful for animals and should be replaced with warming the tail in water.

On 31 August, the chair of the IACUC phoned the PI on the protocol and requested that all blood collection activities under this protocol be suspended until the PI and the investigator could meet with the IACUC. On 6 September, a subcommittee of the NAU IACUC met with both the PI and the investigator and ascertained that the investigator had carried out both of the alleged activities, having self-reported the whole-body warming in an e-mail to the institutional veterinarian and admitting to the tail tip removal of one mouse during the meeting. The subcommittee requested that the PI develop a plan to ensure future noncompliance would not occur and to submit that for review at the next full meeting of the NAU IACUC. On September 16, the NAU IACUC reviewed the plan submitted and made modifications, to which the PI and investigator agreed on 17 September. The plan of action is as follows:


The PI will

- 1) Submit a protocol modification detailing specific procedures to be used for collection of blood.
- 2) Require additional training of the investigator and that the investigator will be accompanied by the PI during blood collection and any other invasive procedures approved under the protocol.
- 3) Remove the investigator from the protocol if another violation is observed.
- 4) Reiterate to all personnel that any changes to protocols must be cleared by the attending veterinarian and approved by the NAU IACUC, even if these protocols are acceptable for use and approved under other protocols.

The IACUC will review the progress on this plan and may recommend further actions at the regularly scheduled meeting on Monday Oct. 7, 2019. We expect to submit a final report after that review. Northern Arizona University is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact Tad Theimer, PhD, IACUC Chair or David Faguy, PhD, Institutional Official.

Thank you for your consideration of this matter.

Sincerely,



David Faguy, Ph.D., Institutional Official
Assistant Vice President for Research Compliance

David.Faguy@nau.edu

cc: Tad Theimer, IACUC Chair

From: OLAW Division of Compliance Oversight (NIH/OD) olawdco@od.nih.gov

Subject: RE: Final report of Non-compliance - Northern Arizona University A3908-01

Date: November 6, 2019 at 8:54 AM

To: David Michael Faguy David.Faguy@nau.edu, OLAW Division of Compliance Oversight (NIH/OD) olawdco@od.nih.gov



Thank you for providing this report Dr. Faguy. We will send an official response soon.

Best regards, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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: David Michael Faguy [<mailto:David.Faguy@nau.edu>]

Sent: Tuesday, November 05, 2019 5:44 PM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Subject: Final report of Non-compliance - Northern Arizona University A3908-01

Please find enclosed the final report of non-compliance at Northern Arizona University. Please let us know if we can provide any further information.

Best regards,
David

David M. Faguy, Ph.D.
Assistant Vice President
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Office of Research Compliance

November 5, 2019

Brent Morse, DVM
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. Morse,


Northern Arizona University (Assurance A3908-01), in accordance with PHS Policy IV.F.3., provides this final report of noncompliance regarding an incident in which procedures were performed that were not approved under Protocol 17-012 entitled "Coccidioides Exposure and Development of B Cell Chronic Lymphocytic Leukemia (B-CLL) in Eu-TCL-1 transgene-bearing mice". This protocol is not funded by federal sources.

On 30 August 2019, the NAU IACUC received an anonymous report that an investigator had:
1) removed tail tips from mice to collect blood while the animals were not anesthetized, and
2) placed mice in a glass water bottle containing bedding and then placed the water bottle in an incubator to "warm up" prior to blood collection. None of these procedures had been approved under the protocol and the investigator had been told previously by the institutional veterinarian that whole-body warming was stressful for animals and should be replaced with warming the tail in water.

The IACUC has reviewed the progress on the previously disclosed plan, which included additional training and oversight, and has found no further non-compliance. The animal care staff, Attending Veterinarian, and IACUC will continue to monitor to ensure compliance with approved protocols. Northern Arizona University is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact Tad Theimer, PhD, IACUC Chair or David Faguy, PhD, Institutional Official.

Thank you for your consideration of this matter.


Sincerely,



David Faguy, Ph.D., Institutional Official
Assistant Vice President for Research Compliance

David.Faguy@nau.edu

cc: Tad Theimer, IACUC Chair

From: [REDACTED] 
Subject: OLAW Case A3908-J
Date: November 7, 2019 at 9:19 AM
To: David Michael Faguy David.Faguy@nau.edu
Cc: nathan.nieto@nau.edu

JW

Dear Dr. Faguy,

Attached please find [REDACTED] final response to OLAW Case A3908-J.

If you have any questions, feel free to contact us by phone or by e-mail.

Best Regards,

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

National Institutes of Health
6700B Rockledge Dr., Suite 2500
Bethesda, MD 20892

[REDACTED]

[REDACTED]



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>

November 7, 2019

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 492-7065

Re: Animal Welfare Assurance
#A3908-01 (OLAW Case J)

Dr. David Faguy
Assistant Vice President for Research Compliance
Northern Arizona University
P.O. Box 4137
Flagstaff, AZ 86011-4137

Dear Dr. Faguy,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 5, 2019 letter reporting an incident of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Northern Arizona University. Your final letter supplements the information in your initial report emailed to our office on September 23, 2019. According to the information provided, OLAW understands that on August 30, 2019 your IACUC received an anonymous report that an investigator had removed tail tips from mice to collect blood while the animals were not anesthetized. Mice were also placed within a glass water bottle containing bedding then the water bottle was placed in an incubator to "warm up" prior to blood collection. The investigator had been previously told by the veterinarian that this is stressful for the animals and to just warm the tails in water. It is understood that the animal activities were not funded by the PHS.

Corrective and preventive actions included counseling the PI and the investigator and them agreeing to a plan of action, including the IACUC requiring: the PI to submit a protocol amendment detailing procedures to be used for collection of blood; additional training of the investigator and that the investigator will be accompanied by the PI during blood collection or any other invasive procedures approved under the protocol; removal of the investigator from the protocol if another violation is observed,

and; reiterate to all personnel that any changes to protocols must be cleared by the attending veterinarian and approved by the IACUC, even if these procedures are acceptable for use and approved under other protocols.

OLAW believes that the corrective and preventative measures put in place by Northern Arizona University are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals. Although this activity was not PHS funded, the application of the standards of the PHS Policy across the animal care and use program reduces any potential appearance of a double standard. We appreciate being informed of this issue and find no cause for further action by this office.

Sincerely,

A handwritten signature in black ink, appearing to be "Jor".

Office of Laboratory Animal Welfare

cc: IACUC contact