



Inspection Report

GENERAL HOSPITAL CORPORATION
RES MGMT 149 13TH ST # 5249
CHARLESTOWN, MA 02129

Customer ID: **108**
Certificate: **14-R-0014**
Site: 001
M G H MAIN CAMPUS

Type: ROUTINE INSPECTION
Date: 11-JUL-2023

2.31(c)(7)

Institutional Animal Care and Use Committee (IACUC).

- A total of eight surgical biopsies are approved for animals enrolled on protocol #XXXXN000128. On June 10, 2021, a ninth biopsy procedure was performed on one animal enrolled on this protocol. Increasing the number of procedures constitutes a significant change to ongoing activities which was not reviewed and approved prior to being implemented.

- An animal enrolled on IACUC approved protocol #XXXXN000018 had a surgical biopsy performed on Friday, May 20, 2022. The approved pain management plan on the protocol included the administration of a long-acting opioid and meloxicam daily 5 days post-procedure. The animal received analgesics per protocol on the day of surgery but did not receive meloxicam on May 21 or May 22, 2022. Failure to administer post-operative analgesia in accordance with the protocol constitutes a significant change that did not undergo IACUC review and approval.

- IACUC approved protocol #XXXXN000020 includes the administration of immunosuppressive agents after a transplant procedure, up to six total doses. One animal received a transplant on July 27, 2022 and was subsequently treated with six doses of the immunosuppressive agents per protocol. On August 15, 2022, an additional dose was administered to the animal, which constituted a significant change that did not undergo IACUC review and approval.

-A rabbit enrolled on IACUC approved protocol #XXXXN000015 underwent a study procedure on January 26, 2023. The monitoring schedule on the protocol includes twice daily monitoring for three days after the procedure. On January 27th, only one observation was performed. Failure to monitor animals in accordance with the protocol may compromise the ability of the researchers to detect problems of animal health and constitutes a significant change that did not undergo IACUC review and approval.

These deviations from IACUC approved protocols were identified by the facility and voluntarily reported to USDA. Corrective measures had been implemented prior to inspection; to remain corrected after July 18th, 2023.

2.32(a) **Critical**

Personnel qualifications.

A pig underwent laparotomy on March 25, 2022 to induce a colitis disease model. The approved protocol describes post-procedural analgesia; one of the analgesic medications was given 3 hours later than as directed by the protocol.

Prepared By: EILIS KARR
USDA, APHIS, Animal Care

Date:
18-JUL-2023

Title: VETERINARY MEDICAL
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Received by Title: Facility Representative

Date:
18-JUL-2023



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Additional analgesic medications were prescribed by the veterinarian on March 27, 2022 after the animal refused oral medication in the morning; these were given later than as directed by the veterinarian, one 2 hours later and one 6 hours later. Protocol directed replacement of analgesic patches was also delayed by approximately 40 hours. In these instances, the individual responsible for post-operative care of the animal did not provide appropriate care despite guidance from the protocol and from clinical veterinary staff. The failure to administer analgesics in a timely manner as directed by the veterinarian or protocol after a major surgery can lead potentially to unrelieved pain; personnel must be qualified to perform appropriate post-procedural care. The facility must ensure that all personnel involved in animal care and use are qualified to perform their duties.

To be corrected from July 18th, 2023 forward.

2.32(c)(1)(ii) Critical

Personnel qualifications.

On April 26, 2023, a pair housed goat became entangled in a hay bag and was injured by a pen mate while entangled, requiring veterinary treatment for a laceration. The employee who placed the hay bag in the pen had not attended the facility training during which employees were trained not to use hay bags in goat enclosures. The facility must ensure that all employees are appropriately trained on the proper handling and care of the various species used by the facility.

Corrective measures had been implemented prior to inspection; to remain corrected after July 18th, 2023.

2.38(f)(1)

Miscellaneous.

Two macaques on two different protocols were housed in the same room; animals at this facility are identified by both a tattoo and a corresponding identification tag on the enclosure. When these animals were replaced in enclosures after being handled by facility staff, they were switched from one enclosure to the other without updating the identification tags on the enclosures. Researchers subsequently failed to confirm an animal's tattoo number when handling for a protocol procedure, resulting in a macaque on protocol #XXXXN000018 receiving immunosuppressive treatments intended for a macaque on protocol #XXXXN000128. Due to the physiologic effect of the treatments, the animal required additional monitoring and a 4 week period of recovery. Failure to carefully handle and identify research animals can lead to unexpected and unnecessarily adverse outcomes. The facility must ensure that all animals are handled as carefully as possible and in a manner that does not cause behavioral stress, physical harm, or unnecessary discomfort.

Corrective measures had been implemented prior to inspection; to remain corrected after July 18th, 2023.

This inspection and exit interview were conducted with facility representatives.

Additional Inspectors:

SARA TOBIAS, VETERINARY MEDICAL OFFICER

Prepared By: EILIS KARR
USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER

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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
108	14-R-0014	001	M G H MAIN CAMPUS	11-JUL-2023

Count	Scientific Name	Common Name
000018	<i>Oryctolagus cuniculus</i>	DOMESTIC RABBIT / EUROPEAN RABBIT
000016	<i>Sus scrofa domestica</i>	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000004	<i>Ovis aries aries</i>	SHEEP INCLUDING ALL DOMESTIC BREEDS
000012	<i>Papio hamadryas</i>	HAMADRYAS BABOON
000037	<i>Macaca mulatta</i>	RHESUS MACAQUE
000081	<i>Macaca fascicularis</i>	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000006	<i>Capra hircus</i>	DOMESTIC GOAT
000174	Total	