



Inspection Report

UNIVERSITY OF KENTUCKY

Customer ID: 898

DIVISION OF LAB ANIMAL RESOURCES
204 BOSOMWORTH HEALTH SCIENCES

Certificate: 61-R-0002

Site: 001

UNIVERSITY OF KENTUCKY

LEXINGTON, KY 40536

Type: ROUTINE INSPECTION

Date: Mar-17-2009

2.31 (c) (3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Sec. 2.31 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:

- (1) Review, at least once every six months, the research facility's program for humane care and use of animals, using title 9, chapter I, subchapter A--Animal Welfare, as a basis for evaluation;
- (2) Inspect, at least once every six months, all of the research facility's animal facilities, including animal study areas, using title 9, chapter I, subchapter A--Animal Welfare, as a basis for evaluation; Provided, however, That animal areas containing free-living wild animals in their natural habitat need not be included in such inspection;
- (3) Prepare reports of its evaluations conducted as required by paragraphs (c)(1) and (2) of this section, and submit the reports to the Institutional Official of the research facility;... The reports must contain a description of the nature and extent of the research facility's adherence to this subchapter, must identify specifically any departures from the provisions of title 9, chapter I, subchapter A--Animal Welfare, and must state the reasons for each departure. The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, with reference to Subchapter A, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule with dates for correcting each deficiency...

The evaluation reports to the Institutional Official dated July 18, 2008 and Jan. 21, 2009 include information regarding the IACUCs semiannual review of the facility's program of humane care and use which states that the IACUC noted deficiencies in the program. The evaluation reports did not indicate whether the deficiencies were minor or significant. The reports also did not include a correction plan or correction schedule with dates for each deficiency. The evaluation reports to the IO must contain this information to allow the IO to understand and address the needs of the program. The IACUC shall prepare reports of its semiannual evaluations that identify any departures from the provisions of title 9, chapter I, subchapter A--Animal Welfare, state the reasons for each departure, distinguish significant deficiencies from minor deficiencies, and contain a reasonable and specific plan and schedule with dates for correcting each deficiency. Correct from this day forward.

Prepared By:

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Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1076

Mar-19-2009

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2.36 (b) (3)

ANNUAL REPORT.

Sec. 2.36 Annual report. (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;

During the inspection it was noted that the IACUC approved two exceptions and that animals were used on the protocols involved during fiscal year 2008. These exceptions involved hamsters maintained in total darkness and sheep housed in metabolism cages. The summary of exceptions to the facility's fiscal year 2008 annual report did not include these two approved exceptions. The annual report must contain a summary of all exceptions along with a brief explanation of the exceptions and the species and number of animals affected. Correct by submitting a revised 2008 Annual Report by April 15, 2009.

3.54 (a)

FEEDING.

Sec. 3.54 Feeding. (a) Rabbits shall be fed at least once each day except as otherwise might be required to provide adequate veterinary care. The food shall be free from contamination, wholesome, palatable and of sufficient quantity and nutritive value to meet the normal daily requirements for the condition and size of the rabbit.

During the inspection it was noted that the Harlan Teklad feed being fed to rabbits in two rooms in the main building had a mill date of 9-11-08 and thus an expiration date of 3-11-09. Expired feed may no longer be nutritious as some feed ingredients may degrade over time. All food fed to rabbits shall be wholesome and of sufficient nutritive value to meet normal daily requirements of the rabbits. Correct by March 26, 2009.

3.84 (c)

CLEANING, SANITIZATION, HOUSEKEEPING, AND PEST CONTROL.

Sec. 3.84 Cleaning, sanitization, housekeeping, and pest control. (c) Housekeeping for premises. Premises where housing facilities are located, including buildings..., must be kept clean and in good repair in order... to facilitate the husbandry practices required in this subpart, and to reduce or eliminate breeding and living areas for rodents, pests, and vermin.

The cage wash used to clean non-human primate cages is not in operating condition at this time as a new unit is being installed. The cages are being cleaned and sanitized in a room in the facility. The ceiling in this room is in disrepair as sections are peeling off and it is not impervious to moisture. The condition of the ceiling makes it difficult to adequately sanitize and pieces of the ceiling may fall onto the cages. Premises must be kept in good repair to

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facilitate husbandry practices required. Correct by April 15, 2009.

Records reviewed: Semiannual evaluation reports dated 1/31/08, 7/18/08 and 1/21/09; IACUC meeting minutes for meetings held November 2007 through January 2009; Nonhuman primate environmental enrichment plan; Fiscal year 2008 annual report; health records; Protocols 2008-0417, 00759M2004, 0095M2005, 2007-0153, 0098M2006 and 2007-0121.

Present during inspection: Attending veterinarian, clinical veterinarian, facility manager, VMO.

Present during inspection: Undersigned attending veterinarian and VMO and clinical veterinarians.

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UNIVERSITY OF KENTUCKY

Customer ID: **898**

Certificate: **61-R-0002**

Site: 001

UNIVERSITY OF KENTUCKY

DIVISION OF LAB ANIMAL RESOURCES

Type: ROUTINE INSPECTION

LEXINGTON, KY 40536

Date: Nov-20-2007

This inspection occurred on Tuesday, November 20, 2007 and the exit interview occurred on Wednesday November 21, 2007.

No non-compliant items observed on this inspection.

This inspection occurred with a clinical veterinarian and the Director, DLAR. The records review occurred with the University Veterinarian and Director, DLAR. The exit interview occurred with Director, DLAR.

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

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DIVISION OF LAB ANIMAL RESOURCES

Type: ROUTINE INSPECTION

LEXINGTON, KY 40536

Date: Jul-11-2007

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 # 759M2004 Modification approved on 1/19/2005 contained neither species nor number justification of animals to be used. It simply stated that the following were requested:

- 1) 250 additional PC 3 guinea pigs
- 2) 20 additional PC 3 Yucatan miniature swine
- 3) addition of transdermal drug delivery by microneedle injection

Protocol # 990A2006 gave no justification for 7 additional dogs requested when the statistical analysis justified the use of 18 dogs.

It is important to the health and well-being of the animals to use no more than is statistically needed to demonstrate scientific validity.

A proposal must contain a rationale for involving animals, and for the appropriateness of the species and numbers of animals to be used.

2.33 (b) (1) REPEAT

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;

A reagent grade Ethanol, 200 proof was being used transdermally on guinea pigs in the treatment room at the Pharmacy building. This was protocol # 759M2004 Modification approved on 1/19/2005.

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It is important to the health and well-being of the animals to use proper purity and strength pharmaceuticals.

Pharmaceutical grade regents should be used on covered specie.

3.56 (b) (3)

SANITATION.

(b) Sanitization of primary enclosures.

(3) Primary enclosures for rabbits shall be sanitized by washing them with hot water (180 ?F.) and soap or detergent as in a mechanical cage washer, or by washing all soiled surfaces with a detergent solution followed by a safe and effective disinfectant, or by cleaning all soiled surfaces with live steam or flame.

The rabbit cages at the Gluck Center Annex were not being disinfected. The cage wash for that facility was inoperable and the cages were being hand washed in detergent and rinsed with a de-scaler (Steris S Cleanse).

It is important to the health and well-being of the rabbits to live in sanitary cages.

Primary enclosures for rabbits shall be sanitized by washing them with hot water (180 ?F.) and soap or detergent as in a mechanical cage washer, or by washing all soiled surfaces with a detergent solution followed by a safe and effective disinfectant, or by cleaning all soiled surfaces with live steam or flame.

Correct by: July 15, 2007.

3.56 (c) (1)

SANITATION.

(c) Housekeeping. Premises (buildings and grounds) 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. Premises shall remain free of accumulations of trash.

The floor in the cage wash room # 146 at the Gluck Center Annex had several pock marked holes in the floor exposing the concrete.

It is important to the health and well-being of the animals to live in facilities that are well maintained with floors that are readily cleaned and sanitized.

The floor in the cage wash room # 146 at the Gluck Center Annex should be repaired as needed and sealed.

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Correct by: 1/15/2008

This inspection occurred over 2 days July 10-11, 2007 with an attending veterinarian. The exit interview occurred with the university veterinarian, an attending veterinarian and an IACUC associate.

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Date: Mar-17-2009

2.33 (a) (2)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Sec. 2.33 Attending veterinarian and adequate veterinary care. (a) Each research facility shall have an attending veterinarian who shall provide adequate veterinary care to its animals in compliance with this section: (2) Each research facility shall assure that the attending veterinarian has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use;

The attending veterinarian has been given the authority in writing to oversee the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use but in practice does not have this authority over the animals in the agriculture and veterinary science divisions of the university. It was discovered by this inspector and the attending veterinarian during this inspection that some of the horses were actually being used on biomedical protocols rather than agricultural studies. The attending veterinarian had notified the agriculture and veterinary science divisions of required facility improvements needed to meet biomedical research standards and none had been implemented prior to starting the use of the horses on the biomedical research protocols. In addition, during the most recent semi-annual review of the program of humane care and use the IACUC identified that veterinary authority was an issue. The IACUC wrote in their evaluation letter (dated 1-21-09) to the Institutional Official in response to the veterinary authority issue that the the veterinarian's authority to carry out their duties is "adequate for AAALAC accredited areas. Inadequate in all other areas." Adequate authority must be given to the attending veterinarian to ensure the health and well-being of all the animals regulated under the Animal Welfare Act. The university shall assure that the attending veterinarian has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use. Correct from this day forward.

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3.127 (a)

FACILITIES, OUTDOOR.

Sec. 3.127 Facilities, outdoor. (a) Shelter from sunlight. When sunlight is likely to cause overheating or discomfort of the animals, sufficient shade by natural or artificial means shall be provided to allow all animals kept outdoors to protect themselves from direct sunlight.

The outdoor enclosures/paddocks housing horses on biomedical studies consist of a fenced in grass covered area. There are no artificial or natural shade producing structures present. Lack of shade may lead to overheating and discomfort of the animals. All outdoor housing facilities must offer shelter from sunlight. Correct by August 1, 2009.

3.127 (b)

FACILITIES, OUTDOOR.

Sec. 3.127 Facilities, outdoor. (b) Shelter from inclement weather. Natural or artificial shelter appropriate to the local climatic conditions for the species concerned shall be provided for all animals kept outdoors to afford them protection and to prevent discomfort to such animals...

The outdoor enclosures/paddocks housing horses on biomedical studies consist of a fenced in grass covered area. There are no artificial or natural structures providing shelter from inclement weather present. Lack of shelter may lead to discomfort and injury to the animals. All outdoor housing facilities must offer shelter from inclement weather. Correct by August 1, 2009.

3.131 (c)

SANITATION.

Sec. 3.131 Sanitation. (c) Housekeeping. Premises (buildings and grounds) 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...

The stalls/enclosures in the barn housing horses on biomedical research studies involving infectious disease studies have walls and floors that are composed of porous unsealed concrete. Porous surfaces cannot be adequately sanitized using one of the required methods consisting of washing the surfaces with a detergent solution followed by the use of a disinfectant or by cleaning the surfaces with saturated live steam under pressure. All buildings shall be kept in good repair to facilitate the prescribed husbandry practices including cleaning and sanitation of enclosures. Correct by August 1, 2009.

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