



Inspection Report

MEDSTAR HEALTH RESEARCH INSTITUTE
GEORGE HYMAN MEM.RESEARCH BLDG RM 126
108 IRVING STREET NW
WASHINGTON, DC 20010

Customer ID: 66
Certificate: 10-R-0001
Site: 001
WASHINGTON HOSPITAL
CENTER

Type: ROUTINE INSPECTION

Date: 17-SEP-2021

2.32(a) Critical

Personnel qualifications.

Surgical records for Pig #9 used under study A conducted on September 15, 2021, show inconsistencies in the monitoring of vital signs and missing information. The pig was under anesthesia for approximately 18hrs. Either no vital signs were recorded or only some monitoring parameters were noted in the records at some timepoints.

Based upon the information on the Anesthesia and Vital Signs Monitoring form:

1. There were no vital signs entered at the 8:15pm and 8:30pm and timepoints
2. No entries of PCO2 from 2:45pm-6:15pm and the CO2 monitor was not working for an unspecified amount of time.
3. No blood pressure readings for the noon-2:00pm timepoints and the 7:30pm-11:15pm timepoints

Noted in the surgical records was an incident in which the tracheal tube was noted to have filled with phlegm at 2:45am. Appropriate interventions were administered but Pig #9 ultimately died under anesthesia because of a decline of its vital signs and O2 desaturation. Records indicate the EtCO2 ranged from 21- 35 mm Hg from 7:55am to 2am. The EtCO2 value was out of range except between 11pm – 2am. (The protocol indicates the EtCO2 would be monitored and maintained at 40 +/- 5.) The pO2 was within normal range until 2:45am when phlegm was noted in the tracheal tube.

Prepared By: GLORIA MCFADDEN
USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL
OFFICER

Date:
06-DEC-2021

Received by Title: Attending Veterinarian

Date:
06-DEC-2021



Inspection Report

Personnel responsible for monitoring the pig #9 under anesthesia missed timepoints for monitoring as indicated in the protocol and facility SOPs and failed to recognize in a timely manner that the animal was not being adequately oxygenated as outlined in the study protocol.

The protocol indicates the principal investigator will provide training and that inexperienced personnel will be under the direction of the principal investigator or senior investigators. Personnel were not following the guidelines for monitoring and interventions outlined in the protocol. Some personnel involved in the study are not adequately trained in the process and interpretation of monitoring of all vital signs as indicated in the facility surgery records.

An appropriate training program must be implemented that ensures all persons on the study are properly trained to perform the necessary procedures and is knowledgeable of monitoring parameters of vital signs as outlined in the protocol and in surgical documents. This training must occur before any additional procedures are performed under for the welfare of the animals on Protocol A. Correct by October 18, 2021.

This inspection and exit interview were conducted with the Attending Veterinarian and Institutional Official.

Prepared By: GLORIA MCFADDEN
USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL
OFFICER

Date:
06-DEC-2021

Received by Title: Attending Veterinarian

Date:
06-DEC-2021



Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
66	10-R-0001	001	WASHINGTON HOSPITAL CENTER	17-SEP-2021

Count	Scientific Name	Common Name
000001	<i>Sus scrofa domestica</i>	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000001	Total	