



## Inspection Report

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TEXAS HEART INSTITUTE

Customer ID: **1478**

P.O. BOX 20345

Certificate: **74-R-0037**

Site: 001

TEXAS HEART INSTITUTE

HOUSTON, TX 77225

Type: ROUTINE INSPECTION

Date: Jun-29-2009

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The last routine inspection and exit review were conducted on 04/29/08. This routine inspection and exit review were conducted with management and USDA VMO, Earnest H. Johnson.

NO NON-COMPLIANT ITEM (S) IDENTIFIED THIS INSPECTION.

NOTE: The procedure used to amend the protocol of changes was a concern when it came to during the amending in a timing manner. I am hoping that changes would be noted at least a week or days prior to making changes in a protocol.

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**Prepared By:**

EARNEST H JOHNSON, D.V.M. USDA, APHIS, Animal Care

**Date:**

**Title:** VETERINARY MEDICAL OFFICER Inspector 4048

Jun-30-2009

**Received By:**

(b)(6), (b)(7)(c)

**Date:**

**Title:**

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### 2.30 (c) (1)

#### REGISTRATION.

(c) Notification of change of operation.

(1) A research facility shall notify the AC Regional Director by certified mail of any change in the name, address, or ownership, or other change in operations affecting its status as a research facility, within 10 days after making such change.

The protocol # 2006-11 was amended and approved by the IACUC on 06/21/07 to house seven sheep at an off site location. The USDA, Western Regional Office was not notified of the additional site within ten days after making such change. This research facility shall notify USDA, Animal Care within ten days of any changes in operation.  
TO BE CORRECTED BY: 05/15/08.

### 3.125 (a)

#### FACILITIES, GENERAL.

The indoor and outdoor housing facilities shall be structurally sound and shall be maintained in good repair.

The ceiling of the ICU was observed to have rust and flaking paint surrounding four different metal plates for the electrical wiring. These areas of were pointed and explained to management that the research housing facilities shall be maintained in good repair. A work order has been turned in to maintenance.

TO BE CORRECTED BY: 05/29/08.

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**3.131** (c)

**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. Accumulations of trash shall be placed in designated areas and cleared as necessary to protect the health of the animals.

Enrichment toys, halters and extra equipment are being stowed in the ICU resulting in cluttering. Management shall use the ICU as a caring unit for post-operative animals and not as a storage room for toys, halters and extra equipments. Accumulation of enrichment toys, halters, and equipments shall be placed in designated areas and cleared as necessary to protect the health of the animals.

TO BE CORRECTED BY: 05/29/08.

The last routine inspection and exit review were conducted on 06/20/07. This routine inspection and exit review were conducted with management and USDA VMOS, Elizabeth Pannill and Earnest Johnson.

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**2.31** (d) (1) (xi)

### **INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).**

(xi) Methods of euthanasia used must be in accordance with the definition of the term set forth in 9 CFR part 1, Sec. 1.1 of this subchapter, unless a deviation is justified for scientific reasons, in writing, by the investigator.

It was noted in Protocol 2005-20 that the method of euthanasia is performed by removal of the sheep heart while under deep anesthesia. Currently, this is not an approved method of euthanasia as referred by the AVMA Guidelines for Euthanasia. CFR part 1, Section 1.1 defines humane euthanasia in the following paragraph.

Euthanasia is defined as the humane destruction of an animal accomplished by a method that produces rapid unconsciousness and subsequent death without evidence of pain or distress, or a method that utilizes anesthesia produced by an agent that causes painless loss of consciousness and subsequent death. Euthanasia methods that do not meet this definition must be scientifically justified as to why the deviation is necessary.

TO BE CORRECTED BY: 08/20/07.

**2.31** (d) (1)

### **INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).**

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 2006-15 did not incorporate the required IACUC modifications. This same draft protocol was used by the investigator to perform animal procedures. Protocols (2006-11, 2006-16, 2007-05) all contained the same discrepancies found in 2006-15. When the IACUC requires modifications in a

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protocol, the IACUC must ensure that a final version is received and approved prior to implementation of the changes.

TO BE CORRECTED BY: 09/20/07.

### 2.31 (e) (2)

#### INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

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;

It was noted that the numbers of animals in several protocols were justified and approved for a certain number of animals. The number of animals approve for use by the IACUC in these protocols was 100-150% greater than the justified numbers. The IACUC must only approve animals that are justified by the investigator and not allow the number to be increased without proper justification.

TO BE CORRECTED BY: 09/20/07.

### 2.31 (e) (3)

#### INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

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.

In two separate protocols (2005-20 & 2007-08) it was noted that the "layman's description" were the same with minor word changes. These two descriptions were vague and failed to describe the complete animal use procedures. A complete discription of the proposed use of the animals in the protocols must be provided for all IACUC members.

TO BE CORRECTED BY: 09/20/07.

### 3.130

#### WATERING.

If potable water is not accessible to the animals at all times, it must be provided as often as necessary for the health and comfort of the animal. Frequency of watering shall consider age, species, condition, size,

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and type of the animal. All water receptacles shall be kept clean and sanitary.

During the routine inspection, it was noted that the water supply for two sheep was contaminated with feces. This noncompliant item was pointed out to management and explained that the water supply for all the animals shall be free from contamination for the well-being of the animals.

However, the Attending Veterinarian did correct this noncompliant item prior to the completion of the routine inspection.

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