



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) 402-7065

June 5, 2020

Re: Animal Welfare Assurance
A3248-01 [OLAW Case 1Q]

Dr. Elizabeth R. Cantwell
Senior Vice President for Research and Innovation
University of Arizona
Administration 601
P.O. Box 210066
Tucson, AZ 85721-0066

Dear Dr. Cantwell,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 17, 2020 response to OLAW's November 26, 2019 request for information regarding an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at The University of Arizona.

According to the information provided, OLAW understands that procedures have been implemented by Facilities Management to prevent recurrence of previous HVAC concerns via use of a Building Automation System monitor with alarms reported to on-call Facilities Management personnel and Facilities Project Manager. In the case of planned shutdowns, personnel are on site to monitor the animal facility HVAC function and address abnormalities as needed to maintain animal welfare standards. Furthermore, a request to recommission via replacement or rebuilding of the failed air-handler was addressed from the Institutional Official to the Vice President for Facilities Management.

OLAW appreciates the prompt consideration of this matter by The University of Arizona which is consistent with the philosophy of institutional self-regulation. OLAW is satisfied that appropriate steps have been taken to investigate this incident and to attempt to prevent recurrence. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Nicole L.
Lukovsky-
akhsanov -S

Digitally signed by
Nicole L. Lukovsky-
akhsanov -S
Date: 2020.06.05
13:35:47 -04'00'

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



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November 26, 2019

Re: Animal Welfare Assurance
A3248-01 [OLAW Case 1Q]

Dr. Elizabeth R. Cantwell
Senior Vice President for Research and Innovation
University of Arizona
Administration 601
P.O. Box 210066
Tucson, AZ 85721-0066

Dear Dr. Cantwell,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 6, 2019 letter responding to OLAW concerns regarding an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at The University of Arizona.

According to the information provided, OLAW understands that the following procedures have been implemented by Facilities Management regarding previous HVAC concerns: a system evaluation and identification of fault sensors will be performed and replaced prior to the next shutdown or if not replaced those points will be monitored via Building Automation System (BAS) and physically in person, continued installation of upgraded components and more alarm points, and have a technician on site to evaluate system performance via the BAS and physically to perform checks of equipment and rooms.

OLAW appreciates the prompt consideration of this matter by The University of Arizona which is consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW requests information regarding the progress of the planned upgrades to the HVAC system to be sent via email along with the Annual Report to the OLAW Division of Assurances (OLAWDOA@mail.nih.gov) to the attention of Dr. Nicole Lukovsky-Akhsanov by **January 31, 2020** and be sure to include **Case A-3248-1Q** on the correspondence. Please ensure to address how future planned and unplanned HVAC shutdown outcomes will be monitored overnight in rooms where animals are housed to prevent recurrence of animal welfare concerns. We appreciate being informed of this matter and please contact us with any further questions or concerns.

Sincerely,

(b) (6)

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



THE UNIVERSITY OF ARIZONA
**Research, Discovery
& Innovation**

Administration 601
PO Box 210066
Tucson, AZ 85721-0066
Ofc: 520-621-3513
Fax: 520-621-7507
Research.Arizona.edu

November 6, 2019

Re: Animal Welfare Assurance A3248-01 [OLAW Case 1Q]

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892

Dear Dr. Lukovsky-Akhsanov,

In response to the request for additional information sent October 21, 2019:

- *Were any of the animals impacted on an NIH funded study?*
 - All 41 mice were on NIH funded projects:
 - R01 GM082978 – 3 mice
 - R01 ES020867 – 16 mice
 - R01 CA092596 – 22 mice
 - 5 of the rats were on an NIH funded project:
 - DP3 DK106933 – 5 rats
 - The remaining rats and all zebrafish were not on NIH-funded projects.
- *Has a procedure been implemented by Facilities Management to ensure that all HVAC settings have been reviewed after planned and unplanned outages?*
 - From a meeting with Facilities Management and UAC representatives, the following actions and procedures will be implemented for all future shutdowns involving animal care HVAC:
 - Do a systems evaluation and identify faulty sensors (hardware) that would affect system performance. Replace if there is time prior to the shutdown, and if not monitor those points on the Building Automation System (BAS) and physically in person.
 - Continue to install upgraded components and provide more alarm points to better evaluate system performance.
 - Have a technician on site to not only evaluate system settings and performance via the BAS, but to also physically do checks of equipment and rooms.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Elizabeth R. Cantwell, Ph.D.
Senior Vice President, Research and Innovation
Institutional Official
The University of Arizona

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, November 06, 2019 1:14 PM
To: ORCR iacuc; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Cantwell, Elizabeth R - (ecantwell); Limesand, Sean W - (limesand)
Subject: RE: OLAW Case A3248-1Q

Thank you for providing this additional information. Doctor Lukovsky-Akhsanov will respond officially soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
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: ORCR iacuc [mailto:ORCR-IACUC@email.arizona.edu]
Sent: Wednesday, November 06, 2019 12:50 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: ORCR iacuc <ORCR-IACUC@email.arizona.edu>; Cantwell, Elizabeth R - (ecantwell) <ecantwell@email.arizona.edu>; Limesand, Sean W - (limesand) <limesand@ag.arizona.edu>
Subject: RE: OLAW Case A3248-1Q

Hello Dr. Lukovsky-Akhsanov,

Please find attached our response to the request for additional information for case A3248-1Q, which I am sending on behalf of our Institutional Official, Dr. Elizabeth Cantwell.

Please let me know if I can provide any additional information.

Thank you,

(b) (6)

(b) (6)





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October 21, 2019

Re: Animal Welfare Assurance
A3248-01 [OLAW Case 1Q]

Dr. Kimberly Ogden
Interim Vice President for Research
University of Arizona Health Sciences Center
P.O. Box 210066
Tucson, AZ 85721-0066

Dear Dr. Ogden,


The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 9th, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at The University of Arizona. Your letter supplements the information provided in a preliminary telephone report made on July 19th, 2019. According to the information provided, OLAW understands that on July 13th, 2019, an HVAC failure impacted several animal housing rooms leading to the death of 1 zebrafish, 41 mice and 39 rats due to high temperatures. An investigation revealed that during a planned outage, a temporary change to a sensor was not reversed, leading to an air handler that re-opened as expected after the planned shutdown but had malfunctioned and closed overnight as the sensors were not reading correctly. The air handler was returned to normal function on the morning of July 13th, 2019 and another planned outage on July 18th, 2019 had no concerns as the air handlers functioned properly.

The IACUC reviewed the incident and determined that there were no corrective actions required.

OLAW appreciates the prompt consideration of this matter by The University of Arizona which is consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is requesting additional information regarding the noncompliance to be submitted by November 8th, 2019. Were any of the animals impacted on an NIH funded study? Has a procedure been implemented by Facilities Management to ensure that all HVAC settings have been reviewed after planned and unplanned outages?

We appreciate being informed of this matter and please contact us with any further questions or concerns.

Sincerely,

 (b) (6)
Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



October 9, 2019

Axel Wolff, MS, DVM
Deputy Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892

Dear Dr. Wolff,

The University of Arizona, in accordance with Assurance D16-00159 (A3248-01) and PHS Policy IV.F.3., provides this report of an HVAC failure which had a negative effect on the health and wellbeing of animals. This incident was first reported to OLAW, on 07/15/2019 via a telephone call by Dr. Cynthia Doane, Veterinarian and Associate Director of University Animal Care.

On 07/13/2019 the IACUC Program was informed by Dr. Doane that, following a planned mechanical/electrical shut down the previous evening, there was a major HVAC failure impacting several animal housing rooms in a UAC vivarium. All animals were evaluated by UAC vet staff on the morning of 7/13/19 and treated if possible. Ultimately 1 zebrafish, 41 mice, and 39 rats died as a result of high temperatures in the animal rooms.

Facilities Management's investigation into the failure determined that the chilled water valve feeding the affected air handler did re-open following the planned shutdown, but then malfunctioned and closed later in the evening. The work proceeded as planned, temporary generators were connected, and the system was brought back online with no issues. However, a temporary change to sensor software made during the connection of the temporary generator to prevent false activation was not reversed, so sensors were not reading correctly, causing several rooms to overheat. The air handler returned to proper function by the morning of 07/13/2019. Another planned shutdown occurred on 07/18/2019, and in that case the air handler came back online and functioned properly.

The IACUC discussed the incident on 09/09/2019 and determined that this was an isolated incident and not a programmatic failure.

The University of Arizona 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 case, please contact (b) (6) or ORCR-IACUC@email.arizona.edu.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Kim Ogden, PhD
Interim Vice President for Research
Institutional Official
The University of Arizona

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, October 15, 2019 8:53 AM
To: ORCR iacuc
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: University of Arizona - Notice of Adverse Event

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

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

From: ORCR iacuc <ORCR-IACUC@email.arizona.edu>
Sent: Friday, October 11, 2019 11:30 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: ORCR iacuc <ORCR-IACUC@email.arizona.edu>; Ogden, Kimberly L - (ogden) <ogden@email.arizona.edu>; Limesand, Sean W - (limesand) <limesand@ag.arizona.edu>
Subject: University of Arizona - Notice of Adverse Event

Hello Dr. Wolff,

On behalf of our Institutional Official Dr. Kim Ogden, I am forwarding this Final Report of an Adverse Event.

Thank you,

(b) (6)

(b) (6)



Initial Report of Noncompliance

By: (b) (6)

Date: 7/19/19

Time: Voicemail from 7/13/19
Acting A/V

Name of Person reporting: C.J. Doane
Telephone #: (b) (6)
Fax #: (b) (6)
Email: (b) (6)

Name of Institution: Univ. of Arizona
Assurance number: A3248

Did incident involve PHS funded activity? ?

Funding component: _____

Was funding component contacted (if necessary): _____

What happened? Overnight HVAC failure. 2 rooms reached ~97°F.

Species involved: Mice/Rats

Personnel involved: _____

Dates and times: 7/12 - 7/13/19

Animal deaths: Yes ~40 mice + ~40 rats

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

Projected submission to OLAW of final report from Institutional Official: _____

OFFICE USE ONLY

Case # _____