



Inspection Report

CAROLINAS MEDICAL CENTER

Customer ID: **808**

Certificate: **55-R-0107**

Site: 001

CAROLINAS MEDICAL CENTER

DIR OF COMPARATIVE MEDICINE, PO BOX 32861

Type: ROUTINE INSPECTION

CHARLOTTE, NC 28232

Date: Dec-09-2009

No noncompliances noted on inspection.

End of report.

Prepared By:

NICOLETTE PETERVARY, V M O USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 6005

Dec-09-2009

Received By:

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

Date:

Title:

Dec-09-2009



Inspection Report

CAROLINAS MEDICAL CENTER

Customer ID: 808

DIR OF COMPARATIVE MEDICINE, PO BOX

Certificate: 55-R-0107

Site: 001

CAROLINAS MEDICAL CENTER

CHARLOTTE, NC 28232

Type: ROUTINE INSPECTION

Date: Mar-18-2009

2.31 (d) (1) (i)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31(d)(1)(i) states "IACUC review of activities involving animals. (1) In order to approve proposed activities or proposed significant changes in ongoing activities, the IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with this subchapter unless acceptable justification for a departure is presented in writing; Further, the IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements: Procedures involving animals will avoid or minimize discomfort, distress, and pain to the animals."

The IACUC needs to re-review rabbit protocol 05-08-02A to ensure that the procedure will avoid or minimize discomfort, distress, and pain. The 3 animals which were operated on had significant complications, including lack of appetite, weight loss, and they did not use their rear legs normally. To be corrected by 4-20-09

2.31 (c) (4)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31(c)(4) states "IACUC functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall review, and, if warranted, investigate concerns involving the care and use of animals at the research facility resulting from public complaints received and from reports of noncompliance received from laboratory or research facility personnel or employees."

An individual filed a complaint with the IACUC alleging the institution did not have an attending veterinarian who filled the role as described in the Animal Welfare Act. The complaint also alleges intimidation of the current attending veterinarian by the Assistant Vice President of Research.

Although the IACUC addressed issues of clarifying who is the chair and who is the attending veterinarian, they did not adequately address the issue of intimidation of the current attending veterinarian. The IACUC stated the concerns in the complaint are administrative in nature and did not compromise the animal care and use program. There was a minority opinion to this. The IACUC needs to investigate the issue of intimidation. To be corrected by 4-20-09.

Prepared By:

LISA K MACELDERRY, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1055

Mar-25-2009

Received By:

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

Date:

Title:

Mar-25-2009



Inspection Report

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: 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."

The rabbit protocol 05-08-02A was not followed as written. The protocol states the rabbits were to be between 3.5 - 5 kg and 3 - 5 months old, but two were operated on at 2.9 kg. and 2.6 kg. The procedure requires a specific size animal and these rabbits operated on did not meet the weight requirement. The rabbit protocol post operative care was not followed as written, possibly resulting in unrelieved pain in 3 rabbits. The rabbits had bilateral knee surgeries, and afterward, the rabbits had decreased appetites, weight losses when they should have been gaining weight, and they did not use their rear legs normally. The veterinarian used different analgesics than what was in the protocol believing less handling for injections would be less stressful for the rabbits, but the rabbits did not appear to respond to the analgesics. The humane endpoints stated in the protocol include non-weight bearing, osteomyelitis, anorexia and weight loss of 15-20% compared with non-operated controls. Rabbit number 2 during the month after the surgery had weight loss of 17 - 20%. This rabbit was most affected as exhibited by not fully using either leg during movement. This rabbit did not exhibit other signs of pain, as it would come to the front of the cage to be picked up, carried, and held.

Although these rabbits showed conflicting signs of pain, the decreased appetites and weight loss should have been an indication to try other analgesics immediately or euthanize the rabbits per protocol if the pain could not be relieved and the endpoints were reached. The protocol needs to be followed as written or amendments submitted.

To be corrected by 4-20-09.

2.31 (d) (1) (viii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31(d)(1)(viii) states "Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures."

The surgeon for rabbit protocol 05-08-02A does not have adequate experience for this species for the surgical procedure. The protocol states the surgeon has 6 years experience in orthopedic surgeries and has done this procedure in humans for 2 years. It says he has one year experience with rabbit and rat bone isolation surgeries for bone marrow retrieval. No experience is listed for joint surgeries in rabbits. Because of the surgical post-operative complications, this investigator needs to receive further training in the surgical techniques in rabbit joint surgery. To be corrected before next surgeries.

This is an amended report for report 387069 dated 3-18-09, correcting citation 2.31(d)(1)(iii) which should have been cited as 2.31(d)(1)(viii).

Prepared By:

LISA K MACELDERRY, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1055

Mar-25-2009

Received By:

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

Date:

Title:

Mar-25-2009



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Customer ID: 808

Certificate: 55-R-0107

DIR OF COMPARATIVE MEDICINE, PO BOX

Site: 001

CAROLINAS MEDICAL CENTER

Type: ROUTINE INSPECTION

CHARLOTTE, NC 28232

Date: Mar-17-2009

2.31 (d) (1) (i)

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Section 2.31(d)(1)(i) states "IACUC review of activities involving animals. (1) In order to approve proposed activities or proposed significant changes in ongoing activities, the IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with this subchapter unless acceptable justification for a departure is presented in writing; Further, the IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements: Procedures involving animals will avoid or minimize discomfort, distress, and pain to the animals."

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Section 2.31(c)(4) states "IACUC functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall review, and, if warranted, investigate concerns involving the care and use of animals at the research facility resulting from public complaints received and from reports of noncompliance received from laboratory or research facility personnel or employees."

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Prepared By:

LISA K MACELDERRY, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1055

Mar-18-2009

Received By:

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

Date:

Title:

Mar-18-2009



Inspection Report

2.31 (d) (1) (iii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31(d)(1)(viii) states "Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures."

The surgeon for rabbit protocol 05-08-02A does not have adequate experience for this species for the surgical procedure. The protocol states the surgeon has 6 years experience in orthopedic surgeries and has done this procedure in humans for 2 years. It says he has one year experience with rabbit and rat bone isolation surgeries for bone marrow retrieval. No experience is listed for joint surgeries in rabbits. Because of the surgical post-operative complications, this investigator needs to receive further training in the surgical techniques in rabbit joint surgery. To be corrected before next surgeries.

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The rabbit protocol 05-08-02A was not followed as written. The protocol states the rabbits were to be between 3.5 - 5 kg and 3 - 5 months old, but two were operated on at 2.9 kg. and 2.6 kg. The procedure requires a specific size animal and these rabbits operated on did not meet the weight requirement. The rabbit protocol post operative care was not followed as written, possibly resulting in unrelieved pain in 3 rabbits. The rabbits had bilateral knee surgeries, and afterward, the rabbits had decreased appetites, weight losses when they should have been gaining weight, and they did not use their rear legs normally. The veterinarian used different analgesics than what was in the protocol believing less handling for injections would be less stressful for the rabbits, but the rabbits did not appear to respond to the analgesics. The humane endpoints stated in the protocol include non-weight bearing, osteomyelitis, anorexia and weight loss of 15-20% compared with non-operated controls. Rabbit number 2 during the month after the surgery had weight loss of 17 - 20%. This rabbit was most affected as exhibited by not fully using either leg during movement. This rabbit did not exhibit other signs of pain, as it would come to the front of the cage to be picked up, carried, and held.

Although these rabbits showed conflicting signs of pain, the decreased appetites and weight loss should have been an indication to try other analgesics immediately or euthanize the rabbits per protocol if the pain could not be relieved and the endpoints were reached. The protocol needs to be followed as written or amendments submitted. To be corrected by 4-20-09.

Prepared By:

LISA K MACELDERRY, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1055

Mar-18-2009

Received By:

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

Date:

Title:

Mar-18-2009



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CAROLINAS MEDICAL CENTER

Customer ID: **808**

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Site: 001

CAROLINAS MEDICAL CENTER

DIR OF COMPARATIVE MEDICINE, PO BOX 32861

Type: ROUTINE INSPECTION

CHARLOTTE, NC 28232

Date: Aug-04-2008

3.131 (c)

SANITATION.

Section 3.131(c) states "Housekeeping. Premises 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."

A large patch of paint is peeling off the wall next to the cage wash on the dirty side. At least two small areas of flaking paint are on the ceiling. Flaking paint needs to be removed to facilitate husbandry practices.

To be corrected by 10-10-08.

Prepared By:

LISA K MACELDERRY, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1055

Aug-05-2008

Received By:

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

Date:

Title:

Aug-05-2008



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CAROLINAS MEDICAL CENTER

Customer ID: 808

Certificate: 55-R-0107

DIR OF COMPARATIVE MEDICINE, PO BOX

Site: 001

CAROLINAS MEDICAL CENTER

Type: ROUTINE INSPECTION

CHARLOTTE, NC 28232

Date: Aug-14-2007

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 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."

Protocol 07-06-03A involves placing a vascular access port to allow for weekly blood draws. The protocol states a squeeze cage will be used for sampling, further stating "the animals should be able to adapt to human intervention and may not need restraint for sampling after the initial contact.....animal should be able to be weaned from the apparatus." During this inspection, two pigs were observed recovering from anesthesia, which they were given to assist in bleeding. A conversation with the attending veterinarian revealed she had approved anesthesia for a pig bled a previous week because it became too upset in the squeeze cage. It appears the technicians may be routinely using the preoperative analgesic regime for the routine blood sampling.

If this procedure is to continue to be used, it needs to be submitted to the IACUC for review and approval. The protocol also does not state how much blood is taken at these bleeds and this needs to be added to the protocol and reviewed and approved by the IACUC.

To be corrected by 9-15-07.

NOTE: Because the main purpose of a vascular access port is to facilitate bleeding, methods should be used to make the bleeding process less stressful such as acclimating the pigs more to the restraint methods used.

Prepared By:

LISA K MACELDERRY, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1055

Aug-14-2007

Received By:

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

Date:

Title:

Aug-14-2007