



Inspection Report

BRIGHAM AND WOMENS HOSPITAL

Customer ID: 144

Certificate: 14-R-0092

Site: 001

BRIGHAM AND WOMENS HOSPITAL

RESEARCH ADMINISTRATION

Type: ROUTINE INSPECTION

BOSTON, MA 02115

Date: Jul-19-2011

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."

1. Review of Protocol #04677: 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 scheduling that is described in the proposal.

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

Correct by 8/22/11.

2.33 (b) (5) REPEAT

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Section 2.33 (b) (5) states - "Each research facility shall establish and maintain programs of adequate veterinary care that include: (5) Adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedures."

1. Pertaining to Protocol #03359: During veterinary rounds in the late summer of 2010, a clinical veterinarian discovered that 2 Rabbits had died following the administration of general anesthesia for a short procedure. Upon further investigation, it was determined that the investigator had administered the dosage of anesthetic that was only approved for use in terminal procedures and was higher than the dose approved for short procedures. As a result of

Prepared By:

PAULA S GLADUE, V M D USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1054

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(b)(6), (b)(7)(c)

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administering the incorrect dose, he/she had overdosed the Rabbits that resulted in the death of the 2 Rabbits.

Per this Section of the Regulations, all personnel at a research facility who are responsible for providing veterinary care to study animals should provide adequate pre-procedural care in accordance with current established veterinary medical and nursing procedures to ensure the health and well being of the animals.

Following this incident, the clinical veterinarian provided additional instruction and re-training to the investigator and all members of his/her staff on the administration of anesthesia and monitoring procedures for animals following general anesthesia. Several Rabbits have undergone anesthesia for survival procedures since the re-training and there have been no additional incidents.

2. Pertaining to Protocol #03167: Medical records of at least 4 Guinea Pigs used under this protocol were reviewed during the inspection. The APHIS inspector noted that each of the Guinea Pig's medical records contained multiple entries that included the term "anesthetize" but the name, dose, and route of administration of the anesthetic agent had not been recorded. In addition, the Guinea Pigs weighed 300 grams at the time of arrival in April 2011 but had grown since their arrival and appeared to have gained additional weight but there was no indication that the animals' weight was being measured.

It could not be determined from the information provided in the Guinea Pigs' medical records whether the animals had been anesthetized in accordance with the method and dose of anesthesia included in the IACUC approved protocol and was described using a mg per kg body weight dosage.

Per this Section of the Regulations, all personnel at a research facility who are responsible for providing veterinary care to study animals should provide adequate pre-procedural care in accordance with current established veterinary medical and nursing procedures. These procedures include that the name, dose, and route of administration of any medications administered to an animal is recorded to document the provision of appropriate medical care to ensure the health and well being of the animals.

The research facility addressed this item during the inspection by contacting the investigator to discuss and review the proper procedures for documenting and recording the administration of anesthesia to study animals.

3.131 (c)

SANITATION.

Section 3.131 (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. T1604: The water supply to the wall mounted water fixtures inside the Sheep enclosures is by copper pipes that had been painted white. The paint was flaking off the water pipes in some areas and the paint had worn off the pipes in other areas exposing the bare surface of the copper. There is the potential for dirt and debris to collect under the

Prepared By:

PAULA S GLADUE, V M D USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1054

Jul-20-2011

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

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edges of the flaking paint and interfere with effective cleaning and sanitization, as well as the potential for health issues in the Sheep from ingestion of the paint flakes. This affected 6 Sheep.

Per this Section of Regulations, premises should 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. The research facility needs to address the condition of the water pipes to maintain the facility and for the health of the Sheep.

Correct by 8/22/11.

NOTE - This inspection was conducted 7/19/11 through 7/21/11. Exit interview held 7/21/11 with facility personnel.
END OF REPORT.

Prepared By:

PAULA S GLADUE, V M D USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1054

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Certificate: 14-R-0092

Site: 001

BRIGHAM AND WOMENS HOSPITAL

RESEARCH ADMINISTRATION

Type: ROUTINE INSPECTION

BOSTON, MA 02115

Date: Aug-10-2010

2.33 (b) (5)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Section 2.33 (b) (5) states - "Each research facility shall establish and maintain programs of adequate veterinary care that include: (5) Adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedures."

1. Pertaining to Protocol #03658 and Sheep #765: The protocol amendment approved 3/16/10 states that laboratory staff will check the animals once a day for 12 weeks following the second procedure. According to IACUC records, Sheep #765 was monitored daily by laboratory staff for the first 2 weeks following the second procedure but after the first 2 weeks the sheep was not monitored daily by laboratory staff as described in the amendment.

All personnel who are responsible for providing veterinary care to study animals at a research facility should provide the post procedural care as specified in the approved proposal for animal use to ensure the health and well being of the animals.

After the IACUC learned of the departure from the approved monitoring schedule, additional training and instruction was provided to laboratory staff. The Registrant appropriately addressed this item.

NOTE - The non-compliant items identified at the time of the previous inspection conducted 2/9/10 have been corrected. Exit interview held with facility personnel 8/10/10. END OF REPORT.

Prepared By:

PAULA S GLADUE, V M D USDA, APHIS, Animal Care

Date:

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Inspection Report

BRIGHAM AND WOMENS HOSPITAL

Customer ID: 144

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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 of the methods and sources.....used to determine that alternatives were not available."

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 determine that the proposed activities/changes meet the requirements as described in Section 2.31 (d) (1) that includes that a principal investigator has considered alternatives to the procedures that may cause more than momentary pain and or distress to the animals that are described in a proposal for animal use. Correct from this date forward.

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 as described on pages 6, 8, and 33 of the proposal.

Prepared By:

PAULA S GLADUE, V M D USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1054

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(b)(6), (b)(7)(c)

Date:

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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

Prepared By:

PAULA S GLADUE, V M D USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1054

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investigation, the IACUC and AV provided the laboratory staff with retraining on medical and anesthesia record keeping requirements, anesthesia methods were reviewed, and the anesthesia regimen in the protocol was modified.

There have been no further incidents in study animals since the retraining of laboratory staff and the change of anesthesia regimen. The Registrant has appropriately addressed this item and it has been corrected.

NOTE - This was a full facility inspection from 2/9/10 through 2/11/10 with the exit on 2/11/10.

Prepared By:

PAULA S GLADUE, V M D USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1054

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RESEARCH ADMINISTRATION

Certificate: 14-R-0092

75 FRANCIS ST

Site: 001

(b)(2) (b)(7)(f)

Type: ROUTINE INSPECTION

BOSTON, MA 02115

Date: Nov-03-2008

2.31 (d) (1) (ix)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31 (d) (1) (ix) - "The IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements: Major operative procedures on non-rodents will be conducted only in facilities intended for that purpose which shall be operated and maintained under aseptic conditions."

1. TH1635A is a dedicated surgical space that may be used for operative procedures on both AWA covered species and non-AWA covered species. At the time of the inspection, the APHIS inspectors observed investigators performing surgery on a non-AWA covered species. The investigators were not using aseptic procedures or using aseptic surgical techniques while performing the surgery in this dedicated surgical space.

Facilities intended for major operative procedures on non-rodents should be operated and maintained under aseptic conditions. The IACUC needs to address this issue. Correct by 12/1/08.

NOTE - This was a full facility inspection of the Main Location of the Registrant in Boston, MA conducted by USDA/APHIS/AC VMOs Paula S. Gladue, V.M.D. and Tonya Hadjis, D.V.M. from 11/3/08 through 11/5/08 with the exit interview on 11/5/08.

Prepared By:

PAULA S GLADUE, V M D USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1054

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Title:

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BRIGHAM AND WOMENS HOSPITAL

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Site: 002

(b)(2) (b)(7)(C)

RESEARCH ADMINISTRATION

75 FRANCIS ST

Type: ROUTINE INSPECTION

Date: Oct-21-2009

BOSTON, MA 02115

There was no AWA covered activity at this site of the Registrant at the time of the inspection.

NOTE - IACUC records and documents are reviewed at the Main Site of Registrant in Boston, MA.

Prepared By:

PAULA S GLADUE, V M D USDA, APHIS, Animal Care

Date:

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Date:

Title:

Oct-22-2009



Inspection Report

BRIGHAM AND WOMENS HOSPITAL

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RESEARCH ADMINISTRATION

Certificate: 14-R-0092

75 FRANCIS ST

Site: 002

(b)(2) (b)(7)(F)

Type: ROUTINE INSPECTION

BOSTON, MA 02115

Date: Oct-07-2008

There was no AWA covered activity at this Location of the Registrant at the time of the inspection.

NOTE - This inspection was of the Norton, MA Location of Site 001 of Registrant 14-R-0092. All IACUC records and documents are reviewed at the Main Location of the Registrant in Boston, MA.

Prepared By:

PAULA S GLADUE, V M D USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1054

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(b)(6), (b)(7)(C)

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Title:

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