

GEDMONDS-WIGGINS INS-0000814763

Inspection Report

University of Houston

Health & Biomedical Sciences Bulding 1

4849 Calhoun Rd HOUSTON, TX 77204 Customer ID: 1458

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Certificate: 74-R-0020

Site: 003

University of Houston

Type: ROUTINE INSPECTION

Date: 25-AUG-2022

2.31(c)(7)

Institutional Animal Care and Use Committee (IACUC).

Records reviewed during this inspection indicate that the PI deviated significantly from the IACUC protocol 15-052. In February 2022, Mannitol – a drug not listed in the protocol - was given. On at least three occasions surgical procedures were not performed as described in the protocol. Deviation from the IACUC-approved protocol can jeopardize the health and well-being of the animals in the study, in addition to potentially altering the outcome of the study which could invalidate the entire purpose of the study and therefore the use of these animals. Regarding activities involving animals, the IACUC shall review and approve, require modifications in (to secure approval), or withhold approval of those components of proposed activities related to the care and use of animals in ongoing activities.

Correction Date: October 7, 2022

2.31(e)(3)

Institutional Animal Care and Use Committee (IACUC).

At the time of inspection it was discovered that the surgical method for the "array" procedure lacked step-by-step details regarding chamber implantation (and removal of) being performed under Protocol 15-052. Lack of a complete description on intended animal use could expose the animals to unnecessary and harmful procedures that could adversely impact

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Date:

Title: VETERINARY MEDICAL

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15-SEP-2022

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USDA, APHIS, Animal Care



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their health and well-being. A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain a complete description of the proposed use for the animals. The facility had the PI amend the protocol where it now includes a complete, detailed explanation of the "array" procedure, and the chamber implantation is no longer apart of the protocol.

Correction Date: To be corrected from this day forward

2.32(b) Critical

Personnel qualifications.

Records reviewed during this inspection indicate that the PI on Protocol 15-052 had issues with his surgical skills which (between March 2018 and July 2022) resulted in NHP's having to undergo multiple repair procedures and endure surgical procedures which lasted much longer than normal. One NHP died on December 10, 2020, after the investigator made a surgical error that resulted in the penetration of the dura during chamber placement surgery. The research facility did not review the qualifications of lab personnel conducting these procedures with sufficient frequency to ensure they were qualified to perform their duties. The qualifications of personnel shall be reviewed with sufficient frequency to fulfill the research facility's responsibilities under sections 2.32 and 2.31. The IACUC investigated these incidents and determined the PI must be retrained, along with pre-, during, and post-operative communications between the research and veterinary staff.

Correct by: To be corrected from this day forward

2.33(b)(4) Critical

Attending veterinarian and adequate veterinary care.

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The veterinarian witnessed lab personnel on protocol 15-052 reusing needles and syringes to flush the skin on the head post of a NHP, and lab personnel on protocol PROTO201800039 fail to leave brain probes in solutions used for cold sterilization for a long enough time to achieve sterilization. As a result, three NHP's experienced CNS signs and brain abscesses - two of which had to be euthanized because of the severity of their condition. Upon discussion with the veterinarians, it was determined that the lab employees never received official training for utilization of aseptic techniques regarding the aseptic procedures. Failure to provide guidance to lab personnel on the aseptic principles necessary to appropriately handle the animals for these research procedures resulted in the use of an improper technique that negatively impacted the health and well-being of these animals. Each research facility shall establish and maintain programs of adequate veterinary care that include guidance to principal investigators and other personnel involved in the care and use of animals regarding handling, immobilization, anesthesia, analgesia, tranquilization, and euthanasia. The facility held a meeting to review the process and aseptic techniques of all individuals who handle the animals, and has also made pre-, during, and post-operative procedural upgrades and trainings.

Correct by: To be corrected from this day forward

2.38(f)(1) Critical

Miscellaneous.

Despite guidance from the veterinarian to use drill guides when performing all cranial surgeries on protocol 15-052, the PI failed to do so, leading to penetration of the dura of two NHP's – one of which had to be euthanized. In addition, the veterinarian also advised the PI to use less surgical cement on another NHP under this protocol due to concerns regarding wound healing and infections. However, according to the veterinarian the PI failed to follow this advice, resulting in excessive skin margin regression (around the cranial hardware) and an infection. Lastly, records indicate that on March 23, 2021, a Rhesus macaque - under protocol PROTO201800039 - experienced anesthetic complications. Revival

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attempts were not successful when she was mistakenly given an anesthetic (Anased) rather than the reversal drug Antisedan. Failure to properly handle the animals [as directed] can negatively impact their health and well-being. Handling of all animals shall be done as expeditiously and carefully as possible in a manner that does not cause trauma, behavioral stress, physical harm, or unnecessary discomfort. Corrective actions taken by the facility regarding the drug mix-up included training and no longer ordering Anased to avoid confusion with Antisedan.

Correct by: September 21, 2022

This inspection and exit interview were conducted with facility representatives.

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Inspection Date: 25-Aug-2022

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1458	74-R-0020	003	University of Houston	25-AUG-2022

CountScientific NameCommon Name000035Macaca mulattaRHESUS MACAQUE000003Callithrix jacchusCOMMON MARMOSET000008Oryctolagus cuniculusDOMESTIC RABBIT / EUROPEAN RABBIT

000046 **Total**