



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) 402-2803

July 18, 2017

Re: Animal Welfare Assurance
A3609-01 [OLAW Case L]

Dr. Peter Dorhout
Vice Provost for Research
Kansas State University
oom Anderson Hall
Manhattan, KS 66506-0113

Dear Dr. Dorhout,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your 10 July 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Kansas State University. Your letter supplements information from **ondary Indivi** in his initial prompt telephone report on July 7, 2017. According to the information provided, OLAW understands that due to multiple unauthorized deviations from the IACUC-approved ACUP, the IACUC officially suspended and terminated said ACUP on 6 July 2017. The PI was sent a formal letter of admonishment and was informed that a new ACUP would have to be submitted and approved by the IACUC for any future animal work and that the IACUC will require retraining of personnel and/or close post-approval monitoring. This animal activity was not PHS-supported.

OLAW believes that the corrective and preventive measures put in place by Kansas State 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 matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse, DVM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

DATE: 10 July 2017

TO: Office of Laboratory Animal Welfare (OLAW)
ATTN: Division of Compliance Oversight (Brent Morse)
National Institutes of Health
RKL 1, Suite 360, MSC 7982
Bethesda, MD 20892-7982

SUBJECT: Report of Animal Care & Use Protocol (ACUP) Suspension

REFERENCE: Kansas State University PHS Assurance No. D16-00369 (A3609-01)

On 6 July 2017, the Kansas State University IACUC voted to:

- permanently suspend/terminate a mouse monoclonal antibody production ACUP due to multiple significant unauthorized deviations from the IACUC approved ACUP;
- send a formal letter of admonishment to the principal investigator (PI); and
- report the suspension to the NIH Office of Laboratory Animal Welfare (OLAW) in accordance with PHS Policy on Humane Care & Use of Laboratory Animals (§IV.F.3.c.) and Federal Animal Welfare Act Regulations (§§9 CFR 2.31(d)(6-7)).

NOTE: *The suspended/terminated ACUP was not funded by a NIH/PHS/Federal Agency grant.*

On 7 July 2017, the ACUP suspension was reported to Dr. Brent Morse (OLAW/DCO; 301.594.2921) and this correspondence is a follow-up to that telephonic notification.

The formal letter of admonishment notified the PI that the IACUC had officially suspended/terminated the ACUP and the reasons for the IACUC's action; informed the PI that a new ACUP would have to be submitted and approved by the IACUC for any future mouse monoclonal antibody production work; and also informed the PI that the IACUC will require retraining of personnel performing hands-on animal work and/or close post-approval monitoring as a condition for securing IACUC approval to help ensure that the new ACUP is carried out as approved.



Peter K. Dorhout, PhD
Vice President for Research/Institutional Official

cc:
VPR/URCO (ATTN: Secondary Individual; Secondary Individual)
VPR/CMG (ATTN: Secondary Individual)
IACUC Chair (ATTN: Sally Olson)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, July 11, 2017 7:37 AM
To: Secondary Individual
Subject: RE: Assurance D16-00369 (A3609-01) protocol suspension

Thank you for this report. Dr. Morse will respond soon.

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

From: Secondary Individual [mailto:Secondary Individual@ksu.edu]
Sent: Monday, July 10, 2017 4:45 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Peter Dorhout <dorhout@ksu.edu>; Secondary Individual @ksu.edu; Sally Olson <solson@vet.k-state.edu>; Secondary Individual@ksu.edu
Subject: Assurance D16-00369 (A3609-01) protocol suspension

Dear Dr. Morse,

Please see attached letter from our IO regarding a recent protocol suspension. Please contact us if we can provide further information.

Thank you,

Secondary Individual

Program Manager
University Research Compliance Office
Kansas State University
Office: Phone Number



Initial Report of Noncompliance

By: [Signature]

Date: 7/7/17

Time: 12:05

Name of Person reporting

Secondary Individual

Telephone #:

Phone Number

Fax #:

Email:

Name of Institution:

Assurance number:

Kansas State U.
A3609

Did incident involve PHS funded activity?

No

Funding component:

Was funding component contacted (if necessary):

What happened? Mab production ASP. Multiple protocol infractions. Eight mice when suspended. All mice euthanized.

Species involved: Mice

Personnel involved: PI

Dates and times: Suspended 7/6/17

Animal deaths:

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

ASP suspended / terminated.

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____