



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

August 7, 2019

Re: Animal Welfare Assurance
#A3518-01 [OLAW Case 1U]

Randolph W. Hall, Ph.D.
Vice President for Research
University of Southern California
3720 Flower Street, (b) (4)
Los Angeles, CA 90089-0706

Dear Dr. Hall:

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 26, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Southern California. According to the information provided, OLAW understands that two protocol amendments were approved administratively rather than by Full Committee or Designated Member Review. No adverse animal issues occurred due to this action.

The corrective actions consisted of counseling the Institutional Animal Care and Use Committee administrator and staff on following the proper procedures and on the consequences of unauthorized administrative approvals. The electronic protocol system will be updated to prevent a recurrence.

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 institution to comply with the PHS Policy. We assume the two protocols in question were subsequently approved by one of the accepted methods.

Sincerely,

(b) (6)

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

cc: IACUC Chair



USC University of Southern California

A3518-14
OFFICE OF RESEARCH
Randolph W. Hall
Vice President of Research
vpres@usc.edu

July 26, 2019

Brent Morse, D.V.M.
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
RKL1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Dear Dr. Morse:

This is to report an administrative non-compliance incident reported to the IACUC at the University of Southern California (animal welfare assurance number D16-00320/A3518-01). (b) (6) provided a preliminary report to Dr. Axel Wolfe on April 10th, 2019. The IACUC protocols for this work were associated with National Institutes of Health funding.

In May 2018 and in February 2019, two protocol amendments were submitted to the IACUC through the electronic protocol system. Both of these amendments contained changes and details that meant they should have been reviewed by full committee review or designated member review per USC IACUC policy. However, these amendments were reviewed and approved administratively. No animal welfare issues occurred as a result of the administrative approvals.

The IACUC voted in a convened meeting on March 20th, 2019, to send a memo to the IACUC Administrator and staff requiring a discussion with the staff in the proper procedures and consequences of unauthorized administrative approval. It was also required that mechanisms to prevent future incidences be explored. The IACUC Administrator responded back on April 25th, that a discussion will occur and a mechanism will be built in the electronic system to prevent future incidences like this from occurring.

The IACUC voted in a convened meeting on May 22nd, 2019 that the response was acceptable and to close this non-compliance report.

Sincerely, (b) (6)

Randolph W. Hall, Ph.D.
Vice President of Research

CC: (b) (6)

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, July 29, 2019 2:30 PM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Letters to OLAW

Thank you for providing these final reports (b) (6) We will send official responses soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

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From: (b) (6)
Sent: Monday, July 29, 2019 2:13 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Letters to OLAW

Please see attached two letters to Dr. Brent Morse.

Sincerely,

(b) (6)

