



Inspection Report

THE JOHNS HOPKINS UNIVERSITY
265 GARLAND HALL
3400 N CHARLES STREET
BALTIMORE, MD 21218

Customer ID: 81

Certificate: 51-R-0006

Site: 003

JOHNS HOPKINS UNIVERSITY,
THE

Type: ROUTINE INSPECTION

Date: 23-AUG-2021

2.31(d)(8)

Institutional Animal Care and Use Committee (IACUC).

Upon IACUC investigation of the injured pig incident, they determined that the laboratory staff did not provide the analgesia to pigs as prescribed by the protocol. According to the laboratory technician, recovery from anesthesia was better for pigs without the use on analgesia. The Principal Investigator had not submitted an amendment to the IACUC for this change in procedures and did not consult the Veterinary Staff.

Proposed activities and proposed significant changes in ongoing activities that have been approved by the IACUC may be subject to further review and approval. Any changes in activity that involves the care and use of animals must be approved by the IACUC.

This has been corrected by the IACUC through a corrective action and retraining of laboratory personnel.

2.32(a)

Personnel qualifications.

The IACUC protocol PRA after an investigation revealed that 50% of the cranial implants performed by the principal investigator had a negative outcome resulting in euthanasia due to infection from environmental contaminants. Three Rhesus macaques had surgical implants performed by the principal investigator and the surgical sites subsequently became infected despite daily cleaning of the site post-operatively. Samples of the implants and margins were taken, and

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laboratory results revealed various environmental contaminants. Other study animals that had established head implants also had a history of chronic implant infections.

Upon further investigation by the IACUC and veterinary staff, it was determined that there was a consistent break in aseptic technique when the surgeries were being performed. The principal investigator had an improper understanding of how to maintain a sterile surgical field. This resulted in chronic antibiotic resistant infections of the surgical sites and significant neurological symptoms that required the animals to be euthanized.

The research facility did not have appropriate procedures in place to ensure the principal investigator was adequately trained in aseptic surgical methods and procedures. The research facility must conduct training and reviews that provides guidance that will ensure all person conducting surgeries are able to appropriately perform aseptic technique.

The facility implemented an appropriate corrective action plan that included training of all study personnel on aseptic techniques and suspending surgical privileges until demonstrated ability to perform such procedures.

During the inspection of the Traylor Laboratory, expired compounds were noted. The compounds identified were approved for use in the protocol, but they were expired. There were two bottles of Heparin that expired in 2017 and 2018 in a container on the workbench. There were also two bags sodium chloride on the workbench that expired in 2019. The lab technician voluntarily informed the inspector that the Heparin and the sodium chloride were currently being used for the two study rabbits in the laboratory.

The use of expired compounds several years out of date should not be used. All expired drugs shall be discarded or marked 'expired' and stored separately from in date drugs. It is the responsibility of the research facility to ensure all

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scientist, research technicians, animal technicians and other personnel involved in animal care are qualified to perform their duties. The research facility must conduct training and reviews that provides guidance that will ensure all person are able to appropriately use study compounds.

Correct by: August 31, 2021

2.38(f)(1) Critical

Miscellaneous.

On March 3rd, 2021 a pig was used in a cardiac study procedure. The pig's recovery from anesthesia was monitor by two laboratory technicians and a post-doctoral fellow. According to the laboratory technician, the anesthesia recovery was difficult. The animal was checked on by the Principal Investigator multiple times. The pig was transported from recovery to its home enclosure at 8:15pm by the Senior Lab Technician. The pig was checked on by the Senior Laboratory Technician at 12:00am.

On March 4th, 2021, the pig was identified as injured during routine observations performed daily by the Research Animal Resource Veterinary Staff. The pig was not able to stand on its own. The pig was immediately euthanized by Veterinary Staff and a necropsy was performed. The necropsy identified the pig sustained two broken elbows.

The IACUC completed an investigation with the Principal Investigator and laboratory technicians. According to the Senior Laboratory Technician, the pig injured itself when transitioning from the transport cage to the home enclosure. The Senior Laboratory Technician decided to leave the pig after injury was sustained without communicating any of the concerns of animal health to the Veterinary Staff.

Handling of all animals shall be done as expeditiously and carefully as possible in a manner that does not cause trauma or physical harm.

This has been corrected by the IACUC suspending the protocol and a corrective action plan.

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This inspection and exit interview were conducted with facility representatives.

This inspection was conducted 08/24/2021 to 08/27/2021.

Additional Inspectors:

GLORIA MCFADDEN, VETERINARY MEDICAL OFFICER

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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
81	51-R-0006	003	JOHNS HOPKINS UNIVERSITY, THE	23-AUG-2021

Count	Scientific Name	Common Name
000074	<i>Mesocricetus auratus</i>	SYRIAN / GOLDEN HAMSTER (COMMON PET/RESEARCH TYPE)
000008	<i>Canis lupus familiaris</i>	DOG ADULT
000002	<i>Glossophaga soricina</i>	PALLAS'S LONG-TONGUED BAT
000019	<i>Cavia porcellus</i>	DOMESTIC GUINEA PIG
000195	<i>Callithrix jacchus</i>	COMMON MARMOSET
000073	<i>Macaca mulatta</i>	RHESUS MACAQUE
000016	<i>Macaca nemestrina</i>	PIG-TAILED MACAQUE
000002	<i>Macaca radiata</i>	BONNET MACAQUE
000031	<i>Papio hamadryas</i>	HAMADRYAS BABOON
000039	<i>Sus scrofa domestica</i>	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000099	<i>Oryctolagus cuniculus</i>	DOMESTIC RABBIT / EUROPEAN RABBIT
000011	<i>Peromyscus maniculatus</i>	DEER MOUSE
000028	<i>Rousettus aegyptiacus</i>	EGYPTIAN FRUIT BAT
000111	<i>Eptesicus fuscus</i>	BIG BROWN BAT
000012	<i>Chinchilla lanigera</i>	CHINCHILLA (DOMESTICATED)
000019	<i>Mustela putorius furo</i>	DOMESTIC FERRET
000004	<i>Felis silvestris catus</i>	CAT ADULT
000014	<i>Cricetulus griseus</i>	CHINESE HAMSTER
000059	<i>Carollia perspicillata</i>	SEBA'S SHORT-TAILED BAT
000816	Total	



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