



## Inspection Report

RHODE ISLAND HOSPITAL

Customer ID: 266

Certificate: 15-R-0002

Site: 001

RHODE ISLAND HOSPITAL

MIDDLE HOUSE 4TH AND 5TH

Type: ROUTINE INSPECTION

Date: Jul-21-2009

PROVIDENCE, RI 02903

### 2.33 (b) (5)

#### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

2.33 (b) (5) - "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. Review of Protocol #0170-08 and Medical Records of Rabbit #2099, #2100, and #2103:

a. The post-operative care for the study animals is described on pages 33 and 34 of the protocol and states that the Rabbits are checked by laboratory personnel at least once on the day of surgery before leaving for the day. The anesthesia/surgical record and the "Daily Observations and Treatment" form for Rabbits #2099, #2100, and #2103 that underwent a surgical procedure within the past week were reviewed. There was no documentation in the Rabbits' medical records that laboratory personnel checked the Rabbits post-operatively on the day of surgery as described in the protocol.

Research animals should receive the prescribed post-procedural care as specified in the IACUC approved proposal for animal use to ensure the well-being of the animals. The IACUC and AV need to address this item. Correct by 7/28/09.

**Prepared By:**

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

**Date:**

**Title:** VETERINARY MEDICAL OFFICER Inspector 1054

Jul-21-2009

**Received By:**

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

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Date: Jan-06-2009

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### 3.53 (a) (4)

#### PRIMARY ENCLOSURES.

3.53 (a) (4) - "All primary enclosures for rabbits shall conform to the following requirements: (a) General. (4) The floors of the primary enclosures shall be constructed so as to protect the rabbits' feet and legs from injury."

1. The end of one of the stainless steel bars making up the grill-type floor in a primary enclosure housing one Rabbit in C-1.61 was noted to be detached from the floor's frame and was bent upward into the enclosure. This finding identified for the floor could result in an injury to the feet, legs, or eyes of the Rabbit.

The floor of a primary enclosure should be constructed so as to protect the Rabbit from injury. The Registrant immediately corrected this item at the time of the inspection by replacing the damaged floor panel with an undamaged panel.

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#### Prepared By:

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

Date:

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Jan-06-2009

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This was a focused inspection based on the non-compliant items that were identified during the last inspection. Registrant has successfully addressed and has implemented corrective actions for the non-compliant items identified at the time of the last inspection.

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**Prepared By:**

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

**Date:**

**Title:** VETERINARY MEDICAL OFFICER Inspector 1054

Jun-06-2008

**Received By:**

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

**Date:**

**Title:**

Jun-06-2008



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MIDDLE HOUSE 4TH AND 5TH

Certificate: 15-R-0002

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RHODE ISLAND HOSPITAL

PROVIDENCE, RI 02903

Type: --RESCINDED--

Date: May-08-2008

**2.31** (d) (1) (viii)

### INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31 (d) (1) (viii) - "The IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements: (viii) Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures."

1. Review of Protocol #0013-08:

a. It was learned during the inspection that one of the individuals who was providing animal care and conducting procedures on the study animals had not been listed on the protocol as one of the personnel to be involved in the project.

All personnel conducting procedures on animals must be named on a proposal for animal use in order for the IACUC to determine that the personnel are qualified and trained in those procedures.

The IACUC needs to address this issue identified for this proposal. Correct immediately.

**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 #0013-08 and Medical Records of GP #1 through 24:

a. The records of six GP (#7, 8, 21, 22, 23, 24) indicate that the substances Calcein and BrdU were administered to the GP by injection. There is no description of the injection of these substances included in the approved protocol.

b. The records of eighteen GP (#1 through 6, #9 through 20) indicate that the antibiotic Cephazolin was injected at

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May-09-2008

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May-09-2008



## Inspection Report

the time of surgery. There is no description of the injection of Cephazolin in the approved protocol.

c. The protocol states on pg 18 that size 4-0 Nylon suture will be used to close the surgical incision. It was noted during the inspection that the size and type of suture used to close the incisions of the GPs that had undergone surgery was different than what was described in the approved protocol.

d. It is not clear from the description of the schedule of administration of analgesics whether Buprenorphine is given only on the day of surgery or also on the first post-operative day.

A proposal for animal use must contain a complete description of the proposed animal use. The IACUC needs to address the items identified for this protocol. Correct by 6/1/08.

### 2.32 (a)

#### 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."

1. The Non-compliant items identified on this inspection report under Sections 2.31 (d) (1) (viii), 2.31 (e) (3), 2.33 (b) (3), and 2.33 (b) (5) pertaining to Protocol #0013-08 indicate laboratory personnel's lack of familiarity with both the details of the approved protocol and currently established veterinary medical and nursing procedures. This lack of familiarity has the potential to negatively affect the welfare of animals.

All personnel involved in animal care, treatment, and use must be adequately trained and qualified to perform the duties described in the protocol. Inadequate training in any aspect of animal care and use can result in harm to the animals. The research facility needs to address this issue. Correct immediately.

### 2.33 (b) (3)

#### DIRECT NCI

#### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

2.33 (b) (3) - "Each research facility shall establish and maintain programs of adequate veterinary care that include: (3) Daily observation of all animals to assess their health and well-being; Provided, however, That daily observation of animals may be accomplished by someone other than the attending veterinarian; and Provided, further, That a mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian."

1. DIRECT ITEM: At the time of the inspection at approximately 11 AM on 5/8/08, the APHIS inspector noted that GP #15 used under Protocol #0013-08 was depressed, thin, had sunken eyes, a ruffled hair coat, a red and swollen surgical incision on the right rear leg, and was reluctant to move. According to the animal's medical record, the investigator had observed the animal to be sedentary, undernourished, and having small eyes on 5/7/08. The PI administered the antibiotic Cephazolin but did not contact the clinical veterinarian regarding the animal's condition as was described in the approved protocol under post-operative monitoring.

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Title:

May-09-2008



## Inspection Report

The clinical veterinarian was first made aware of the condition of this animal at the time of the inspection on 5/8/08. The PI was immediately contacted by the clinical veterinarian and instructed to euthanize the GP.

A mechanism of direct and frequent communication by laboratory personnel to the veterinarian regarding problems of animal health and behavior is important to protect the health and well-being of the animals. The facility needs ensure that all personnel responsible for the daily observations of research animals provide any information concerning any problem of animal health to the veterinarian for evaluation. Correct from this date forward.

### 2.33 (b) (5)

#### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

2.33 (b) (5) - "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. Review of Protocol #0013-08 and the Medical Records of GP #1 - 6 and #9 - 20:

a. The protocol states that the GP will monitored twice a day for one week post-operatively. There was no documentation available that the post-operative monitoring schedule was followed as described in the protocol.

b. The protocol states that any GP having surgery in the morning will have a second dose of the analgesic Buprenorphine administered in the evening. It could not be determined from the information available whether the schedule of administration of analgesic was followed.

c. GP #15 received an injection of the antibiotic Cephazolin by the PI on 5/7/08 without consulting the clinical veterinarian. The protocol states that any possible wound infections will be brought to the attention of the veterinarian for consultation.

d. The medical records of the GP contained insufficient information to determine that the procedures performed on the animals had been conducted as described in the approved protocol.

Research animals should receive the prescribed pre and post procedural care as specified in the IACUC approved proposal for animal use to maintain the health of the animals and ensure that discomfort and pain to the animals will be limited. The IACUC and AV need to address the items identified for this protocol. Correct immediately.

### 2.36 (b) (7)

#### ANNUAL REPORT.

2.36 (b) (7) - "The annual report shall: (7) State the common names and the numbers of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely

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May-09-2008



## Inspection Report

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affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used shall be attached to the annual report."

1. The Annual Report that was submitted by the research facility to USDA for FY 2007 did not include 8 Rabbits that were used under Protocol #0182-06 during FY 2007. The 8 Rabbits were considered likely to have experienced unrelieved pain and/or distress as a result of the failure of the investigator to administer post-operative analgesia as per the approved protocol.

The research facility needs to submit a corrected Annual Report for FY 2007 to the Eastern Regional Office that reports the 8 Rabbits in the correct pain category and attach an explanation of the incident. Correct by 7/1/08.

NOTE - This inspection was conducted on 5/8/08 and 5/9/08 with the exit interview on 5/9/08.

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RHODE ISLAND HOSPITAL

Type: ROUTINE INSPECTION

PROVIDENCE, RI 02903

Date: May-08-2008

**2.31** (d) (1) (viii)

### INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31 (d) (1) (viii) - "The IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements: (viii) Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures."

1. Review of Protocol #0013-08:

a. It was learned during the inspection that one of the individuals who was providing animal care and conducting procedures on the study animals had not been listed on the protocol as one of the personnel to be involved in the project.

All personnel conducting procedures on animals must be named on a proposal for animal use in order for the IACUC to determine that the personnel are qualified and trained in those procedures.

The IACUC needs to address this issue identified for this proposal. Correct immediately.

**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 #0013-08 and Medical Records of GP #1 through 24:

a. The records of six GP (#7, 8, 21, 22, 23, 24) indicate that the substances Calcein and BrdU were administered to the GP by injection. There is no description of the injection of these substances included in the approved protocol.

b. The records of eighteen GP (#1 through 6, #9 through 20) indicate that the antibiotic Cephazolin was injected at

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Jun-03-2008

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

**Date:**

**Title:**

Jun-06-2008





## Inspection Report

the time of surgery. There is no description of the injection of Cephazolin in the approved protocol.

c. The protocol states on pg 18 that size 4-0 Nylon suture will be used to close the surgical incision. It was noted during the inspection that the size and type of suture used to close the incisions of the GPs that had undergone surgery was different than what was described in the approved protocol.

d. It is not clear from the description of the schedule of administration of analgesics whether Buprenorphine is given only on the day of surgery or also on the first post-operative day.

A proposal for animal use must contain a complete description of the proposed animal use. The IACUC needs to address the items identified for this protocol. Correct by 6/1/08.

### 2.32 (a)

#### 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."

1. The Non-compliant items identified on this inspection report under Sections 2.31 (d) (1) (viii), 2.31 (e) (3), 2.33 (b) (3), and 2.33 (b) (5) pertaining to Protocol #0013-08 indicate laboratory personnel's lack of familiarity with both the details of the approved protocol and currently established veterinary medical and nursing procedures. This lack of familiarity has the potential to negatively affect the welfare of animals.

All personnel involved in animal care, treatment, and use must be adequately trained and qualified to perform the duties described in the protocol. Inadequate training in any aspect of animal care and use can result in harm to the animals. The research facility needs to address this issue. Correct immediately.

### 2.33 (b) (3)

#### DIRECT NCI

#### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

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1. DIRECT ITEM: At the time of the inspection at approximately 11 AM on 5/8/08, the APHIS inspector noted that GP #15 used under Protocol #0013-08 was depressed, thin, had sunken eyes, a ruffled hair coat, a red and swollen surgical incision on the right rear leg, and was reluctant to move. According to the animal's medical record, the investigator had observed the animal to be sedentary, undernourished, and having small eyes on 5/7/08. The PI administered the antibiotic Cephazolin but did not contact the clinical veterinarian regarding the animal's condition as was described in the approved protocol under postoperative monitoring.

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

Date:

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Jun-06-2008



## Inspection Report

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The clinical veterinarian was first made aware of the condition of this animal at the time of the inspection on 5/8/08. The PI was immediately contacted by the clinical veterinarian and instructed to euthanize the GP.

A mechanism of direct and frequent communication by laboratory personnel to the veterinarian regarding problems of animal health and behavior is important to protect the health and well-being of the animals. The facility needs ensure that all personnel responsible for the daily observations of research animals provide any information concerning any problem of animal health to the veterinarian for evaluation. Correct from this date forward.

### 2.33 (b) (5)

#### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

2.33 (b) (5) - "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. Review of Protocol #0013-08 and the Medical Records of GP #1 - 6 and #9 - 20:

a. The protocol states that the GP will monitored twice a day for one week post-operatively. There was no documentation available that the post-operative monitoring schedule was followed as described in the protocol.

b. The protocol states that any GP having surgery in the morning will have a second dose of the analgesic Buprenorphine administered in the evening. It could not be determined from the information available whether the schedule of administration of analgesic was followed.

c. GP #15 received an injection of the antibiotic Cephazolin by the PI on 5/7/08 without consulting the clinical veterinarian. The protocol states that any possible wound infections will be brought to the attention of the veterinarian for consultation.

d. The medical records of the GP contained insufficient information to determine that the procedures performed on the animals had been conducted as described in the approved protocol.

Research animals should receive the prescribed pre and post procedural care as specified in the IACUC approved proposal for animal use to maintain the health of the animals and ensure that discomfort and pain to the animals will be limited. The IACUC and AV need to address the items identified for this protocol. Correct immediately.

NOTE - This inspection was conducted on 5/8/08 and 5/9/08 with the exit interview on 5/9/08.

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**Date:**

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## Inspection Report

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NOTE - This is an amended version of the inspection report that was delivered to the facility at the 5/9/08 exit interview.

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

**Title:** VETERINARY MEDICAL OFFICER Inspector 1054

**Date:**

Jun-03-2008

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**Date:**

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## Inspection Report

RHODE ISLAND HOSPITAL

Customer ID: 266

MIDDLE HOUSE 4TH AND 5TH

Certificate: 15-R-0002

Site: 001

RHODE ISLAND HOSPITAL

Type: ROUTINE INSPECTION

PROVIDENCE, RI 02903

Date: Mar-15-2007

### 2.33 (b) (2)

#### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

2.33 (b) (2) - "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. Rabbit #501 was noted by the inspector to have weepy eyes and reddened skin at the medial canthus. The condition had not been noted by facility personnel. Facility corrected item during the inspection by assessing the eye condition of the Rabbit and instituting therapy.
2. The following outdated medical supply was identified in 504 - Tube of KY Jelly, #1, exp 2/02. Facility corrected item at time of inspection by discarding tube.
3. A bottle of Betadine diluted in 0.9% Saline was identified in 504. The date the dilution was made was written on the label (8/25/06) but the exp date of the Betadine stock bottle was not noted. The exp date of the stock bottle should be recorded on a label whenever some of the stock is transferred to another container in order to ensure that the transferred material is in current dating. Correct from this day forward.

### 2.33 (b) (5)

#### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

2.33 (b) (5) - "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. Protocol #0182-06 states that the analgesic Buprenorphine will be administered pre-operatively and every 8-12 hours for 2 days post-operatively to Rabbits. The IACUC was informed in January 2007 that some of the animals may not have not received the post-operative regimen of analgesia as specified in the approved protocol.

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Mar-15-2007



## Inspection Report

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The IACUC formed a sub-committee to investigate the allegation. It was determined that eight Rabbits did not receive post-operative analgesia as specified in the protocol. As a result, the IACUC required additional training and supervision of laboratory personnel associated with Protocol #0182-06.

Facility has corrected this item by providing additional training and supervision to the laboratory personnel. The medical records of Rabbits which have recently undergone surgery were reviewed during the inspection. All of the animals had received the post-operative regimen of analgesia as specified in the approved protocol.

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