



Inspection Report

MASSACHUSETTS EYE AND EAR INFIRMARY

Customer ID: 119

Certificate: 14-R-0022

Site: 001

MASSACHUSETTS EYE & EAR INFIRMARY

243 CHARLES STREET

Type: ROUTINE INSPECTION

BOSTON, MA 02114

Date: Feb-01-2012

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 Protocol #04-08-019: During the review of the records for study animals it was noted that the type of anesthetic agent used to maintain general anesthesia during the surgeries had been changed to an agent not included in the IACUC approved protocol. In addition, the animals were not monitored following the administration of drug therapies as was described in the IACUC approved protocol.

There was no documentation that these significant changes in the ongoing activity had undergone review and approval by the IACUC prior to the investigator having implemented the changes.

Per this Section of the Regulations, the IACUC should review and approve any proposed significant changes to ongoing research activities before the investigator can implement the proposed changes. The IACUC needs to: (1) address the deviations identified for this protocol and (2) ensure that all active proposals including AWA covered species are in compliance with Section 2.31 (c) (7).

Correct (1) and (2) by 3/9/12.

2.31 (d) (1) (ii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31 (d) (1) (ii) states - "The IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements: (ii) The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources.....used to determine that alternatives were not available."

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1. Review of Protocol #91-11-027: The written narrative of the methods and sources used to determine that alternatives were not available to the potentially painful or distressful procedures described in the proposal for animal use does not include the procedure of tracheostomy that is described in the protocol.

2. Review of Protocol #04-08-019: The written narrative of the methods and sources used to determine that alternatives were not available to the potentially painful or distressful procedures described in the proposal for animal use does not include the procedure of water deprivation that is described in the protocol.

Per this Section of the Regulations, the IACUC should determine during the review of proposed animal use activities that the proposed activities meet all of the requirements as per Section 2.31 (d) (1) that includes the consideration of alternatives by the investigator to the potentially painful or distressful procedures described in the proposal for animal use.

The IACUC needs to: (1) address this item as identified for the 2 protocols and (2) ensure that all active proposals including AWA covered species are in compliance with Section 2.31 (d) (1) (ii).

Correct (1) by 3/8/12 and (2) by 8/10/12.

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. The review of Protocol #04-08-019 and the review of records maintained for study animals identified incomplete descriptions of some proposed animal use activities in the IACUC approved protocol.

a. The protocol called for "water deprivation" of non human primates and required the determination of a baseline weight of each animal on this particular study. However the protocol did not describe how the baseline weights of the animals would be determined and no records were identified with baseline weights of any of the NHPs. A complete description of how a baseline weight is determined is necessary to prevent excessive weight loss during this study that includes water deprivation. Failure to provide a description of this procedure may be detrimental to an animal's normally expected weight gain.

b. Therapeutic agents were administered multiple times to the study animals, however there was no description in the protocol as to the total number of courses of drugs to be administered. The repeated administration of therapeutic agents may lead to unintended effects on the health of study animals.

Per this Section of the Regulations, a proposal for animal use must contain a complete description of the proposed use of the animals so the IACUC can determine that the proposed activities are in accordance with the requirements of this subchapter.

The IACUC needs to: (1) address this item as identified for this proposal and (2) ensure that all active

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proposals including AWA covered species are in compliance with Section 2.31 (e) (3). Correct (1) by 3/8/12 and (2) by 8/10/12.

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. The surgical/medical record for one animal was identified in a laboratory of one the institution's Principal Investigators (PI) that indicated an animal died from blood loss due to a craniotomy. The review of records for some of the other animals used by the PI's laboratory also indicated death during the procedure. Although the procedure was a terminal procedure, the end of the procedure was not to have the animal die during the procedure from blood loss or to die during the procedure from other causes. There were no records or documents available on the training of individuals performing this procedure to ensure that they were trained and/or qualified to perform the surgical procedure.

Currently the institution's requirement or policy as described to APHIS officials was that the PI is responsible for training of individuals working in their laboratory. However per this Section of the Regulations, it is the responsibility of the research facility is to ensure that all scientists, research technicians and other personnel are adequately trained to perform their duties.

Correct for all active protocols using AWA species by 4/9/12.

2.33 (b) (2)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Section 2.33 (b) (2) states - "Each research facility shall establish and maintain programs of adequate veterinary care that include: (2) The use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries. "

1. Medical Records containing treatment of animals were found to be incomplete in the documentation of prescribed treatment and resolution of conditions identified by staff. Treatment regimens should be documented consistently until the conditions are resolved. Incomplete documentation in medical records does not guarantee that animals are treated in a manner consistent with good veterinary medical care.

2. Chemical grade pentobarbital sodium solution was being used by one group of laboratory staff to euthanize study animals. The use of chemical grade pentobarbital solution had not been approved for use as a method of euthanasia by the IACUC or the Attending Veterinarian. Pharmaceutical-grade medications should be used by investigators whenever they are available, even in acute procedures. Non-pharmaceutical-grade chemical compounds should only be used in regulated animals after specific review and approval by the IACUC for reasons such as scientific necessity or non-availability of an acceptable veterinary or human pharmaceutical-grade product. Cost savings alone are not an adequate justification for using non pharmaceutical-grade compounds in regulated animals.

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Per this Section of the Regulations, a research facility should establish and maintain a program of veterinary care in accordance with current established veterinary medical and nursing procedures.

Correct from this date forward.

3.56 (c)

SANITATION.

Section 3.56 (c) states - " Housekeeping. Premises (buildings and grounds) shall be kept clean and in good repair in order to protect the animals from injury and to facilitate the prescribed husbandry practices set forth in this subpart. "

1. The casters on some of the cage racks were noted to be rusty and there was rust noted along some of the edges of the ceiling mounted steel panel in 506. The presence of rust on surfaces can interfere with the effectiveness of cleaning and disinfection.

Per this Section of the Regulations, premises should be kept clean and in good repair to facilitate the prescribed husbandry practices. The facility needs to address this item. Correct by 3/9/12.

3.81 (a)

ENVIRONMENT ENHANCEMENT TO PROMOTE PSYCHOLOGICAL WELL-BEING.

Section 3.81 (a) states - " Social grouping. The environment enhancement plan must include specific provisions to address the social needs of nonhuman primates of species known to exist in social groups in nature. Such specific provisions must be in accordance with currently accepted professional standards, as cited in appropriate professional journals or reference guides, and as directed by the attending veterinarian."

1. There were two single housed NHPs in the same room without a scientific justification in place for housing the animals in that manner. Both NHPs have been at the institution for the past 3 months and social housing had not been considered or identified as an option for the 2 animals.

Per this Section of the Regulations, the NHP Enrichment Plan must include specific provisions to address the social needs of NHPs known to exist in social groups in nature. Institutions that do not have the space or appropriate sized caging available should place a priority on this aspect of their environmental enrichment plan and take proactive measures to ensure that all NHPs are socially housed when appropriate.

Correct by 8/10/12.

3.81 (b)

ENVIRONMENT ENHANCEMENT TO PROMOTE PSYCHOLOGICAL WELL-BEING.

Section 3.81 (b) states - " Environmental enrichment. The physical environment in the primary enclosures must be enriched by providing means of expressing non-injurious species-typical activities. "

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1. At the time of the inspection, an NHP was observed holding a rubber tipped plunger from a 20 cc syringe and the plastic case for the syringe was noted inside the animal's primary enclosure. The APHIS officials observed the animal take the rubber tip off the end of the plunger and put it into its mouth and then into its cheek pouch. It was learned that the plastic items had been given to the NHP as a toy by a member of the laboratory staff.

Per this Section of the Regulations, primary enclosures for NHPs should be enriched by providing non-injurious types of activities. The type of plastic the plunger and syringe case are made of can be readily chewed by NHPs and the rubber tip of the plunger can be easily removed by the animals. In both situations, the pieces of the syringe and case can be swallowed and ingested by the NHPs or can result in an airway obstruction. Enrichment devices provided to NHPs should be such that they are safe and do not pose a risk to the animal's health.

Correct from this date forward.

3.84 (c)

CLEANING, SANITIZATION, HOUSEKEEPING, AND PEST CONTROL.

Section 3.84 (c) states - " Housekeeping for premises. Premises where housing facilities are located, including buildings and surrounding grounds, must be kept clean and in good repair in order to protect the nonhuman primates from injury, to facilitate the husbandry practices required in this subpart. "

1. There were areas of peeling paint noted in the ceiling of the cage washer room and the ceiling of the hallway outside 501.
2. The shelf in the cabinet underneath the sink was made of unsealed wood and the edge of the wooden wall bumper in the cage washer room was chipped so that unsealed wood underlying the surface of the wall bumper was exposed. Unsealed wooden surfaces are not substantially impervious to water and may not be effectively cleaned and sanitized.
3. There was grout missing between several tiles in the wall of the cage washer room. As a result there was a gap between adjacent tiles that can trap dirt and debris and interfere with effective cleaning and sanitation.
4. The cabinet underneath the sink in 501 was cluttered in appearance due to an assortment of items and was in need of cleaning.
5. The ceiling mounted air vent in the cage washer room had an accumulation of dust and particulate debris and needed to be cleaned.

Per this Section of the Regulations, premises must be kept clean and in good repair to facilitate prescribed husbandry practices. The facility needs to address these items. Correct 1, 2, and 3 by 5/15/12; correct 4 and 5 by 2/17/12.

NOTE - The inspection and exit interview were conducted by APHIS personnel Drs. Paula Gladue and Michael Smith. Inspection conducted 2/1/12 through 2/3/12. Exit interview held 2/3/12 on-site with facility personnel. Report delivered by e-mail on 2/9/12. *END OF REPORT*

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