



Inspection Report

UNIVERSITY OF KANSAS MEDICAL CENTER

Customer ID: 1460

Certificate: 48-R-0003

Site: 001

3901 RAINBOW BLVD

1040 WESCOE PAVILION - MS 2014

UNIVERSITY OF KSMENTAL RETARDATION RESEARCH

Type: ROUTINE INSPECTION

Date: Jun-30-2009

KANSAS CITY, KS 66160

2.31 (d) (1) (ii) **REPEAT**

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; Provided, however, That field studies as defined in part 1 of this subchapter are exempt from this requirement. 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;

Two protocols were identified in which the investigators failed to conduct an appropriate search for alternatives to procedures that may cause more than momentary or slight pain or distress:

1) Protocol 2007-1619 is a swine protocol. Swine on this protocol undergo teaching surgical procedures including laminectomy, craniotomy, cholectomy, Nissen fundoplication, hernia repair, adrenalectomy, splenectomy, bowel resection and anastomosis, nephrectomy, ureterectomy, cystectomy, hysterectomy, oophorectomy, csytorraphy, and suturing. The search for alternatives did not include terms that relate to all of the procedures that may cause more than momentary or slight pain or distress. Search words included: swine (pigs), laparoscopic, training, surgery.

2) Protocol 2006-1581 is a swine protocol. Swine on this protocol have a surgical opening made through the frontal bones on their skulls. The search for alternatives did not include terms that relate to all of the procedures that may cause more than momentary or slight pain or distress. Search words included: deep brain cooling, brain cooling with implanted probes, invasive cooling.

Principle investigators must consider alternatives to procedures that may cause more than momentary or slight pain or distress in order to protect the health and well-being of the animals. The principle investigator must provide a written narrative describing the methods and sources used to determine that alternatives were not available. The written narrative should include adequate information for the IACUC to assess that a reasonable and good faith effort

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was made to determine the availability of alternatives or alternative methods. If a database search or other source identifies a bona fide alternative method (one that could be used to accomplish the goals of the animal use proposal), the written narrative should justify why this alternative was not used.

The IACUC must ensure that the principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals.

This is a repeat non-compliant item. It was also not in compliance on March 10, 2009 and April 14, 2009.

2.31 (d) (2)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(d) IACUC review of activities involving animals. (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 those activities. If full Committee review is not requested, at least one member of the IACUC, designated by the chairman and qualified to conduct the review, shall review those activities, and shall have the authority to approve, require modifications in (to secure approval), or request full Committee review of any of those activities. If full Committee review is requested for a proposed activity, approval of that activity may be granted only after review, at a convened meeting of a quorum of the IACUC, and with the approval vote of a majority of the quorum present. No member may participate in the IACUC review or approval of an activity in which that member has a conflicting interest (e.g., is personally involved in the activity), except to provide information requested by the IACUC, nor may a member who has a conflicting interest contribute to the constitution of a quorum;

At least four protocols were identified that were "approved with contingencies" at an IACUC meeting. When the investigator had addressed the contingencies, they were reviewed and approved by a single member of the Committee without first making these materials available for review by all IACUC members and without giving the other IACUC members the opportunity to request full Committee review of the changes. Review of all proposed animal activities and changes to approved protocols must be conducted in accordance with the Animal Welfare Act regulations in order to ensure that the well-being of the animals is protected. The Committee must ensure that each member of the Committee is provided with a list of all proposed activities for review and that any member of the IACUC may obtain, upon request, full Committee review of these activities.

TO BE CORRECTED BY: August 1, 2009

2.31 (d) (5)

REPEAT

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(d) IACUC review of activities involving animals. (5) The IACUC shall conduct continuing reviews of activities covered by this subchapter at appropriate intervals as determined by the IACUC, but not less than annually;

Investigators for protocol 2008-1735 (a macaque protocol) are not conducting animal activities as delineated in the

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IACUC approved protocol. The description of the MRI anesthetic procedures states that nonhuman primates will be tranquilized with ketamine. A chart in the protocol states that ketamine will be given at a dose of 10 mg/kg i.m. 1 time per month. The laboratory's actual written procedure for MRIs utilized by laboratory staff states that the animals are given a full dose of ketamine followed by "Dormitor" for transport, which is then followed by a 1/2 dose of ketamine every 30 minutes thereafter.

Continuing review of animal activities is necessary to ensure that they are conducted as stated in the approved protocol is required in order to ensure that all activities are conducted in compliance with the Animal Welfare Act regulations in order to protect the health and well-being of the animals.

The IACUC must conduct continuing review of activities in order to ensure that all animal activities are conducted as stated in the approved protocols and in compliance with these regulations.

This is a repeat non-compliant item. It was also not in compliance on March 10, 2009 and April 14, 2009.

2.31 (e) (2) REPEAT
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(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: (2) A rationale for involving animals, and for the appropriateness of the species and numbers of animals to be used;

Protocol 2009-1796, a squirrel monkey protocol, does not contain a scientific justification for the appropriateness of the numbers of animals being used. The rationale for the appropriateness of numbers of animals to be used must be scientifically justified for reasons such as, but not limited to, statistical significance, results of pilot studies, or other scientific reasons in order to ensure that an appropriate, but not excessive, number of animals are utilized. The IACUC must ensure that all protocols include an appropriate rationale for the number of animals to be used.

This is a repeat non-compliant item. It was also not in compliance on April 14, 2009.

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

(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 2007-1680, a macaque protocol, did not contain a complete description of the proposed use of the animals. The currently approved version of the protocol states that the investigator will abruptly withdraw morphine from the animals and provides a time line over which symptoms of withdraw are expected to occur but does not describe the expected symptoms and/or clinical course.

A complete description of the proposed use of the animals is required in order to facilitate evaluation of the protocols by the IACUC to ensure that they are in compliance with the Animal Welfare Act regulations in order to protect the

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health and well-being of the animals.

The IACUC must ensure that all proposals to conduct animal activities contain a complete description of the proposed use of the animals.

This is a repeat non-compliant item. It was also not in compliance on March 10, 2009 and April 14, 2009.

2.33 (b) (2) REPEAT

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;

Animal records showed that medications were not administered as prescribed by the veterinarian: Macaque #AV82: 4 missed doses metronidazole; macaques #5A9, 5A3, 702, 3A1: 1 missed dose metronidazole; macaque #99R1837: 1 missed dose cephalexin; squirrel monkey #11F: 1 missed dose "Rimadyl".

Medications must be given as prescribed by the veterinarian in order to protect the health of the animals. Failure to administer the medications as directed by the veterinarian could result in ineffective treatment outcomes.

The research facility must establish and maintain a program of adequate veterinary care that includes the use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care in order to protect the health and well-being of the animals.

This is a repeat non-compliant item. It was also not in compliance on August 27, 2008, March 10, 2009, and April 14, 2009.

2.33 (b) (5)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

(b) 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.

On 5/6/2009 squirrel monkey #11F was anesthetized with ketamine, "dormitor", and isoflurane for a procedure. After movement was noted, animal was returned to its cage. Later that morning the animal was found in respiratory arrest with a temperature of 89.9 degrees F. No documentation was available to demonstrate that the animal had been provided with adequate post-procedural care to monitor and/or maintain the animal's body temperature in accordance with current established veterinary medical and nursing procedures. The registrant must ensure that the facility's program of veterinary care includes adequate pre- and post-procedural care in accordance with current established veterinary and nursing procedures in order to protect the health of the animals.

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3.76 (c)

INDOOR HOUSING FACILITIES.

(c) Lighting. Indoor housing facilities must be lighted well enough to permit routine inspection and cleaning of the facility, and observation of the nonhuman primates. Animal areas must be provided a regular diurnal lighting cycle of either natural or artificial light. Lighting must be uniformly diffused throughout animal facilities and provide sufficient illumination to aid in maintaining good housekeeping practices, adequate cleaning, adequate inspection of animals, and for the well-being of the animals. Primary enclosures must be placed in the housing facility so as to protect the nonhuman primates from excessive light.

At least 8 enclosures housing squirrel monkeys and 6 enclosures housing macaques had insufficient lighting that made it difficult to perform routine inspection and observation of the animals. The lighting was not uniformly diffuse, causing the back half of the enclosure to be darkened and shadowed. Lighting must be uniformly diffuse and provide sufficient lighting to permit routine inspection and cleaning of the facility, and facilitate observation of the nonhuman primates. The registrant must ensure that all non-human primates have have adequate lighting that is uniformly diffuse and that all non-human primates are provided with a regular diurnal lighting cycle of either natural or artificial light.

This item is still within the correction deadline of July 5, 2009 from the April 14, 2009 inspection report.

This routine inspection was conducted between June 30 and July 2, 2009 by Katheryn Ziegerer, VMO, Jami Niemann, VMO, and facility representatives.

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