



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

December 4, 2018

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

Dr. Shlomo Melmed  
Senior Vice President for Academic Affairs  
Cedars-Sinai Medical Center  
North Tower, Room [REDACTED]  
8700 Beverly Blvd.  
Los Angeles, CA 90048-1865

Dear Dr. Melmed,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 28, 2018 letter reporting a noncompliance with the PHS Policy on the Humane Care and Use of Laboratory Animals at the Cedars-Sinai Medical Center (CSMC). Your letter supplemented the information in the preliminary telephone report on October 22, 2018. From the information provide, it is understood that on September 10, 2018 two pigs were recovered from anesthesia for an MRI procedure. The pigs were euthanized nine days later. The protocol only allowed for the animals to be euthanized while still under anesthesia for the MRI procedure. It was stated that the animals were on a project funded by the PHS.

Corrective and preventive actions included a 6 month probation period for one of the investigators. During this period, he and his involved research staff must retake the CITI training. In addition, the IACUC reviewed and approved a protocol modification allowing a fully proficient member of the study team to euthanize anesthetized animals after the MRI procedure. It is understood that grant funds used have been reimburse to the grant from institutional funds. We note that the Grant Management Specialist has been notified.

OLAW believes that the corrective measures by the Cedars-Sinai Medical Center (CSMC) are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals for institutional self-monitoring, self-correction, and self-reporting. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

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

cc: IACUC Contact

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## Morse, Brent (NIH/OD) [E]

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Thursday, November 29, 2018 8:21 AM  
**To:** (b) (6) OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** Wilson, Sunshine (NIH/NHLBI) [C]; Melmed, Shlomo, M.D.; Magoffin, Denis, Ph.D.; (b) (6)  
**Subject:** RE: Cedars-Sinai Follow-Up Report of Non-Compliance

Thank you for providing this final report. We will send an official response 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:** Wednesday, November 28, 2018 5:16 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Wilson, Sunshine (NIH/NHLBI) [C] <sunshine.wilson@nih.gov>; kbayne@aaalac.org; Melmed, Shlomo, M.D. <Melmed@csmc.edu>; Magoffin, Denis, Ph.D. <Denis.Magoffin@cshs.org>; (b) (6)  
**Subject:** Cedars-Sinai Follow-Up Report of Non-Compliance

Dear Dr. Wolff,

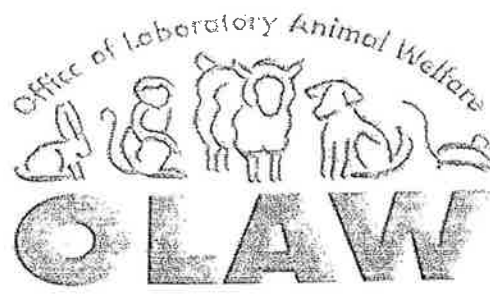
Please find attached a letter from Dr. Shlomo Melmed reporting a non-compliance incident in research conducted at Cedars-Sinai Medical Center. Feel free to contact us with any questions or concerns.

Best,

(b) (6)

**Follow-up report of noncompliance regarding National Heart, Lung and Blood Institute R01 HL133407 (Developing a MRI-Guided Disease-Modifying Therapy for Post-Infarction Chronic Heart Failure; Animal Species: Pigs)**

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Initial Report of Noncompliance

By: *[Signature]*

Date: 10/22/18

Time: 3:15  
(b) (6)

Name of Person reporting:  
Telephone #:  
Fax #:  
Email:

(b) (6)

Name of Institution: Cedar Sinai Med. Cen  
Assurance number: A3714

Did incident involve PHS funded activity? ☒ R01HL133407  
Funding component: \_\_\_\_\_  
Was funding component contacted (if necessary): \_\_\_\_\_

What happened? 2 pigs survival imaging should have been euthanized while under anesthesia by veterinary staff.  
Species involved: Sus scrofa  
Personnel involved: \_\_\_\_\_  
Dates and times: 9/10  
Animal deaths: \_\_\_\_\_

Projected plan and schedule for correction/prevention (if known):  
Counseling of 2 researchers.  
Mod. of protocol to allow researchers to perform euthanasia.  
Projected submission to OLAW of final report from Institutional Official:  
After Nov 30, 2018

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Case # \_\_\_\_\_