



Inspection Report

BROWN UNIVERSITY

Customer ID: 267

Certificate: 15-R-0003

Site: 001

BIO MEDICAL CENTER, MEDICAL RESEARCH LABS.

34 OLIVE ST., BOX G-F287

Type: ROUTINE INSPECTION

Date: Jul-28-2010

PROVIDENCE, RI 02912

2.31 (c) (7)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31 (c) (7) states - "IACUC functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall: (7) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities."

1. Pertaining to teaching Protocol #0808025: On 5/9/09 student investigators performed surgical procedures on 3 animals that were not described in the IACUC approved proposal for animal use. Two of the animals experienced complications during the surgical procedure and were euthanized while under anesthesia. The faculty investigator notified the IACUC after he/she realized that unapproved procedures had been conducted by the students.

The IACUC must review and approve any proposed significant changes to ongoing research activities before the proposed change(s) can be implemented by the investigator. After the IACUC was notified of the deviations, it undertook corrective measures including: (1) providing additional training on IACUC requirements to the investigators; (2) implementing additional oversight procedures to ensure that no other deviations occur; and (3) notifying federal agencies of the deviations. The next time the teaching protocol was offered was the Spring 2010 semester; no unapproved procedures were conducted.

2.31 (e) (3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31 (e) (3) states - "A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain the following: (3) A complete description of the proposed use of the animals."

1. Review of Protocol #1002008: There were inconsistencies or incomplete descriptions provided in the IACUC approved protocol for each of the following proposed uses of the animals.

a. The protocol states on pg 6 that an MRI will last no longer than 1 hour but on pg 4 states that it may last 1 to 4

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hours.

b. The protocol states on pg 1 of Appendix 5 that supplemental water will be provided to the NHPs after they are returned to their home cage following testing sessions; but the answer to question 3 of the addendum to Appendix 5 states that supplemental water will be provided to the NHPs while the animal is still in the laboratory area after the testing sessions.

c. The protocol contained an incomplete description of how the NHPs will be provided unlimited access to water during non-study periods.

A proposal for animal use must contain a complete description of the proposed use of the animals. The IACUC needs to: (1) address this item as identified for this protocol and (2) ensure that all active proposals comply with Section 2.31 (e) (3). Correct (1) by 9/3/10 and (2) by 4/4/11.

2.32 (a)

PERSONNEL QUALIFICATIONS.

Section 2.32 (a) states - "It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction to those personnel."

1. NHP #H310 used under Protocol #1002008 went without water for 72 hours from 4/5/10 through 4/7/10 when the investigator was out of town. The investigator forgot to make arrangements with other laboratory staff to take care of the animal during his/her absence. The protocol also states that NHPs will be given unlimited access to water during periods when the NHP is not undergoing testing. As soon as personnel discovered what had happened, the NHP was evaluated by the veterinary staff, provided full access to water and closely monitored. The NHP experienced no adverse effects as a result of the 72 hours without access to water.

It is the responsibility of a research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties to ensure the health and well-being of the animals. The research facility addressed this item by: (1) providing additional training to the investigator on the requirements and standard operating procedures, and (2) implementing additional measures to track the provision of water to NHPs on study. To date there have been no additional incidents of NHPs going without access to water when not on study.

2. In order to inspect the Bats housed in the BMC quarantine area, the members of the inspection team wore the personal protective equipment (PPE) specified on the door that was required in order to enter the room. The door opened while the inspection team was in the room and 2 students came in; neither student was wearing the required PPE as was clearly posted on the door. When the students were questioned, it was clear that they were unfamiliar with all aspects of the Bat quarantine procedure.

Inadequate training in any aspect of animal care and use can result in harm to the animals and negatively affect the

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animals' welfare. The research facility needs to ensure that all personnel identified on research proposals using Bats are appropriately trained and familiar with the prescribed Bat quarantine procedures. Correct from this date forward.

3.75 (c) (1) (i)

HOUSING FACILITIES, GENERAL.

Section 3.75 (c) (1) (i) states - "Any surfaces that come in contact with nonhuman primates must: (i) Be free of excessive rust that prevents the required cleaning and sanitization."

1. SFH-551: There were enrichment devices constructed of white PVC pipe and metal circular shaped clamps were mounted on the outside of the front of the primary enclosures. The surface of the clamps were rusty and the outside of the PVC pipes in contact with the clamps were stained orange. The clamps were located on the enclosures so that the clamps could be handled or licked/chewed on by the NHPs housed in the enclosures. This affected 7 NHPs.

The presence of rust on surfaces can interfere with the required cleaning and sanitization practices. The Registrant corrected this item during the inspection by removing the enrichment devices from the NHP enclosures and then replacing the rusted clamps with newly purchased moisture resistant metal clamps.

3.75 (e)

HOUSING FACILITIES, GENERAL.

Section 3.75 (e) states - "All food must be stored in a manner that prevents contamination and deterioration of its nutritive value.....open food supplies must be kept in leakproof containers with tightly fitting lids to prevent spoilage and contamination."

1. A plastic grocery bag containing an opened bag of carrots, an opened bag of peanuts, and a banana was located on the top shelf of the cart outside BMC-358. The shelves of the cart were cluttered in appearance with several boxes containing PPE and some other husbandry items. There was also a plastic pump bottle of hand sanitizer next to the grocery bag of food items and a covered trash receptacle next to the cart. Facility personnel immediately removed the bag of food items from the cart.

Opened food supplies for NHPs must be kept in a leakproof container with a tightly fitting lid to prevent contamination, spoilage, and deterioration of nutritive value. The Registrant needs to ensure that all personnel working with NHPs are familiar with this requirement for the health of the animals. Correct by 8/9/10.

3.81 (c) (1)

ENVIRONMENT ENHANCEMENT TO PROMOTE PSYCHOLOGICAL WELL-BEING.

Section 3.81 (c) (1) states - "Research facilities must develop, document, and follow an appropriate plan for environment enhancement adequate to promote the psychological well-being of nonhuman primates.....The plan, at a minimum, must address each of the following: (c) Special considerations. Certain nonhuman primates must be

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provided special attention regarding enhancement of their environment, based on the needs of the individual species and in accordance with the instructions of the attending veterinarian. Nonhuman primates requiring special attention are the following: (1) Infants and young juveniles."

1. The "Special Considerations" section of the research facility's Environmental Enrichment Plan for NHPs (EEP) dated 10/1/09 addresses the need for and the provision of special attention for several groups of NHPs including infants. However young juvenile NHPs are now being housed at the research facility; the current EEP does not address the special consideration regarding the enhancement of the environment for young juvenile NHPs.

The Environmental Enrichment Plan for NHPs must address each of the provisions outlined in this Section. The research facility's EEP must address the special attention required for young juvenile NHPs. Correct by 9/3/10.

3.81

ENVIRONMENT ENHANCEMENT TO PROMOTE PSYCHOLOGICAL WELL-BEING.

Section 3.81 states - "Research facilities must develop, document, and follow an appropriate plan for environment enhancement adequate to promote the psychological well-being of nonhuman primates."

1. The research facility has an Environmental Enrichment Plan for Non-Human Primates (EEP) in place that is directed by the Attending Veterinarian (AV). According to the AV, facility personnel are following the provisions of the EEP as well as providing some additional measures under his/her direction; however facility personnel are not routinely documenting that the EEP is being followed as required per this Section.

A research facility must document that the Enrichment Plan for Non-Human Primates is being followed to demonstrate compliance with this Section. The Registrant needs to ensure that personnel document that the EEP is being followed. Correct from this date forward.

3.83

WATERING.

Section 3.83 states - "Potable water must be provided in sufficient quantity to every nonhuman primate housed at the facility.....it must be offered to them as often as necessary to ensure their health and well-being, but no less than twice daily for at least 1 hour each time, unless otherwise required by the attending veterinarian, or as required by the research proposal approved by the Committee at research facilities."

1. According to the April 2010 daily observation sheet for NHP #H310 under Protocol #1002008, the NHP went without water for 72 hours from 4/5/10 through 4/7/10 when the investigator was out of town. The investigator forgot to make arrangements with other laboratory staff to take care of the animal during his/her absence. The protocol also states that NHPs will be given unlimited access to water during periods when the NHP is not undergoing testing.

As soon as personnel discovered what had happened, the NHP was evaluated by the veterinary staff, provided full

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access to water and closely monitored. The NHP experienced no adverse effects as a result of the 72 hours without access to water.

Water must be provided to NHPs in sufficient quantity to ensure their health and well-being but no less than twice a day for at least one hour at a time unless otherwise required by the Attending Veterinarian or by the IACUC approved research proposal. The research facility addressed this item by: (1) providing additional training to the investigator on the requirements and standard operating procedures and (2) implementing additional measures to track the provision of water to NHPs on study to ensure that no further incidents occur. To date, there have been no additional incidents of NHPs going without access to water when not on study.

3.125 (a)

FACILITIES, GENERAL

Section 3.125 (a) states - "The indoor.....housing facilities shall be structurally sound and shall be maintained in good repair to protect the animals from injury and to contain the animals."

1. BMC 447: One of the coated wire small mesh panels that make up the top of the Bat enclosure had detached from the metal frame in one area so that there was an opening approximately 3 x 1 inches in size. This opening was large enough for a Bat to squeeze through and escape from the enclosure and be loose inside the room. 16 Bats were housed in the enclosure.

2. BMC 347: The ceiling mounted light fixture directly above the primary enclosures of 2 Pigs was missing its protective cover. The cover on a light fixture protects the glass light bulb from breakage that would drop into the room.

Indoor housing facilities should be structurally sound and in good repair to contain the animals and to protect the animals from injury. The Registrant corrected these items during the inspection by: (1) re-securing the wire mesh panel to the metal frame to close the opening in the top of the Bat enclosure and (2) replacing the missing light fixture cover.

NOTE - This inspection was conducted 7/28/10 and 7/29/10. Exit interview held 8/2/10 with facility personnel. END OF REPORT.

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