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

June 14, 2017

Re: Animal Welfare Assurance
A3056-01 [OLAW Case 1H]

Ms. Beth Taraban
Assistant Vice President for Research
Office of Research
Texas Tech University Health Sciences Center
3601 4th Street, Room #
Lubbock, TX 79430-6252

Dear Ms. Taraban,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 13, 2017 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at Texas Tech University Health Sciences Center, following up on an initial report on May 30, 2017. According to the information provided, OLAW understands that five mice died due to lack of food and dehydration. The cage was placed low on the rack and was difficult to visualize.

The corrective actions consisted of the Institutional Veterinarian reviewing husbandry procedures and modifying standard operating procedures (SOP) as necessary, having the clinical veterinarian notify the Institutional Veterinarian of any animal health concerns immediately, adding an additional husbandry employee, providing supervisory training for the Facility Manager, disciplining staff as needed, and informing the Institutional Animal Care and Use Committee about any SOP changes.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy on Humane Care and Use of Laboratory Animals.

Sincerely,

Axel Wolff, M.S., D.V.M.
Director
Division of Compliance Oversight

cc: IACUC Chair

TEXAS TECH UNIVERSITY
HEALTH SCIENCES CENTER.
Office of Research

June 13, 2017

Axel V. Wolff, M.S., D.V.M.
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
RKL1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Dear Dr. Wolff:

Subsequent to your correspondences with Dr. Samuel Prien, TTUHSC IACUC Chair for both the TTUHSC Lubbock and El Paso IACUCs, who initially reported the incident below, I am writing to you to provide the official report of the animal incident from our animal facility at Abilene first reported to your office 5/24/2017. This letter is in accordance with our Assurance # A3056-01.

The Violation Subcommittee met on 5/25/17. Individuals present at start of meeting included the subcommittee chair, one scientific member, one community member the, institutional veterinarian, and two non-voting members of IACUC and Research Integrity Office.

Review of Incident:

On Thursday May 25th our IVet reported that five animals had died in a cage (four dead and a fifth died later) that was lacking food at our LARC facility in Abilene. Because the incident involved LARC facilities and LARC personnel, the IACUC Chair assumed the lead on the investigation. The IVet provided the following statement to the Chair about the incident and his findings based on photos supplied at necropsy.

> "On 25 May I was made aware of a problem at the LARC facility in Abilene. On 24 May the contract Vet Dr. ***** identified a cage with 4 dead mice and 1 live mouse. Water was present but the food hopper was empty. The live mouse was transferred to a new cage with water and food but was found dead the next morning. A necropsy was performed where significant autolysis precluded accurate diagnosis. What can be noted from the necropsy is there is very dry stool with a potential strand of mucous/fiber/nestlet present externally and that there is fat around the kidneys and in the subcutis. While the absence of food in the hopper suggests they may have died from lack of food, the peri-renal fat does not support this. The extremely dry fecal output suggest dehydration was the cause of death.
> The animals were from ********* breeding protocol ******. To my knowledge this specific strain is a Human P53 knock-in that has no lethal phenotype or other problems that could explain the deaths.

In the absence of more definitive necropsy findings my opinion is these animals died from dehydration. The empty food hopper adds to my concern as this is a definite failure on my staff's part."

Given animals had died, The IACUC Chair felt the incident needed full subcommittee review and the meeting was set for 5/30/17.

Full Subcommittee Discussion:

With all in the room, the subcommittee had the IVet review the above. He also added that the facility was down a technician, but still assured the subcommittee this incident should not have happened and that he ultimately assumes responsibility. The subcommittee then heard from the two LARC staff at the Abilene facility. Both started by sincerely apologizing for the incident but were uncertain as to how it happened. When questioned on the location of the cage involved it was determined that the cage was low in the rack and that the rack was full of cages obscuring easy view of the food. When questioned about the last cage changes (i.e. last time food would have routinely been placed), the cage change had occurred the previous Monday meaning the animals were approximately 2 days without food. At that point the subcommittee dismissed LARC Staff. The discussion then continued with IVet, who informed the committee of recent changes in staffing (naming of new supervisor, who had not held these type of responsibilities in the past and the need for training). He stated he would provide the subcommittee with a list (see below).

At that point all non-voting subcommittee members were excused.

Voting Member Discussion, Observations and Recommendations

Voting members decided no further discussion was necessary and made the following observations and recommendations:

Observations:

1) The subcommittee concurs the incident did happen and corrective action was needed.

2) The subcommittee deferred the type of corrective training to the IVet for full committee review before recommending to IO.

Recommendations to Full Committee:

1) That the IACUC require the IVet to develop a corrective action plan, to be approved by the IACUC, to train or retrain Abilene LARC staff in their newly assigned roles (Plan provided -- see below).
2) That the IVet continue with plans to return the Abilene staff to full strength.

IVet Corrective action:

- I will send some of my more experienced folks to do a complete review of procedures in the Abilene with a report to me.

    - Following that I will modify SOPs as needed with regard to procedures, reporting, and oversight.
- I will speak to the contract Veterinarian to ensure she will immediately notify me of any and all health concerns.
- I will ensure we hire another staff member in the very near future to bring staffing up to the minimum of 3 people.
- I will ensure there is supervisor training for the supervisor who has just recently been promoted to Facility Manager.
- I will be holding all pertinent LARC staff accountable via official written disciplinary action.
- I will consider any recommendation by the IACUC to prevent a repeat occurrence.
- I will report to the IACUC the changes made to SOPs and any other actions taken once they are in place.
- I am considering compensating the Investigator in some way (to be determined).

After presentation and discussion, the full Lubbock IACUC approved the plan of action as written and sent its recommendations to my office (6/9/2017). As the Institutional Official of TTUHSC, I have reviewed this report and have instructed that the IACUC recommendations be implemented as reported here. We hope all of these actions meet with your approval and expect that they will prevent this type of incident from occurring in the future.

Sincerely,

Beth Taraban, MA

Beth Taraban M.A.
Assistant Vice President for Research
Institutional Official

xc: Dr. Samuel Prien, IACUC Chair
Dr. Scott Trasti Institutional Veterinarian
Executive Director, AAALAC

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, June 14, 2017 7:43 AM
To: 'Prien, Samuel'
Subject: RE: IO Report animal Incident Reported 5/30/2017

Thank you for this report, Dr. Prien. I will send a response soon.

Axel Wolff

From: Prien, Samuel [mailto:Samuel.Prien@ttuhsc.edu]
Sent: Tuesday, June 13, 2017 11:56 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Taraban, Beth <beth.taraban@ttuhsc.edu>; Trasti, Scott <scott.trasti@ttuhsc.edu>; condary Individ condary Individ@ttuhsc.edu>; Secondary Individual @ttuhsc.edu>; Secondary Individual @ttuhsc.edu>
Subject: IO Report animal Incident Reported 5/30/2017

Attached please find the IO final report for the animal incident first reported to Dr. Wolff 5/30/17. Please let us know if any further action is needed.

A3056-14

Wolff, Axel (NIH/OD) [E]

From: Prien, Samuel <Samuel.Prien@ttuhsc.edu>
Sent: Tuesday, May 30, 2017 3:05 PM
To: Wolff, Axel (NIH/OD) [E]
Subject: RE: animal incident

We will report

sp

"No one (or program) can bestow the title mentor on themselves. It is a special honor bestowed on us by others. A title, once given, we should strive daily to deserve."

From: Wolff, Axel (NIH/OD) [E] [WolffA@OD.NIH.GOV]
Sent: Tuesday, May 30, 2017 11:18 AM
To: Prien, Samuel
Subject: RE: animal incident

Hello Dr. Prien,
Thank you for this report. This is a reportable incident, however, because it is DOD funded, you have the option of not reporting to OLAW. If you wish to report this, I will use your description as the preliminary. Let me know how you would like to proceed.

Axel Wolff

From: Prien, Samuel [mailto:Samuel.Prien@ttuhsc.edu]
Sent: Tuesday, May 30, 2017 11:59 AM
To: Wolff, Axel (NIH/OD) [E] <WolffA@OD.NIH.GOV>
Cc: Secondary Individual @ttuhsc.edu>; Secondary Individual @ttuhsc.edu>; Taraban, Beth <beth.taraban@ttuhsc.edu>; Trasti, Scott <scott.trasti@ttuhsc.edu>
Subject: animal incident

Dr. Wolff,
I need to report an animal incident that involved the death of 5 animals on a DOD funded protocol. On Thursday May 25th our IVet reported that five animals had died in a cage (four dead and a fifth died later) that was lacking food at our LARC facility in Abilene. Because the incident involved LARC facilities and LARC personnel, I have assumed the lead on the investigation. The IVet has provided a statement about the incident and his findings based on photos supplied at necropsy.
"On 25 May I was made aware of a problem at the LARC facility in Abilene.
On 24 May the contract Vet Dr. ***** identified a cage with 4 dead mice and 1 live mouse. Water was present but the food hopper was empty. The live mouse was transferred to a new cage with water and food but was found dead the next morning. A necropsy was performed where significant autolysis precluded accurate diagnosis. What can be noted from the necropsy is there is very dry stool with a potential strand of mucous/fiber/nestlet present externally and that there is fat around the kidneys and in the subcutis. While the absence of food in the hopper suggests they may have died from lack of food, the peri-renal fat does not support this. The extremely dry fecal output suggest dehydration was the cause of death.

The animals were from ********* breeding protocol ******. To my knowledge this specific strain is a Human P53 knock-in that has no lethal phenotype or other problems that could explain the deaths.
In the absence of more definitive necropsy findings my opinion is these animals died from dehydration. The empty food hopper adds to my concern as this is a definite failure on my staff's part."
This morning I have conducted interviews with all facility staff via video link. Because of a scheduling mistake, we had also had all members of the violation subcommittee present so we combined the subcommittee meeting with the inquiry. We had the staff walk us through what was found and had the IVet, who is based in Lubbock, take us through his proposed plan of corrective action. While I will save the subcommittee report until we have the formal plan from our IVet for review, the subcommittee did agree an issue took place and should be reported to OLAW. I will keep you informed as we move forward to the full committee meeting (June 9th) and the IO.

Sincerely,

Sam Prien, PhD
IACUC Chair