



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

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Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

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Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
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January 30, 2018

Re: Animal Welfare Assurance
A3878-01 [OLAW Case B]

James Coleman, Ph.D.
Provost and Executive Vice Chancellor
For Academic Affairs
University of Arkansas
Room Administration Building
Fayetteville, AR 72701

Dear Dr. Coleman,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 23, 2018 letter reporting the suspension of seven animal activities at the University of Arkansas- Fayetteville involving mice and hamsters, following up on an initial telephone report on December 21, 2017. The Institutional Animal Care and Use Committee (IACUC) took this action in response to a variety of noncompliant incidents as follows:

- 1) Two separate species on different protocols were exposed under the same hood to separate carcinogens.
- 2) Procedures were performed without a protocol in place.
- 3) Mice were housed in a space not approved by the IACUC.
- 4) Mice were euthanized prior to the study endpoint.
- 5) Adequate animal procedure records were not maintained.
- 6) Environmental health and safety (EHS) procedures were not followed.

Also, for a period of approximately seven weeks, the institution had no Attending Veterinarian (AV) in place, and individuals filled acting positions for facility manager and Director of Research Compliance for varying time periods. No official IACUC business was conducted during the absence of the AV and a staff veterinarian provided for animal health and welfare.

The corrective actions to address the suspended protocols consisted of:

- 1) Having investigators obtain and implement EHS protocols.
- 2) Having investigators maintain adequate animal records.
- 3) Having the Department Chairs oversee the investigators' work.
- 4) Placing investigators under enhanced post-approval monitoring by the AV/veterinary staff.
- 5) Submitting the suspended protocols for IACUC review.
- 6) Reporting the suspensions to the funding components and USDA, as applicable.

The AV, facility manager, and compliance director positions were filled by permanent hires. These staff changes, including changes in IACUC membership, were reported to OLAW in the Annual report. The institution's compliance policies and practices will be updated to improve oversight of the research programs. Training and outreach will be conducted to maintain a compliant animal care and use program.

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Based on its assessment of these explanations, OLAW understands that measures have been implemented to correct and prevent recurrence of these problems. OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. Thank you for keeping OLAW apprised on this matter.

Sincerely,

Signature

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

cc: IACUC Chair
Robert Gibbens, D.V.M., USDA-APHIS-AC



UNIVERSITY OF ARKANSAS

Office of the Provost and Executive Vice Chancellor for Academic Affairs

January 23, 2018

Assurance Number A3878-01

Axel Wolff, D.V.M.
Office of Laboratory Animal Welfare
National Institutes of Health
RKL 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Dear Dr. Wolff,

Pursuant to the requirements of the PHS Policy on Humane Care and Use of Laboratory Animals, this letter serves as a voluntary reporting of incidents of noncompliance, including suspensions of protocols involving the use of animals. The letter contains a description of the activities prompting this letter and the actions taken at the University of Arkansas to address the issues.

Seven University of Arkansas Animal Use Protocols (AUP) were suspended in November 2017. Six of these involved the use of mice:

- AUP 15035 – *Intravital microscopy of tumor oxygenation and metabolism in metastatic and non-metastatic breast cancers*
- AUP 16022 – *Functional optical marker of radiation resistance in tumors*
- AUP 17030 – *Terahertz imaging for breast cancer margin assessment*
- AUP 15009 – *Structural and spectral features in colorectal cancer development*
- AUP 16064 – *Microstructural and metabolic features of colorectal adenocarcinoma*
- AUP 17072 – *Quantifying tumor perfusion response with diffuse reflectance spectroscopy in murine allograft model of colon carcinoma following immunomodulation of tumor-associated macrophages*

One protocol involved the use of hamsters:

- AUP 16083 – *Wide-field optical imaging of the oral cavity*

The reasons for the suspensions of the above protocols include the following:

1. Two different species, used on different protocols, were being used simultaneously in the same hood, exposing the animals to separate carcinogens
2. Procedures, including colonoscopies, were being performed without an IACUC-approved AUP.
3. Animals were being housed in space that had not been approved by the IACUC.
4. Animals were euthanized prior to study endpoint.
5. Accurate and detailed records of animal procedures were not being maintained.
6. Environmental Health & Safety (EHS) protocols were not being followed where required.

An investigative committee was formed to look closely into these issues; the committee completed its investigation on 10/27/2017 and presented its findings to the full IACUC which voted to suspend the protocols on 11/3/2017.

The following corrective actions have been taken:

1. Investigators are required to obtain and implement the required EHS protocols.
2. Investigators are required to maintain accurate, detailed records of all animal usage.
3. The Department Chairperson will be responsible for oversight of the investigators' work through October 2018.
4. The Attending Veterinarian or her designee will conduct announced and unannounced walk-throughs to ensure that a) adequate records are being maintained; and b) only approved procedures are being performed.
5. All protocols were resubmitted and presented to the IACUC in December 2017.
6. Notice of the suspended protocols was provided to the funding agency, and in the case of AUP 16083, to USDA/APHIS.

In addition to these suspensions, the University of Arkansas was without an Attending Veterinarian from June 30 through August 20, 2017. During this period, no official IACUC business was conducted, and oversight of animal health and welfare was provided by a University staff veterinarian. On August 21, Dr. Kate Williams was hired and appointed as the Attending Veterinarian.

Further, the role of animal facilities manager was filled on an interim basis by **Secondary Individual** on May 4, 2017 when the position became vacant. **Secondary Individual** was hired permanently for this role on June 18, 2017. Last, the position of Director of Research Compliance had been filled on an interim basis from February 1, 2017 through December 3, 2017. **Secondary Individual** was hired to be the new Director; his start date was December 4, 2017. These updates, and changes to the composition of the IACUC, were included on the University's Annual Report to OLAW. 2017 was a period of transition for the University's compliance programs. Going forward, the Office of Research Compliance will be updating and developing policies and procedures to improve oversight of the University's research programs, as well as conducting continuous outreach and training to ensure the highest standards of care for animals used in research.

Should you have any additional questions or suggestions, please feel free to contact me at jscolema@uark.edu.

Regards,

Signature

James Coleman, Ph.D.
Provost and Executive Vice Chancellor for Academic Affairs



Initial Report of Noncompliance

By: AWDate: 12/21/17Time: 11:30

Name of Person reporting:

Secondary Individual

Telephone #:

Phone Number

Fax #:

Email:

Name of Institution: U of Arkansas - FayettevilleAssurance number: A3878Did incident involve PHS funded activity? Yes

Funding component: _____

Was funding component contacted (if necessary): _____

What happened? 1) No AV June 30 - Sept 1, No IACUC business conducted

2) 7 protocols suspended w/ 2 PHS

3) University funded protocol suspended, then reinstated

4) Problems w/ feed, water, cages, record keeping, training, etc, endpoints

Species involved: Mice, rats, hamsters

5) Change in IACUC membership, non-compliance director

Personnel involved:

6) IACUC still the same

Dates and times:

Animal deaths:

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

Major transition at university.Said to also report to program officials, info to OARL in Annual Report re new staff

Projected submission to OLAW of final report from Institutional Official:

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Case # _____