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

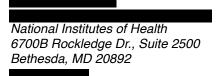
Subject: RE: Preliminary report of Non-compliance - Northern Arizona University A3908-01

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,



From: David Michael Faguy <<u>David.Faguy@nau.edu</u>>
Sent: Monday, September 23, 2019 11:06 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <<u>olawdco@od.nih.gov</u>>
Cc: Tad Theimer <<u>Tad.Theimer@nau.edu</u>>
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,



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) <<u>olawdco@od.nih.gov</u>>
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 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

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:

0

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

Dear Dr. Faguy,

Attached please find **Manual Final** 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,

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

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

FOR EXPRESS MAIL Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500

Bethesda, Maryland 20817

Telephone: (301) 496-7163 Eagsimile: (301) 402-7065

FOR US POSTAL SERVICE DELIVERY: Office of Laboratory Animal Welfaro 6700B Rockledge Drive, Suite 2300, MSC 6910 Bothesda, Maryland 20892-6910 Home Page: http://grants.nlh.gov/grants/olaw/olaw.htm

November 7, 2019

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

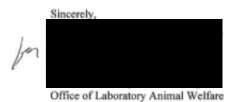
Dear Dr. Faguy,

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.



cc: IACUC contact