



Inspection Report

TIER 1 GROUP L L C

Customer ID: **41479**

Certificate: **71-R-0111**

Site: 001

TIER 1 GROUP LLC

3100 Angelletti Rd

Type: ROUTINE INSPECTION

Date: Aug-31-2011

CRAWFORDSVILLE, AR 72327

2.31 (d) (5)

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;

According to protocol A001-10, goats will be anesthetized with a premix of xylazine and ketamine at a rate of 0.1 ml/kg body weight IM, then given a secondary injection of the premix at a rate of 0.10-0.20 ml/kg body weight IM 10 minutes later, and maintained at a surgical plane of anesthesia with the premix given at a rate of 1-2 ml every 20-40 minutes thereafter throughout the procedure. According to at least 50 animal medical records, ketamine was the only drug recorded as being given during a procedure.

The protocol also states that the animals' anesthetic depth will be monitored constantly, and documentation of the monitoring will be recorded every 15 mins. According to the protocol, the level of anesthesia will be determined by the absence or presence of certain reflexes (withdrawl, corneal/palpebral, pharyngeal) and vital sign monitoring. However, at least 50 animal medical records only document vital sign monitoring, and frequently the vital signs are not recorded at the specified 15 minute interval.

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

To be corrected immediately.

2.33 (b) (4)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

(b) Each research facility shall establish and maintain programs of adequate veterinary care that include: (4) Guidance to principal investigators and other personnel involved in the care and use of animals regarding handling,

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immobilization, anesthesia, analgesia, tranquilization, and euthanasia;

According to at least 50 animal medical records for Protocol # A001-10, goats were being anesthetized with ketamine as a stand alone anesthetic agent. This is not an appropriate agent to provide a balanced surgical plane of anesthesia for the invasive procedures (including visceral manipulation) outlined in the protocol. According to the protocol, all anesthetic regimens used will be approved by the attending veterinarian prior to training.

In order to ensure that all procedures are conducted in compliance with the Animal Welfare Act regulations, and in order to protect the health and well-being of the animals, the program of adequate veterinary care must provide appropriate guidance to the principal investigators with regard to handling, immobilization, anesthesia, analgesia, tranquilization and euthanasia of the animals used at the facility.

To be corrected immediately.

This routine inspection and exit interview were conducted with Natalie R. Cooper, VMO, Jeff Baker, VMO, Erika Leisner, VMO and a facility representative.

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