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

April 10, 2019

Re: Animal Welfare Assurance
#A3237-01 (OLAW Case 2U)

Ms. Steffani Webb
Vice Chancellor for Administration
Institutional Official
University of Kansas Medical Center
3901 Rainbow Road, MS 2015
Kansas City, KS 66160

Dear Ms. Webb,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 26, 2019 letter reporting an adverse event in a mouse cancer study at the University of Kansas Medical Center. According to the information provided, OLAW understands that a cancer cell line was found to be more aggressive than anticipated which resulted in faster tumor growth and more rapid and frequent mortality.

The corrective actions consisted of the Principal Investigator temporarily stopping all animal activities, submitting an adverse event report to the Institutional Animal Care and Use Committee (IACUC), and amending the protocol to reduce the number of tumor cells injected. Various training venues will be used to remind investigators to report adverse animal events to the IACUC.

Based on its assessment of this explanation, 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 on Humane Care and Use of Laboratory Animals.

Sincerely,

(b) (6)

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

cc: IACUC Chair

A3237-2U

KU MEDICAL CENTER
The University of Kansas

March 26, 2019

Axel Wolff, MS, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive – MSC 7982
Bethesda, MD 20892-7982

| | |
|---|---|
| **Regarding:** | **University of Kansas Medical Center -- Assurance #A3237-01** |
| **Research Project:** | **Bitter Melon Component and Colon Cancer Prevention**<br>**IACUC Number: 2016-2373** |
| **Funding Agency:** | **NIH-NCI R01-CA190291** |

Dear Dr. Wolff:

In accordance with PHS Policy IV.F.3, the University of Kansas Medical Center (KUMC) Institutional Animal Care and Use Committee (IACUC) is reporting an adverse event associated with the above project.

On 12/20/18, Laboratory Animal Resources (LAR) veterinary staff reported an unexpected high rate of mortality associated with animals undergoing intrapancreatic injections of line-UNKC6141 cancer cells. Upon investigation by our Post-Approval Monitor (PAM) we learned that this cell line was much more aggressive than anticipated, thus tumors progressed more quickly and animals expired sooner than expected (~2 weeks vs. ~ 37 days, 11/40 animals or 27.5% mortality). In addition, research staff, reported that further studies had been put on hold pending reassessment with the PI.

**Specific Corrective Action:**

After meeting with the PAM, the post-doctoral fellow in charge of this experiment agreed to work with the PI to submit an adverse event report to the IACUC. Additionally, an addendum to reduce the number of cells injected to allow further studies using this orthotopic pancreatic cancer mouse model was submitted on 2/1/19 and approved by Designated Member Review (DMR) on 2/18/19.

Office of the Executive Vice Chancellor
3901 Rainbow Blvd. | Mail Stop 2015 | Kansas City, KS 66160 | (913) 588-1440 | FAX (913) 588-1412 | www.kumc.edu

**IACUC and RABS Action:**

This information was presented to the convened IACUC on 2/19/19. Upon further review of the adverse event, the committee determined that the situation was handled appropriately and voted unanimously to report the event to the pertinent regulatory and accrediting agencies. This information is also being provided to the Association for the Accreditation of Laboratory Animal Care (AAALAC).

The IACUC and RABS, in conjunction with the LAR, will continue to help PIs understand the need to report unexpected adverse events associated with their animal research studies. Continuing education related to adverse events and reporting requirements is covered in our Animal User Training with additional avenues associated with Post Approval Monitoring reviews and veterinary assistance in related cases. If you have questions or need more information, please feel free to contact me at (b) (6)

Sincerely,

(b) (6)

Steffani Webb
Vice Chancellor for Administration

cc: (b) (6)
Nathan Culley, DVM, DACLAM, Chair, IACUC
Douglas Brandt, DVM, Executive Director, Laboratory Animal Sciences, Attending Veterinarian

## Wolff, Axel (NIH/OD) [E]

**From:** OLAW Division of Compliance Oversight (NIH/OD)
**Sent:** Friday, March 29, 2019 12:39 PM
**To:** Nathan Culley
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)
**Subject:** RE: Incident Reports for the University of Kansas Medical Center A3237-01

Thank you for these reports, Dr. Culley. We will send responses soon.
Axel Wolff

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**From:** Nathan Culley <nculley@kumc.edu>
**Sent:** Friday, March 29, 2019 10:44 AM
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
**Cc:** (b) (6)
**Subject:** Incident Reports for the University of Kansas Medical Center A3237-01

Dr. Wolff,

Please find attached, two (2) animal welfare compliance report letters from the University of Kansas Medical Center (A3237-01). Please let me know if you have any further questions regarding the reports.
Have a wonderful weekend.

Regards,

Nathan C Culley, DVM, DACLAM
IACUC Chair
Executive Director, Regulatory Affairs for Biological Sciences
University of Kansas Medical Center
nculley@kumc.edu
(b) (6)