



Inspection Report

Cedars-Sinai Medical Center
8700 Beverly Blvd
Los Angeles, CA 90048

Customer ID: 1179

Certificate: 93-R-0032

Site: 001

CEDARS-SINAI MEDICAL
CENTER

Type: FOCUSED INSPECTION

Date: 01-AUG-2023

2.31(c)(7)

Institutional Animal Care and Use Committee (IACUC).

Records reviewed show during post-surgical monitoring by Comparative Medicine (CM), it was noted that a surgeon working on an IACUC approved protocol had not followed the IACUC approved sterilization technique for a pacemaker implanted in a pig on October 31, 2022. Records show the surgeon, on the day of the surgery, observed a deficiency in the pacemaker they were planning to use. To avoid prolonged anesthesia and a second major operative procedure, he replaced the faulty device with a fully functioning pacemaker that he had immersed for approximately 20 minutes in Cidex disinfectant solution, which the IACUC noted was a protocol violation. According to the CSMC AV Guideline: Chemical Sterilization for Reuse of Implanted Devices document, a guideline that is referred to in the approved protocol, "devices will soak for a minimum of 10 hours in the chemical sterilant, rinsed thoroughly with sterile saline, and soaked for 10 hours (up to 48 hours) in sterile saline. Devices are then ready for immediate implantation." A review of documents and a discussion with the attending veterinarian (AV) confirmed the approved protocol was not followed as written.

Documents show there have been 4 prior occasions when the same surgeon has deviated off protocol since 2018.

-On 3/8/2018 a bilateral femoral vein cutdown was performed on a pig without prior veterinary consultation from CM. There were no complications associated with the procedure.

-On 12/21/2018 a pig underwent peripheral venous injection of autologous (pig) stem cells not described on the approved IACUC protocol.

-On 2/13/2019 the PI scheduled a pig to undergo surgery for telemetry implantation as a stand-alone procedure. The protocol includes more invasive procedures, so the pig underwent a less invasive procedure than what is described.

-On 1/27/22 an unapproved non-survival thoracotomy surgery was performed on one pig. Although a modification was submitted 2 additional procedures were performed prior to IACUC approval of the modification.

The IACUC has determined there were no animal welfare concerns regarding these occurrences. Records show corrective action has been implemented after each incident to prevent reoccurrence, but additional events have occurred. Failure to follow an approved protocol may affect the health and well-being of the animals. These deviations from the protocols were significant changes regarding the care and use of animals in ongoing activities that were not reviewed by the IACUC. The IACUC must ensure that all significant changes regarding the care and use of animals in ongoing activities are reviewed and approved prior to implementation.

To be corrected by close of business August 9, 2023

Prepared By: ALEXANDRA ANDRICOS

USDA, APHIS, Animal Care

Date:

25-AUG-2023

Title: VETERINARY MEDICAL
OFFICER

Received by Title: Facility Representative

Date:

25-AUG-2023



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This inspection and exit interview were conducted with the facility representatives.

Prepared By: ALEXANDRA ANDRICOS
USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL
OFFICER

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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1179	93-R-0032	001	CEDARS-SINAI MEDICAL CENTER	01-AUG-2023

Count	Scientific Name	Common Name
000000	NONE	NONE
000000	Total	