



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: 19-JUN-2017

2.33(b)(5) CRITICAL

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Adequate pre-procedural and post-procedural care.

***In January 2017 an NHP was noted to be recumbent in its enclosure the morning following an operative procedure conducted as per the IACUC approved protocol. The facility veterinarian was contacted, immediately assessed the animal, and began treatment. The condition of the animal declined during the day despite intensive appropriate treatment and the NHP was euthanized. Upon being notified and in response to this information, the IACUC and AV immediately looked into the incident.

It was determined that there were inconsistencies in the actions of investigator staff for some of the procedures described in the approved protocol related to compound dosing, timing of the administration of compound relative to the operative procedure, and the monitoring the animal following dosing of the compound. In addition, investigator staff failed to contact the facility veterinarian when the NHP developed unexpected symptoms intra and post operatively. These inconsistencies contributed to the adverse effects experienced by the NHP that resulted in the euthanasia of the animal.

***In June 2016 an NHP was noted to be weak and recumbent in its enclosure several days following the administration of a compound that was given to the animal as per the IACUC approved protocol. The facility veterinarian was contacted, immediately assessed the animal, and began treatment. Following several days of intensive treatment, the animal went on to make a full recovery. Upon being notified and in response to this information, the IACUC and AV immediately looked into the incident.

It was determined that the NHP was not monitored and treated by investigator staff as described in the IACUC protocol following the administration of the compound that resulted in the animal experiencing adverse effects that required veterinary intervention. In addition, investigator staff failed to notify the facility veterinarian of the unforeseen changes in the NHP's condition that were identified prior to the onset of the illness.

Per this Section of the Regulations, each research facility shall establish and maintain program of adequate veterinary care that includes adequate pre-procedural and post-procedural care that are in accordance with current

Prepared By: GLADUE PAULA, V M D USDA, APHIS, Animal Care

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established veterinary medical and nursing procedures. Investigator staff must follow the pre and post procedural care as described in the IACUC approved protocols to ensure the health and well-being of the animals, and to ensure the provision of adequate veterinary medical care.

The research facility acted promptly to address both of these incidents by conducting an investigation, reporting the incident to OLAW and USDA, and swiftly implementing appropriate corrective actions to prevent similar incidents in the future. Corrective actions included but were not limited to implementing changes to study procedures and providing additional retraining of investigator staff. To date, no additional incidents have occurred.

This item has been appropriately addressed and corrected by the research facility.

NOTE – Inspection conducted 6/19/17 thru 6/21/17. Exit briefing held on-site 6/21/17 with facility representatives.

END OF REPORT

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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
108	14-R-0014	001	M G H MAIN CAMPUS	19-JUN-17

Count	Scientific Name	Common Name
000074	<i>Macaca fascicularis</i>	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000036	<i>Macaca mulatta</i>	RHESUS MACAQUE
000029	<i>Oryctolagus cuniculus</i>	DOMESTIC RABBIT / EUROPEAN RABBIT
000007	<i>Papio hamadryas</i>	HAMADRYAS BABOON
000020	<i>Sus scrofa domestica</i>	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000166	Total	