



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) 480-3387

March 25, 2022

Re: Animal Welfare Assurance
A3255-01 [OLAW Case 2V]

Dr. Christopher S. Brown
Institutional Official
Vice President for Research
University of Alabama- Birmingham
1720 2nd Ave. S, 720C
Birmingham, AL 35294-0107

Dear Dr. Brown,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 24, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals within the animal care and use program at the University of Alabama - Birmingham. Your letter supplemented the information contained in an initial telephone report to this office on December 13, 2021. According to the information provided, OLAW understands that a laboratory was approved to use a variety of xenograft tumor models but added a melanoma cell line without IACUC approval. Fifteen mice were observed with ocular tumors and were euthanized. The mice involved in this incident were not supported by PHS funds.

Corrective and preventative measures included immediate discontinued use of the unapproved cell line pending a protocol amendment describing the new model and additional monitoring criteria. The laboratory received training on reviewing the approved protocol before study initiation and for appropriate monitoring of tumor development. The laboratory will also be subject to increased oversight by the veterinary staff and post-approval monitor for the next 6 months.

OLAW appreciates the consideration of this matter by the University of Alabama - Birmingham which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident and prevent recurrence. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Robyn M. Engel - Digitally signed by Robyn M.
Engel - 5
S Date: 2022.03.25 10:47:06 -04'00'

Robyn M. Engel, DVM
Animal Welfare Program Specialist
Office of Laboratory Animal Welfare

cc: IACUC Chair

A3255-28

UAB THE UNIVERSITY OF ALABAMA AT BIRMINGHAM
Institutional Animal Care and Use Committee (IACUC)

February 24, 2022

Brent Morse, D.V.M.
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
6705 Rockledge Drive
RKL1, Suite 360, MSC 7982
Bethesda, Maryland 20892-7982
Assurance # A3255-01

Dear Dr. Morse:

Below is the description of unapproved deviations from the Guide for the Care and Use of Laboratory Animals and/or the PHS Policy identified and included in a preliminary report to OLAW on December 13, 2021. The incident of non-compliance was identified through routine veterinary care. The corrective action is also described.

Deviation from approved protocol with adverse outcome

One instance of deviating from the approved protocol for a tumor study was found during routine veterinary follow-up on a clinical case. The lab was approved for a variety of xenograft tumor models, but added a melanoma cell line not previously approved. Fifteen mice were observed with ocular tumors and were euthanized to prevent further trauma or complications to the tumor site. This incident did not involve PHS funds. The investigator immediately discontinued use of the unapproved cell line and submitted a modification describing the new model and additional monitoring criteria. The lab received retraining on the importance of reviewing the approved protocol before beginning studies and for providing appropriate monitoring of tumor development. This lab will receive additional oversight by the veterinary staff and post-approval monitor for the next 6 months.

If you require additional information or clarification, please do not hesitate to let me know.

Sincerely,

(b) (6)

Christopher S. Brown, Ph.D.
Institutional Official and Vice President for Research

cc: (b) (6)
Robert A. Kesterson, Ph.D., IACUC Chair

(b) (6)

Institutional Animal Care and Use Committee
403 Community Health
933 19th St S
205.934.7692
FAX 205.934.1188

Mailing Address:
403 CH19
1530 3RD AVE S
BIRMINGHAM AL 35294-2041

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, March 16, 2022 7:24 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: final reports

Thank you for these reports, (b) (6) We will send replies soon.
Axel Wolff

From: (b) (6)
Sent: Tuesday, March 15, 2022 9:27 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: [EXTERNAL] final reports

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Good morning,
Please find attached the final reports to for 2 incidents already filed as preliminary reports. Please let me know if you have any questions.
Thank you,

(b) (6)



Initial Report of Noncompliance

By: (b) (6)

Date: 12/13/21

Time: 9:45
(b) (6)

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: U of Alabama - Birmingham
Assurance number: A3255

Did incident involve PHS funded activity? No

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

Unapproved cell lines given to mice + tumors appeared.

Species involved: Mice

Personnel involved:

Dates and times:

Animal deaths:

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

Enhanced oversight. Retrain

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____