

From: [Gibbens, Robert - APHIS](#)
To: [Keller, Martha - APHIS](#); [Garland, Kathleen M - APHIS](#)
Subject: FW: OLAW Case A3714-K
Date: Monday, May 11, 2020 9:28:00 AM
Attachments: [0211_001.pdf](#)

FYI

From: Walker, Keri (NIH/OD) [C] [mailto:keri.walker@nih.gov]
Sent: Monday, May 11, 2020 7:26 AM
To: shlomo.melmed@cshs.org
Cc: (b) (6) Gibbens, Robert - APHIS <robert.m.gibbens@usda.gov>;
(b) (6)
Subject: OLAW Case A3714-K

Dear Dr. Melmed,

Attached please find Dr. Tubbs' final response to OLAW Case A3714-K.

If you have any questions, feel free to contact us by phone or by e-mail.

Best Regards,
Keri

*Keri Walker
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DEPARTMENT OF HEALTH & HUMAN SERVICES

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FOR US POSTAL SERVICE DELIVERY:

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May 1, 2020

Re: Animal Welfare Assurance
A3714-01 [OLAW Case K]

Dr. Shlomo Melmed
Senior Vice President for Academic Affairs
Cedars-Sinai Medical Center
North Tower, (b) (4)
8700 Beverly Blvd.
Los Angeles, CA 90048-1865

Dear Dr. Melmed,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 28, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Cedars-Sinai Medical Center following up on an initial March 30, 2020 notification by telephone.

According to the information provided, this Office understands that the Cedars-Sinai Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: an individual performing a surgical procedure on a pig while in training and without supervision on an approved protocol. The final report states on February 17, 2020, a pig underwent a surgical procedure to evaluate how infusion of cool saline around the heart via catheter may mitigate detrimental effects of myocardial infarction. The animal died under anesthesia ~15min after beginning the cooling stage. The incident was reviewed with the principal investigator (PI) and surgeon and veterinarians. While the cause of death could not be determined, the most likely contributing factors were the cooling procedure and/or the myocardial infarction (per the final report). It was also determined that the individual who primarily performed the cooling procedure was "in training" for this procedure and not directly supervised by the lead surgeon who was occupied by a separate surgery in an adjacent operating room.

The IACUC discussed the incident at the March 16, 2020 meeting. The committee determined the incident was considered a serious deviation from the provisions of the PHS Policy and the *Guide*. A memo was sent to the PI from the IACUC Chair on March 24, 2020 summarizing the details of the event and requiring the PI to submit a corrective action plan by April 8, 2020.

On April 1, 2020 the PI responded and confirmed the lead surgeon stepped out of the surgical suite to observe another procedure and moving forward the lead surgeon will remain present during surgeries involving procedures performed by individuals in-training. It is noted the PI has initiated training procedures to ensure the trainee will become fully qualified to perform the surgeries. The IACUC accepted the PI's response and corrective action plan at the convened IACUC meeting on April 20, 2020. The committee also recommended refinements to the cooling procedure based on discussions between Comparative Medicine and the PI and surgeons before proceeding with additional surgeries. A modification to update the cooling procedure was submitted and approved.

It is noted that this project is supported by PHS funds. Based on its assessment of this explanation, OLAW understands that the Cedars-Sinai Medical Center 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.

Sincerely,

(b) (6)

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

cc: IACUC Contact
Robert M. Gibbens, DVM, Director, Animal Welfare Operations