



Inspection Report

UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL
55 LAKE AVENUE NORTH
WORCESTER, MA 01655

Customer ID: **130**

Certificate: **14-R-0035**

Site: 001

UNIV. OF MASS. MEDICAL
CENTER

Type: FOCUSED INSPECTION

Date: 27-FEB-2024

2.31(c)(7)

Institutional Animal Care and Use Committee (IACUC).

Pertaining to IACUC approved Protocol 028: The proposal for animal use was reviewed along with the medical records for 5 pigs on the study. The following instances of the laboratory staff implementing significant changes in an ongoing activity without prior review and approval by the IACUC and instances of the laboratory staff not following the approved protocol were identified.

1. According to the medical record of Pig 726, it underwent "Fluid Replacement" procedure on 2/6/24 that included the insertion of an intravenous catheter and the administration of inhalant anesthesia prior to "Fluid Replacement". This procedure is not described in the IACUC approved protocol and was a significant change regarding the use of animals in an ongoing activity that was not reviewed or approved by the IACUC committee.
2. IACUC approved protocol states that following the MI procedure the animals "are monitored for the 5 days post-op period" and "will be checked at least once a day during the experiment". There was no documentation noted in the review of the medical records of 2 pigs that the monitoring of the animals was performed as described in the approved protocol. Pig #726 underwent MI on 1/4/24 but there was no monitoring recorded in the medical record for 1/7/24 (post-op day 3), and there are multiple other days during the experiment when no monitoring of the animals was recorded in the medical records of pig #726 and pig #722.
3. IACUC approved protocol states that aspirin will only be administered to pigs prior to the "IPG" procedure. However, aspirin was administered to pig #726 and pig #733 prior to the MI procedure; the animals did not have the "IPG" procedure. The administration of aspirin prior to MI procedure is not described in the IACUC approved protocol.
4. IACUC approved protocol states that "survival studies that do not involve an open chest surgery require the following.....cefazolin". Pig #717 and pig #722 underwent a survival study that did not involve an open chest surgery. Review of the pigs' medical records revealed that a different antibiotic was given to the pigs and cefazolin was not administered as is described in the approved protocol.

Per this Section, with respect to activities involving animals, the IACUC shall review and approve, require modifications to

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05-MAR-2024

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secure approval, or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities prior to implementation by the investigator. Principal investigators are to follow the IACUC approved proposals and any proposed changes shall be reviewed and approved by the IACUC prior to implementation. The IACUC needs to address the deviations with the IACUC approved protocol that were identified for this proposal for animal use and ensure that all significant changes regarding the care and use of animals in ongoing activities are reviewed and approved prior to implementation. Correct by 4/5/24.

2.33(b)(2) Critical

Attending veterinarian and adequate veterinary care.

Pertaining to IACUC approved Protocol 028: The proposal for animal use was reviewed along with the medical record for pig #726 on the study. IACUC approved protocol states that the MI model animals are generally stable throughout the study and describes several postoperative conditions/parameters that are "rare" or "very rare" including loss of appetite, dehydration, and signs of heart failure.

1. Entries made by veterinary and laboratory staff in the record of pig #726 for 2/3/24 and 2/5/24 noted that the animal was lying down, lethargic, not finishing food, and was offered a special dietary product or fruit to entice it to eat. The morning of 2/6/24 prior to a scheduled non-invasive study procedure, the entries in the record state that the pig was lethargic and had "peripheral cyanosis" however laboratory staff administered the injectable anesthetic and performed the noninvasive procedure as planned. The last entry in the record on 2/6/24 was at 1410 when the pig was returned to its enclosure. There was no indication from the record that additional monitoring of the animal's condition was performed on 2/6/24 following its return to its enclosure.

2. Entries made by veterinary staff in the record of pig #726 for 2/7/24 noted at 8:50 AM that the pig was "lateral, cyanotic extremities" and the pig tried to stand up twice but then fell on its side each time. Veterinary staff contacted laboratory staff to inform them of the animal's symptoms. A veterinarian assessed the animal at 10:15 AM as being recumbent, pale mucus membranes, and the animal had cyanotic legs and ears. Despite the progression of the pig's clinical signs, the veterinarian did not euthanize the animal and prescribed the administration of a dose of the analgesic buprenorphine, to be repeated at 3 PM. According to the record, the pig was not checked again by veterinary staff and laboratory staff arrived at 12:02 PM to check the pig. The pig died at 12:08 PM. Necropsy revealed infection in the tissues of the neck and in the heart of the pig.

Per this Section, each research facility shall maintain a program of adequate veterinary care that includes the use of appropriate methods to control, diagnose, and treat diseases and problems of animal health. The entries made by veterinary staff in the record on 2/7/24 document that the clinical condition of the pig was deteriorating, yet the animal was not humanely euthanized when the veterinarian assessed the animal at 10:15 AM on 2/7/24, the animal was not checked again by veterinary staff following buprenorphine administration, and the animal subsequently died less than 2 hours later. Correct from this date 3/5/24 forward by ensuring that appropriate methods are used to control, diagnose, and treat any problems of animal health that develop to ensure that the research animals receive appropriate veterinary care.

2.33(b)(3) Critical

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Pertaining to IACUC approved Protocol 028: The proposal for animal use was reviewed along with the medical record for pig #726 on the study. IACUC approved protocol states that the MI model animals are generally stable throughout the study and the protocol describes several postoperative conditions/parameters that are "rare" or "very rare" in these animals including loss of appetite, dehydration, and signs of heart failure. The following instances of veterinary and laboratory staff failing to contact the Attending Veterinarian regarding problems of animal health observed postoperatively following the MI procedure in pig #726 were identified.

1. There were several entries in the animal's record by veterinary and laboratory staff noting decreased interest in food following a study procedure on 2/2/24. Entries in the animal's record for 2/3/24 and 2/5/24 noted that the animal was lying down, lethargic, not finishing food, and was offered a special dietary product or fruit to entice it to eat. A second IACUC approved procedure under injectable anesthesia was scheduled for 2/6/24 and the animal was fasted overnight. The morning of 2/6/24 the entries in the animal's record state that the pig was lethargic and had "peripheral cyanosis" however laboratory staff administered the injectable anesthetic and performed the second procedure. There was no indication from the medical record that the Attending Veterinarian was contacted about the animal's health prior to administering injectable anesthetic prior to performing the study procedure on 2/6/24.

2. According to the medical record, at the conclusion of the 2/6/24 procedure under injectable anesthesia, laboratory staff placed an intravenous catheter, and an inhalant anesthesia agent was then administered to the pig for the "Fluid Replacement" procedure. This procedure is not described in the IACUC approved protocol and there was no indication from the animal's record that the Attending Veterinarian was contacted about the changes in the animal's health prior to administering the inhalant anesthesia agent, prior to placing the intravenous catheter, or prior to performing the "Fluid Replacement" procedure on the animal.

Per this Section, each research facility shall maintain a program of adequate veterinary care that includes the observation of all animals daily to assess their health and well-being. The daily observation of animals may be accomplished by someone other than the Attending Veterinarian (AV). However, a mechanism of direct and frequent communication must be in place to relay timely and accurate information concerning any problems of animal health to the Attending Veterinarian to ensure animals are provided adequate veterinary care. The failure to contact the AV regarding problems of animal health when the pig exhibited clinical signs following the 2/2/24 study procedure resulted inadequate veterinary care and treatment of the animal. The research facility needs to ensure that all personnel understand that timely and accurate problems of health observed in the animals are conveyed to the AV who has the authority to ensure that the animals are provided adequate veterinary care. Correct by 4/5/24.

This inspection and exit briefing were conducted with facility representatives.

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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
130	14-R-0035	001	UNIV. OF MASS. MEDICAL CENTER	27-FEB-2024

Count	Scientific Name	Common Name
000008	<i>Cavia porcellus</i>	DOMESTIC GUINEA PIG
000310	<i>Mesocricetus auratus</i>	SYRIAN / GOLDEN HAMSTER (COMMON PET/RESEARCH TYPE)
000010	<i>Sus scrofa domestica</i>	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000020	<i>Oryctolagus cuniculus</i>	DOMESTIC RABBIT / EUROPEAN RABBIT
000009	<i>Mustela putorius furo</i>	DOMESTIC FERRET
000357	Total	