



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

August 31, 2020

Re: Animal Welfare Assurance  
A3276-01 [OLAW Case Y]

Mr. Jodi Ogden Rivera  
Vice President, Research Operations  
Children's Hospital of Los Angeles  
4650 Sunset Blvd. (b) (4)  
Los Angeles, California 90027

Dear Mr. Rivera,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 21, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Children's Hospital Los Angeles following up on an initial March 31, 2020 notification by telephone.

According to the information provided, this Office understands that the Children's Hospital Los Angeles Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: conduct of animal-related activities without appropriate IACUC review and approval. The final report states on February 17, 2020, the IACUC received information that limited pilot experiments performed by a principal investigator's laboratory in late 2017 and early 2018 to test optogenetic imaging in mice may have been performed without prior IACUC review and approval. This discovery was made after the principal investigator (PI) left the institution, when the project and associated NIH award were transferred to a new PI. An evaluation of billing records revealed that direct costs associated with the procurement, care, and use of the mice from May 2017-April 2018 were not charged to any NIH-supported cost centers. However, since the data was enclosed in a progress report, the NIDDK program officer was notified of the matter. The following corrective actions have been implemented to prevent future recurrence:

- The new PI notified the NIDDK program officer and grants management specialist of the incident and amended the progress report filed on award transfer to remove data from the experiment.
- The PI notified all research staff associated with this project of the IACUC's requirement for securing approval for all procedures prior to work involving animals.
- The PI assured the IACUC that all research staff will from now on carefully review and adhere to approved study protocols.
- The PI pledged to not use data from the pilot experiment in any way, including in grant applications, publications, or presentations.

Based on its assessment of this explanation, OLAW understands that the Children's Hospital Los Angeles has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy. We appreciate being informed of these matters and find no cause for further action by this Office.

Page 2 – Mr. Rivera  
August 28, 2020  
OLAW Case A3276-Y

Sincerely,

(b) (6)

Jacquelyn T. Tubbs, DVM  
Animal Welfare Program Specialist  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Contact



We Treat Kids Better

A3276-7

New case

July 21, 2020

Axel Wolff, DVM  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Rockledge 1, Suite 360  
6705 Rockledge Drive  
Bethesda, MD 20892

Dear Dr. Wolff:

Children's Hospital Los Angeles, in accordance with Assurance D16-00175 (formerly A3276-01) and PHS Policy IV.F.3., provides this report of noncompliance regarding a surgical procedure for optogenetic analysis not reviewed and approved by the IACUC in a Principal Investigator's (PI) animal study protocol, entitled "Leptin and the nutritional programming of obesity and diabetes." This incident was first reported to Dr. Brent Morse, OLAW, on March 31, 2020 via a telephone call by Mark Frey, PhD, who was IACUC Chair at the time.

On February 17, 2020, the IACUC received information that limited pilot experiments done by (b) (6) laboratory in late 2017 and early 2018 to test optogenetic imaging in mice may have been performed without prior IACUC review and approval. This was discovered after (b) (6) left the institution, when the project and associated NIH award (R01 DK084142) were transferred to a new PI, Dr. Pat Levitt. A subsequent investigation of protocols and amendments from (b) (6) active in 2017 and 2018 confirmed that no approval for the experiment was active at the time.

A review of billing records showed that direct costs associated with the procurement, care, and use of the mice from May 2017-April 2018 were not charged to any NIH-supported cost centers. Nonetheless, since the data were included in a progress report, the NIDDK program officer was notified of the situation.

To address the situation, preventive actions have been taken as follows:

1. The new PI (Dr. Levitt) informed the NIDDK program officer and grants management specialist of the incident and revised the progress report filed on award transfer to remove data from the experiment.
2. The PI informed, in writing, all research staff working on this project of the IACUC's requirement for securing approval for all procedures prior to work involving animals.

3. The PI assured the IACUC that all research staff will from now on carefully review and adhere to approved study protocols.
4. The PI committed to not using data from the pilot experiment in any way, including in grant applications, publications, or presentations.

At their meeting on June 18, 2020, the IACUC also reviewed and accepted the action plans.

Children's Hospital Los Angeles is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact Yong-Mi Kim, MD, PhD, IACUC Chair ([iacuc@chla.usc.edu](mailto:iacuc@chla.usc.edu)).

Thank you for your consideration of this matter.

(b) (6)

Digitally signed by  
Ogden Rivera, Jodi  
Date: 2020.08.21  
07:23:12 -07'00'

Jodi Ogden Rivera, MBA, CRA  
Vice President, Research Operations  
The Saban Research Institute at Children's Hospital Los Angeles

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

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**From:** Laboratory Animal Welfare, Office of (NIH/OD)  
**Sent:** Monday, August 24, 2020 11:02 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD); Morse, Brent (NIH/OD) [E]; Wolff, Axel (NIH/OD) [E]  
**Subject:** FW: (b) (6) noncompliance  
**Attachments:** (b) (6) noncompliance OLAW.pdf

Hi Brent and Axel,

A noncompliance report is attached for DCO.

Thanks.  
Neera

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**From:** Kim, Yong-Mi <YmKim@chla.usc.edu>  
**Sent:** Monday, August 24, 2020 7:34 PM  
**To:** Laboratory Animal Welfare, Office of (NIH/OD) <OLAW@OD.NIH.GOV>  
**Cc:** IACUC <IACUC@chla.usc.edu>; (b) (6)  
(b) (6)  
**Subject:** (b) (6) noncompliance

TO: Office of the Director

ATTN:  
Axel Wolff, DVM  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Rockledge 1, Suite 360  
6705 Rockledge Drive  
Bethesda, MD 20892

Dear Dr. Wolff,

I would like to introduce myself as the new Chair of the Institutional Animal Care and Use Committee (IACUC) of Children's Hospital Los Angeles (CHLA) serving since July 17<sup>th</sup>, 2020.

We are sending you this report of noncompliance regarding a surgical procedure for optogenetic analysis not reviewed and approved by the IACUC in a Principal Investigator's (PI) animal study protocol, entitled "Leptin and the nutritional programming of obesity and diabetes." This incident was first reported to Dr. Brent Morse, OLAW, on March 31, 2020 via a telephone call by Mark Frey, PhD, who was IACUC Chair at the time when the letter was issued. Please contact me with any question you may have.

Thank you very much for your consideration of this matter.

Best regards, Yong-Mi Kim

Yong-Mi Kim, MD MPH PhD  
Associate Professor of Pediatrics and Pathology  
Department of Pediatrics  
Division of Hematology and Oncology  
Childrens Hospital Los Angeles  
Universty of Southern California

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