



Inspection Report

UNIVERSITY OF LOUISVILLE

Customer ID: 897

Certificate: 61-R-0001

Site: 001

UNIVERSITY OF LOUISVILLE

511 S FLOYD ST

Type: ROUTINE INSPECTION

Date: Jun-22-2010

LOUISVILLE, KY 40202

2.31 (c) (7)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31(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 08018 uses a drug to induce diabetes in rabbits. The approved protocol states that 100mg/kg will be administered and specifically states that 50mg/kg and 150mg/kg doses will not be used. IACUC records show that "four to six rabbits" died after being given a larger than approved (150mg/kg) dose of the drug. The principal investigator stated that he thought that the 150mg/kg dose was in his protocol. The IACUC must review and approve all significant changes regarding the use of animals in ongoing activities to ensure the care and well-being of the animals. The IACUC must review and approve, require modifications in or withhold approval of proposed significant changes regarding the care and use in ongoing activities. Correct from this day forward.

2.31 (d) (1) (vi)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31 (d)(1)...the IACUC shall determine that the proposed activities... meet the following requirements: (vi) The animals' living conditions will be appropriate for their species in accordance with part 3 of this subchapter, and contribute to their health and comfort...

Protocol 09087 includes the use of water restriction of tree shrews to maximize the effect of a fruit juice reward (behavioral study). The description of this restriction is very brief and just includes how much water will be offered vs. what is normal for the species, a statement that the animals have been maintained in good health on these amounts, that on days that behavioral testing is not scheduled ad lib water is provided, and that fresh fruit is included in the regular diet. There is no description of any baseline physiological data being collected on individuals selected for this part of the study nor any description of what physiological parameters will be monitored during the study. A review of the animals and their records show that records are sparse. The animal's cages are marked with signs indicating that husbandry staff should not give the animals water or fruit. All 4 animal's water bottles were empty at the time of inspection (was told they would be studied later that day and they would be given their daily water after being

Prepared By:

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

Date:

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studied). The animal records do not include any notations to indicate that they are on water restriction, on which days they are restricted and which days they have ad-lib water, how much water or fruit juice they are offered or consuming, or any physiological or behavioral parameters that might be monitored to ensure their health and comfort. The IACUC shall determine that in this proposed activity the animals' living conditions will be appropriate for their species in accordance with part 3 of this subchapter, and contribute to their health and comfort. Correct by 10/23/10.

2.31 (d) (7)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31(d)(7) If the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to APHIS and any Federal agency funding that activity;

The IACUC meeting minutes dated 8/20/09 state that the IACUC suspended two protocols (same principal investigator) one using pigs (07023) and one including woodchucks (08000). A letter dated 8/26/09 was sent to the PI notifying him of the suspension. A letter dated 9/24/09 was sent to OLAW informing OLAW of the suspension. No letter reporting the action was sent to APHIS. If the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to APHIS. Correct by July 23, 2010.

2.31 (e) (4)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31(e) A proposal to conduct an activity involving animals...must contain the following:(4) A description of procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research, including provision for the use of analgesic, anesthetic, and tranquilizing drugs where indicated and appropriate to minimize discomfort and pain to animals;

Protocol 08051 includes an eye enucleation surgery in pigs. One pig was noted to have a buildup of dried brown discharge from the inner corner of the enucleated right eye extending down its face. Anesthetic use is described in multiple sections of the protocol and is not consistent between the sections making it difficult to determine what anesthetics will be used. A list of all approved analgesic and anesthetic drugs is included but does not state when the drugs are to be given. There is no description of post-operative monitoring procedures/treatment provisions to assure that post-op pain and discomfort will be minimized. The pig's records and conversations with staff do show that post-op pain analgesics were administered and the surgery site is treated in this pig. The proposal must contain a description of procedures designed to assure that discomfort and pain to all animals used will be limited to that which is unavoidable for the conduct of scientifically valuable research, including provision for the use of analgesic, anesthetic, and tranquilizing drugs where indicated and appropriate to minimize discomfort and pain. Correct by Oct. 23, 2010.

Records reviewed: IACUC roster, IACUC meeting minutes 5/09 through 5/10; IACUC Semiannuals 5/09, 11/09 and 5/10; selected animal records& protocols; FY 09 annual report.

An exit briefing was conducted with the Attending Veterinarian and two additional facility veterinarians.

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

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Date: May-19-2009

LOUISVILLE, KY 40202

2.31 (d) (1) (ii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31(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;

Protocol 08042 involves the injection of endotoxin into the vitreous of rabbits. The protocol acknowledges that it will elicit an inflammatory response. The protocol does not consider alternatives to this potentially painful/distressful procedure. Protocol 06120 includes an alternative search whose keywords do not reflect the potentially painful procedures (such as for example the craniotomy) being performed. The principal investigator must consider alternatives to any procedure that may cause more than momentary or slight pain or distress to the animals to help ensure humane use of animals and to help the IACUC review the proposed animal activities. All protocols including protocols 08042 and 06120 must include an alternative search and narrative for all procedures that may cause more than momentary or slight pain or distress to the animals. Correct by August 20, 2009.

2.31 (d) (1) (ix)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31(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: (ix)...All survival surgery will be performed using aseptic procedures, including surgical gloves, masks, sterile instruments, and aseptic techniques. 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...

Major survival surgeries (craniotomies) are being conducted in room PPP that is currently neither operated nor maintained in aseptic conditions. The floors are stained with rusty areas. Stored non-surgery and surgery related

Prepared By:

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

Date:

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items are present on counters. The light fixtures and ceiling are dirty and dusty. A leaking, old and currently nonsanitizable sink structure is present in the room. Lack of aseptic conditions for major operative procedures may lead to infection and stress in the animals undergoing surgery. Major operative procedures on tree shrews shall be conducted in room PPP only if the room is intended for major operative procedures and is operated and maintained under aseptic conditions. correct prior to the next use of the room for major operative procedures.

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 08095 includes provision for survival surgery in calves. Records reflect that pancuronium is being used in the survival surgeries. There is no mention or description of the use of pancuronium during survival surgery in the protocol. Protocol 06120 includes provision for both non-survival and survival surgery in tree shrews. The use of drugs to include atropine sulfate, flaxedil, IV fluids and post-op analgesics and antibiotics is not clearly and completely described. In some cases the name of the drug to be used is not given, in other cases the dosage, timing or route of administration are not identified. A complete description of the proposed use of the animals is required to allow the IACUC to properly review the proposal in order to ensure that all animal related activities are in accordance with the Animal Welfare Act. All protocols including protocols 08095 and 06120 must contain a complete description of the proposed use of the animals. Correct by August 20, 2009.

2.36 (b) (3)

ANNUAL REPORT.

2.36(b) The annual report shall: (3) Assure that the facility is adhering to the standards and regulations under the Act, and that it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the IACUC. A summary of all such exceptions must be attached to the facility's annual report. In addition to identifying the IACUC-approved exceptions, this summary must include a brief explanation of the exceptions, as well as the species and number of animals affected;

Protocol 08095 (active protocol), as approved, calls for a 48 hr fast of calves prior to surgery and calls for longterm tethering of calves such that they cannot turn around. Protocol 05139 (approved 3/3/06 and expired 3/3/09) called for rearing of kittens in the dark. The last three annual reports submitted by the facility to the USDA do not describe any IACUC approved exceptions. The annual report must identify and summarize the exceptions to include a brief explanations of the exceptions, the species and the number of animals affected. Correct by submitting a corrected annual report for the FY 2007-2008 including the exceptions to the USDA Eastern Regional Office by June 20, 2009.

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Records reviewed: IACUC meeting minutes Jan. 2008 through April 2009; Semiannual letters to the IO dated Oct 19, 2007, April 17, 2008 and Oct. 16, 2008; Dog and cat acquisition/disposition records; Policy on Proposal Review; Rabbit and calf health records; Annual reports for last three years; Protocols 08095, 08042, 06120, 05139 and 07110; IACUC roster.

Inspection conducted by VMO and RRC veterinarian and two RRC staff members.
Exit conducted by undersigned VMO and Attending Veterinarian.

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Date: Jan-03-2008

2.33 (b) (1)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

(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;

There was an expired box of Valium injectable in surgery suite # 2, building 24 that had been used on a recent experiment on covered animals. The Valium injectable was expired 11/2007, lot # 46765.

It is important to the health and well-being of the animals to maintain adequate programs of veterinary care that include appropriate equipment, which includes the use of current dated pharmaceuticals.

The expired Valium box was discarded during the the inspection.

This inspection and exit interview was conducted with an attending veterinarian and/or director.

Prepared By:

JOHN W POE, D. V. M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1073

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2.33 (b) (1)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

(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;

There was an expired box of Valium injectable, expired 11/2007, lot # 27655, in the RRC, room #24 called operating room # 2. It had been used on a recent experiment on covered animals.

It is important the health and well-being of the animals to have programs of veterinary care that include the availability of appropriate equipment such as current dated pharmaceuticals.

The box of expired pharmaceuticals was discarded during the inspection.

This inspection and exit interview occurred with an attending veterinarian and/or director and animal care workers.

Prepared By:

JOHN W POE, D. V. M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1073

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