



CEDARS-SINAI

Shihong Mohamed, MD, ChB, MACP, FRCP  
Executive Vice President and Dean of the Medical Faculty  
Helen A. and Philip H. Helson Distinguished  
Chair in Investigative Medicine  
Director, Bernz & Allen Research Institute

Transmit via E-mail

April 28, 2020

Brent Morse, D.V.M.  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare (OLAW)  
National Institutes of Health  
RKL 1, Suite 360, MSC 7982  
6705 Rockledge Drive  
Bethesda, MD 20892-7982

**RE: Follow-up report of noncompliance regarding National Heart, Lung and  
Blood Institute (NHLBI) R01 HL133407 (CSMC IACUC Study Title: Developing  
an MRI-guided disease-modifying therapy for myocardial infarction and  
chronic heart failure; CSMC IACUC #5257; Animal Species: Pigs)**

Dear Dr. Morse:

In my capacity as the Institutional Official at Cedars-Sinai Medical Center (CSMC) (Assurance #D16-00420, Legacy #A3714-01), and in accordance with the PHS Policy on Humane Care and Use of Laboratory Animals (Policy) IV.F.3, I am writing this letter to provide a follow-up report regarding an incident of noncompliance and deviation from the provisions of the Guide for the Care and Use of Laboratory Animals (the *Guide*) related to the above-referenced NHLBI Grant. This case was previously reported to Dr. Axel Wolff, Deputy Director, OLAW by Ajay Sagar, IACUC Manager, Research Compliance and Quality Improvement at CSMC in a telephone conversation on March 30, 2020.

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. Approximately 15 minutes after beginning the cooling stage, the pig died under anesthesia. The incident was reviewed in depth with the PI and surgeons and according to our veterinarians. Although the cause of death could not be determined conclusively, the most likely contributing factors were the cooling procedure and/or the MI. 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.

Academic Affairs	3500 Beverly Blvd., Suite 2015, Plaza Level Los Angeles, California 90018	office 310.423.4691 fax 310.423.0119	mohamed@cedarsinai.org cedars-sinai.edu
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The Committee was notified and discussed the incident at the March 16, 2020 IACUC meeting. They determined that performing experimentation on animals without close supervision by qualified and experienced personnel is considered a serious deviation from the provisions of the PHS Policy and the *Guide*. The IACUC Chair followed-up by sending a memo to the PI on March 24, 2020 summarizing the above details and requiring the PI to submit a corrective plan of action by April 8, 2020.

The PI responded on April 1, 2020, confirming that the lead surgeon had stepped out of the surgical suite to observe another procedure taking place in an adjacent surgical suite during part of the surgery. The PI confirmed that moving forward, the lead surgeon would always be present during surgeries involving procedures performed by individuals in-training. In addition, the PI has initiated training procedures to ensure the trainee will become fully qualified to perform the surgeries.

At the convened IACUC meeting on April 20, 2020, the Committee accepted the PI's response and the actions taken to address this incidence of noncompliance. For additional context, 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.

Please be assured that the institution considers the protection of laboratory animals to be of utmost importance. Please contact me at (b) (6) Dr. Denis Magoffin, IACUC Chair, at (b) (6) with any questions or concerns about this matter.

Sincerely,

(b) (6)

Shlomo Melmed, MB ChB  
Executive Vice President of Academic Affairs  
Dean of the Medical Faculty  
Professor of Medicine

cc: Karen Brummett, Grant Management Specialist, NHLBI  
Gary L Borkowski, D.V.M., M.S., Global Director, AAALAC Int.  
(b) (6)  
Department Chair for PI of Record, CSMC  
Denis Magoffin, Ph.D., IACUC Chair, CSMC

(b) (6)  
Principal Investigator of Record, CSMC