



Inspection Report

VANDERBILT UNIVERSITY

Customer ID: 858

Certificate: 63-R-0005

Site: 001

VANDERBILT UNIVERSITY

ASST VC FOR RSCH DIR ANIMAL CARE

Type: ROUTINE INSPECTION

NASHVILLE, TN 37232

Date: Jun-13-2011

2.31 (c) (7)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(c) 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;

Protocol M/06/552 as approved includes a description of a craniotomy procedure that involves placement of a polymer and replacement of the bone flaps but does not mention placement of any permanent chambers. Medical records for NHP 4414 show that a craniotomy with placement of a permanent chamber was performed. Medical records show repeated medical problems related to the chamber culminating in removal of the chamber 3 months later. To ensure the IACUC has knowledge of proposed activities and can review them to ensure that they meet requirements, the IACUC must 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. Correct by Sept. 30, 2011.

2.31 (d) (1) (ii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(d) 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: (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, e. g., the Animal Welfare Information Center, used to determine that alternatives were not available;

*Protocol M/07/354 includes water/fluid restriction and chaired restraint of non-human primates. Records for

Prepared By:

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Date:

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nonhuman primate RQ5541 state that an anti-anxiety medication is being given to help treat his anxiety during restraint/working tasks.

*Protocol M/06/441 includes forced treadmill activity for post-surgical dogs on study.

*Protocol M/08/053 includes harness restraint of dogs on study.

The alternative search conducted for each of the above protocols did not include a search for fluid restriction, restraint or forced treadmill activity. Fluid restriction for longer than that required for pre-surgical preparation, physical restraint of conscious animals, and forced exercise/treadmill work may lead to distress in animals and even pain in some animals. The IACUC shall ensure that 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. Correct by Sept. 30, 2011.

2.31 (d) (1) (viii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(d) 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: (viii) Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures;

A researcher who is not listed as an approved surgeon on protocol M/06/552 performed a craniotomy surgery on NHP 4414 in Sept. 2010. Immediately post-surgery the NHP presented with complications requiring treatment by the veterinary staff. Additional imaging and surgical procedures were conducted in Dec. 2010 and April 2011 by three other persons also not approved on the protocol. The IACUC must be made aware of personnel conducting procedures on species being studied on a protocol in order to be able to assess that the persons are qualified and trained in the procedures that will be required for that protocol. In order to approve proposed activities the IACUC shall determine that personnel conducting procedures on species being maintained or studied will be appropriately qualified and trained in those procedures. Correct by Sept. 30, 2011.

2.38 (k) (1)

MISCELLANEOUS.

(k)(1) Each research facility shall comply in all respects with the regulations set forth in subpart C of this part and the standards set forth in part 3 of this subchapter for the humane handling, care, treatment, housing, and transportation of animals; Provided, however, That exceptions to the standards in part 3 and the provisions of subpart C of this part may be made only when such exceptions are specified and justified in the proposal to conduct the activity and are approved by the IACUC.

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Protocol M/07/354 states that access to water will be restricted "for the duration of their training and data collection". The protocol contains no further specification of the nature of the restriction nor any scientific justification for the restriction. The IACUC approved this protocol with the exception to the standards in part 3 and the annual report for FY 2010 states that two macaques were studied under this exception. To ensure the humane handling, care, and treatment of the animals, exceptions to the standards in part 3 may only be made when such exceptions are specified and justified in the proposal to conduct the activity. Correct by Sept. 30, 2011.

3.28 (c) (2) (ii)

PRIMARY ENCLOSURES.

(2) Hamsters. (ii) The interior height of any primary enclosure used to confine hamsters shall be at least 6 inches (15.24 cm).

Six hamsters were individually housed in plastic enclosures. The enclosures were manufactured with a height of 6 in. but the effective height available for the hamsters varied from 3 in to 5 1/2in depending on the portion of the enclosure measured because of added housing/feeding items. Adequate height is necessary to allow the hamsters to perform species typical postural reactions. The interior height of any primary enclosure used to confine hamsters shall be at least 6 inches. Corrected during the inspection.

Exit conducted by undersigned VMO and Director, Division of Animal Care with other facility representatives.

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SUSANNE BRUNKHORST, V M O USDA, APHIS, Animal Care

Date:

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NASHVILLE, TN 37232

Date: Nov-22-2010

No non-compliant items identified during this inspection.

This is a focused inspection reviewing emergency medical surgical training.

Exit conducted with undersigned VMO and Director, Division of Animal Care; IACUC Chair and Veterinarian Reviewer.

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SUSANNE BRUNKHORST, V M O USDA, APHIS, Animal Care

Date:

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Nov-22-2010

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VANDERBILT UNIVERSITY

ASST VC FOR RSCH DIR ANIMAL CARE

AA-6206 MEDICAL CENTER NORTH

Type: ROUTINE INSPECTION

Date: Jan-04-2010

NASHVILLE, TN 37232

2.31 (d) (1) (x) (C)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31(d) 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: (x) No animal will be used in more than one major operative procedure from which it is allowed to recover, unless: (C) In other special circumstances as determined by the Administrator on an individual basis. Written requests and supporting data should be sent to the Animal and Plant Health Inspection Service, Animal Care...

The IACUC approved protocol M/09/120 in July 2009. The protocol describes dogs undergoing three major operative survival surgeries. Vanderbilt requested and was granted an exemption under 9CFR 2.31(d)(1)(x)(C) on Sept. 14, 2009 by USDA, APHIS, Animal Care to perform the three survival surgeries on three dogs that had undergone other major survival surgeries under a previous protocol. On Nov. 24, 2009 the IACUC reviewed and approved a modification of protocol M/09/120 that included the addition of a fourth major survival surgery and informed the PI that the fourth surgery could not be performed until USDA approval was obtained. On Dec. 11, 2009 Vanderbilt submitted a written request to USDA, APHIS, Animal Care for an exemption for three additional major survival surgeries on protocol M/09/120. Review of IACUC records show that there is written justification for and IACUC review of only one of the three additional surgeries requested in the Dec. 11, 2009 letter. The IACUC shall determine that the proposed activities are in accordance with regulations and that all departures from regulations are justified in writing prior to submitting a written request with supporting data to USDA, APHIS, Animal Care. Correct by Feb. 28, 2010.

2.31 (d) (2)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31(d)(2) Prior to IACUC review, each member of the Committee shall be provided with a list of proposed activities to be reviewed. Written descriptions of all proposed activities that involve the care and use of animals shall be available to all IACUC members, and any member of the IACUC may obtain, upon request, full Committee review of

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Jan-13-2010



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those activities...

One voting IACUC member did not receive the weekly email distributions containing the list of proposed activities to be reviewed by the IACUC for 10 months (Sept. 2008 to July 2009) and a second voting IACUC member did not receive the same distributions for 7 months (Dec. 2008 to July 2009). The Office of Animal Welfare Assurance did discover this lapse in July 2009 and added both IACUC members to the distribution list at that time. Without the list of proposed activities involving the care and use of animals to be reviewed the two IACUC members were not able to exercise their option of requesting full Committee review of the activities. Corrected.

2.31 (e) (3) REPEAT INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31(e) 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;

*Protocol M/06/406 includes the performance of imaging studies in gerbils. The description of how often and for how long survival imaging studies will be conducted is incomplete and contradictory. In addition it conflicts with the procedures section of the protocol that states that imaging studies will only be conducted on gerbils prior to euthanasia.

*Protocol C/06/443 involves the use of pentobarbital sodium as a rabbit anesthetic for a thoracotomy prior to euthanasia by removal of the heart (exsanguination). The protocol does not include a description of how the pentobarbital sodium is to be prepared or a description of the surgery to be performed.

*Protocol M/09/120. The facility requested a second exemption for three dogs to undergo three additional multiple major survival surgeries. The protocol only described the need for, scientific justification of and description of one of the three requested surgeries.

A protocol must contain a complete description of the proposed use of the animals in order to allow the IACUC to conduct a thorough review of the protocol and to ensure the health and well-being of the animals.

2.33 (b) (1) ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

2.33(b) Each research facility shall establish and maintain programs of adequate veterinary care that include: (1) The availability of appropriate facilities, personnel, equipment, and services to comply with the provisions of this subchapter;

Protocol C/06/443 involves the use of pentobarbital sodium as a rabbit anesthetic for a thoracotomy prior to euthanasia by removal of the heart. During the inspection it was determined by talking to the lab personnel that a pharmaceutical grade of powder form of pentobarbital sodium was being diluted with a lab mixed Tyrode's solution (non pharmaceutical grade product) prior to IV injection. Investigators are expected to use pharmaceutical-grade anesthetics whenever they are available, even in acute procedures to ensure the well-being of the animal. Non-pharmaceutical grade chemical compounds should only be used in regulated animals after specific review and

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approval by the IACUC for reasons such as scientific necessity or non-availability of an acceptable veterinary or human pharmaceutical-grade product. No records were available to show that the IACUC reviewed and approved the use of the non pharmaceutical grade product. Correct before next use of the drug in rabbits.

2.35 (a) (1)

RECORDKEEPING REQUIREMENTS.

2.35(a) The research facility shall maintain the following IACUC records: (1) Minutes of IACUC meetings, including records of attendance, activities of the Committee, and Committee deliberations;

The IACUC meeting minutes do not always include the substance of the deliberations of the IACUC. While reviewing the Nov. 18, 2009 meeting minutes regarding IACUC review of a protocol request for additional multiple major surgeries the inspector could not ascertain from the minutes what the IACUC actually discussed and deliberated. The inspector thus asked multiple IACUC members what the deliberations consisted of and received multiple different answers. The Oct. 28, 2009 meeting minutes regarding IACUC approved exceptions included a list of protocol numbers and the exception titles. There were no notations regarding the species involved or the details of the approved exception. Incomplete minutes of IACUC meetings can lead to incomplete information for future reference. The IACUC meeting minutes need to include the substance of the deliberations of the IACUC. Correct from this day forward.

Records reviewed: IACUC Meeting Minutes Jan. 2009 through Dec. 2009; Dog, cat and nonhuman primate records; Dog/cat acquisition records: Annual Report FY09; Semiannual Review letters to the IO dated Mar. 6, 2009 and Aug. 26, 2009; Protocols M/06/356, M/08/533, M/09/138, M/09/120, C/06/443, M/06/406, C/06/564, M/06/376 and M/06/438; husbandry records, training records, emails.

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Customer ID: **858**

Certificate: **63-R-0005**

Site: 001

VANDERBILT UNIVERSITY

ASST VC FOR RSCH DIR ANIMAL CARE

Type: ROUTINE INSPECTION

NASHVILLE, TN 37232

Date: Aug-04-2009

2.38 (f) (1)

MISCELLANEOUS.

(f) Handling. (1) Handling of all animals shall be done as expeditiously and carefully as possible in a manner that does not cause trauma, overheating, excessive cooling, behavioral stress, physical harm, or unnecessary discomfort.

A dog with an abdominal surgery incision was inappropriately lifted by an employee. The employee picked the dog up by grabbing the skin at the back of its neck with one hand and the skin over its back with the other in order to place it in its cage. The employee had been trained on the appropriate way to handle dogs but did not follow the approved protocol. Inappropriate handling of dogs, especially post-operatively, may lead to physical harm and/or unnecessary discomfort to the dog. All handling of dogs shall be done as expeditiously and carefully as possible. Correct from this day forward.

This is a focused inspection reviewing a complaint.

Inspection conducted by undersigned VMO and Director OAWA, Assistant Director DAC and Post-approval monitor. Exit conducted by undersigned VMO and Director DAC and IACUC Vice-Chair, Director OAWA.

Records reviewed: Non-human primate enrichment logs, Non-human primate environmental enrichment plan, SOP for Canine Handling, Training records, Protocol M/06/375, IACUC complaint logs, IACUC subcommittee reports, IACUC Meeting Minutes 12-08 and 7-09, Annual report FY 07-08.

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SUSANNE BRUNKHORST, V M O USDA, APHIS, Animal Care

Date:

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Inspection Report

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AA-6206 MEDICAL CENTER NORTH

Site: 001

VANDERBILT UNIVERSITY

Type: ROUTINE INSPECTION

NASHVILLE, TN 37232

Date: Dec-16-2008

2.31 (d) (1) (ii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Sec. 2.31 Institutional Animal Care and Use Committee (IACUC).

(d) IACUC review of activities involving animals. (1) 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, e. g., the Animal Welfare Information Center, used to determine that alternatives were not available;

Two approved protocols included procedures under anesthesia that may cause more than momentary pain or distress to the animals but the written proposal did not address the consideration of alternatives to these procedures: 1)protocol M/06/438 includes vocal fold biopsy and tracheostomy procedures and 2)protocol M/06/552 includes craniotomy and dorsal column section surgeries. The written narrative for these protocols does not contain a search for all painful procedures described and therefore does not describe a search that was adequate for the IACUC to determine that alternatives were not available. The principal investigator must provide a written narrative description of methods used to determine that alternatives to all procedures that may cause more than momentary or slight pain or distress to the animals were not available. Correct by June 1, 2009.

2.31 (e) (3) **REPEAT**

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Sec. 2.31 Institutional Animal Care and Use Committee (IACUC). REPEAT

(e) 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;

Protocol M/07/044 does not have a complete description of the proposed use of the animals. The descriptions of the surgeries to be performed and the use of the paralytics is not clear and complete. Protocols must include a complete description of the proposed use of animals to allow the IACUC to make a determination that proposed activities are in

Prepared By:

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Date:

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accordance with Animal Welfare Act Regulations. This citation was previously cited in June 2008. The protocol is currently in the process of being revised and reapproved by the IACUC. No extension to the correct by date was obtained. All proposals to conduct an activity involving animals must contain a complete description of the proposed use of the animals.

2.33 (b) (2)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Sec. 2.33 Attending veterinarian and adequate veterinary care.

(b) 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, and the availability of emergency, weekend, and holiday care;

One 20ml vial of Doxapram HCl lot 958726 expired 10/08 and one 100ml vial Sleepaway inj lot 471321 expired 10/08 were found in the safe in room GGG. The use of expired drugs on regulated species is not considered to be acceptable veterinary practice. The effectiveness of the expired drugs is not known. Only appropriate unexpired drugs shall be available to provide adequate veterinary care. Correct from this day forward.

2.38 (f) (1)

MISCELLANEOUS.

Sec. 2.38 Miscellaneous.

(f) Handling. (1) Handling of all animals shall be done as expeditiously and carefully as possible in a manner that does not cause trauma, overheating, excessive cooling, behavioral stress, physical harm, or unnecessary discomfort.

*Medical records state that squirrel monkey 4216 required two amputation surgeries (Sep-Oct 2008) to treat a necrotic tail secondary to a burn lesion. Investigation by the facility determined that the lesion occurred during a fMRI procedure during which the equipment set-up allowed the temperature to rise too high.

*Macaque 3A7B2F medical and procedural records show that on 9/28/08 a chamber cleaning was done without the use of any analgesics or anesthetics. The record did not describe the extent of the procedures performed. Records state the animal started vomiting and would only eat treats that evening and the following day the animal was lethargic, vomiting, eyes were closed and the left eye was irritated and red. Analgesics were administered at that time with excellent response. The lack of use of analgesics/anesthetics in potentially painful or distressful procedures may lead to pain, distress and harm to the animal.

Handling of all animals shall be done in a manner that does not cause trauma, overheating, physical harm or unnecessary discomfort. Correct from this day forward.

Prepared By:

SUSANNE BRUNKHORST, V M O USDA, APHIS, Animal Care

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Records reviewed: IACUC Meeting Minutes dated 5/28/08, 6/25/08, 7/23/08, 8/27/08, 9/24/08 and 10/22/08; FY 2007-2008 Annual Report; SemiAnnual Review and Letter to Institutional Official dated 2/28/08 and 8/20/08; multiple SOPs; canine, rabbit and non-human primate animal records; Protocols M/07/044, M/06/374 (now M/08/618), C/06/426, M/06/438, M/08/053, M/08/056, M/08/162, M/06/552, C/06/564, M/06/392.

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SUSANNE BRUNKHORST, V M O USDA, APHIS, Animal Care

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AA-6206 MEDICAL CENTER NORTH

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VANDERBILT UNIVERSITY

Type: ROUTINE INSPECTION

NASHVILLE, TN 37232

Date: Oct-30-2008

2.31 (e) (3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31(e) 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;

Protocol M/06/374, as approved, includes multiple procedures on hamsters including injections of several exogenous compounds. On Monday October 6, 2008 it was noted by one of the Division of Animal Care (DAC) veterinary staff that hamsters 'appeared off' and were lethargic. One of the veterinarians was notified as was the principal investigator (PI) for the study. The three hamsters were euthanized the same day. It was determined that the hamsters had been injected with a compound that was not listed in the approved protocol by one of the PI's research scientists. Apparently this scientist had discussed this particular compound with the PI and was aware that this compound was not approved for use in the hamsters. Protocols must include a complete description of the proposed use of animals to allow the IACUC to make a determination that proposed activities are in accordance with Animal Welfare Act Regulations. All proposals to conduct an activity involving animals must contain a complete description of the proposed use of the animals. This citation was previously cited on the June 27, 2008 inspection and correction time is still remaining.

Records reviewed: IACUC Meeting minutes dated 9/24/08; Protocol Monitoring Checklist dated 7/30/08; necropsy results; letter to director of Office of Animal Welfare Assurance (OAWA) from Assistant Director DAC; letter from IACUC Chair to PI dated 10/23/08 and response letter from PI to IACUC dated 10/28/08
Inspection conducted by: Susanne Brunkhorst, VMO; Director OAWA; Assistant Director DAC; Clinical Veterinarian; Principal Investigator
Exit conducted by: undersigned VMO and Director OAWA
This is a focused inspection reviewing a self-reported incident.

Prepared By:

SUSANNE BRUNKHORST, V M O USDA, APHIS, Animal Care

Date:

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