



Inspection Report

BRIGHAM AND WOMENS HOSPITAL

Customer ID: 144

Certificate: 14-R-0092

Site: 001

HARVARD SCHOOL OF MEDICINE

RESEARCH ADMINISTRATION

75 FRANCIS ST

Type: ROUTINE INSPECTION

Date: Feb-09-2010

BOSTON, MA 02115

2.31 (d) (1) (ii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31 (d) (1) (ii) - "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...

1. Review of Protocol #03658 that was approved by the IACUC on 5/29/09:

a. 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 immunosuppression in Sheep that is described in the proposal.

In order to approve proposed animal use activities or proposed changes to ongoing activities, the IACUC should...
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2.31 (e) (3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31 (e) (3) - "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 #03658:

a. There is a discrepancy in the total number of animals requested for the study, the number of animals per group, and the number of groups on file of 22 of the proposed groups.

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b. There are incomplete details provided for the proposed use of the animals that are assigned to group 5.

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 meet the requirements outlined under Sections 2.31 (d) (1) and 2.31 (e). The IACUC needs to address the items identified for this proposal. Correct by 3/15/10.

2.32

PERSONNEL QUALIFICATIONS.

2.32 (a) - "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. During the semi-annual facility inspection on 9/8/09 the inspection team identified a Sheep on Protocol #03658 exhibiting anorexia, weight loss, labored breathing and signs of upper airway infection. The AV was immediately contacted and treatment was started, but the animal died the following day.

The IACUC immediately began an investigation and subsequently identified several issues that may have contributed to the death of the Sheep. These included: (1) a lack of familiarity of the laboratory staff in required record keeping and proper documentation of observations, procedures performed and substance administration of/to study animals, (2) a lack of familiarity of laboratory staff with the procedure to contact the attending veterinarian concerning problems of animal health or behavior, and (3) a lack of familiarity of some laboratory members with all of the procedures included in the approved proposal.

It is 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. Following the investigation, the IACUC and AV provided all of the laboratory staff with additional training and instruction on the research facility's record keeping requirements, the appropriate methods for communication with the attending veterinarian regarding problems of animal health or behavior, and familiarity with the details of all procedures included in the proposal for animal use to ensure that another incident does not occur.

The Registrant has appropriately addressed this item and it has been corrected.

2. Dog #706914 on Protocol #02336 died unexpectedly during a procedure on 1/18/09. Upon further investigation, the IACUC and AV determined that the death was due to anesthesia overdose, the length of the procedure was longer than expected based on the description in the approved proposal, and inadequate medical and anesthesia records were kept by the laboratory staff.

It is 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. Following the

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