



Inspection Report

UNIVERSITY OF CALIFORNIA, DAVIS

Customer ID: **9192**

ONE SHIELDS AVE

Certificate: **93-R-0433**

Site: 001

UNIVERSITY OF CALIFORNIA, DAVIS

DAVIS, CA 95616

Type: ROUTINE INSPECTION

Date: Jun-04-2008

2.31 (c)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

INDIRECT NON COMPLIANT ITEM

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: (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; and

Protocol # 12888: The antibiotics were changed from Cefazolin to Baytril by one of the veterinarians. There was no amendment or SOP approved by the IACUC allowing these changes without IACUC approval. This issue was not a veterinary care issue but was a routine change that was applied to all the animals in the protocol. The inspector was told by the IACUC administrator that all protocols are pre-reviewed by a member of the veterinary staff. If the veterinarian is working on a specific protocol, and wants to use a specific drug (of their choice), then this change needs to be reflected in the original protocol or as an amendment. This change in the protocol needs to be approved by the IACUC before the procedure can take place (unless an SOP gives them the latitude to change the specific medications). Depending on the medication, this could be critical for the animal's well-being, and could impact the results of the research.

The committee needs to increase the awareness of the principal investigators and veterinarians that they need to get approval for changes if there is not already a SOP addressing these issues.

2.31 (d)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

INDIRECT NON COMPLIANT ITEM

Sec. 2.31 Institutional Animal Care and Use Committee (IACUC) (d) IACUC review of activities involving animals: (1)

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Date:

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Jun-04-2008

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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;

Protocol # 12179: Feral cats would be trapped, anesthetized and blood samples drawn and fecal samples taken to check for toxoplasmosis. Then, the animals would be transported by university personnel and vehicles to a local cat shelter for neutering and then adoption (I was told that the animals would be checked for any chips etc, spayed, neutered and then adopted out.) No animals have been used for this protocol.

The IACUC approved this protocol without making sure that the Animal Welfare Act regulations would be followed. If this inspector had not discovered this, the research would have been done. The researcher changed what they were going to do. They are obtaining samples collected by the shelter. This protocol will not be used. The committee needs to properly review all protocols and if there is a question on the regulations, they should contact USDA APHIS to assure that they are in compliance.

In the future, the IACUC needs to ensure that animal use protocols with dogs and cats comply with the regulations for identification, source, or transportation.

2.31 (c) DIRECT NCI INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

DIRECT NON COMPLIANT ITEM

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: (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; and

DIRECT NON COMPLIANT ITEM

Sec. 2.31 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;

Protocol #12773: The investigator made a major change in the protocol without IACUC approval. Originally, the cats were fed a diet with just the melamine. Then, the researcher found out that there was another contaminant in the food, cyanuric acid. Then, three cats were fed a diet with an additional chemical, cyanuric acid with the melamine. This produced similar results to what was being seen in the client animals. The committee was contacted by the investigator after doing the test on three cats. The committee admonished the researcher and then approved the amendment to add the cyanuric acid to the diet.

To correct this situation, the IACUC needs to increase the awareness of the principal investigators to the importance

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of getting get approval for changes in their protocols before implementing the changes.

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