2.31 (c) (7)
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

IACUC functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall 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.

One of the squirrels used in Protocol # 704, which is now completed, was injured during a procedure. For treatment he was given buprenorphine every 12 hours and needed to be sedated prior to the buprenorphine injection to be handled. Isoflurane sedation in a chamber was approved for the squirrels by the IACUC, but he was sedated with isoflurane in a bell jar, a method which was not approved, and died. The PI must submit a proposal for any significant changes for approval by the IACUC before conducting activities not already approved. The IACUC must review any significant changes to a protocol for appropriateness to the species, safety to the handlers, and safety to the animals.

Correct by Dec. 15, 2010

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

Protocol #704, which is completed, contains a amendment for a new procedure. The amendment contains a description of the procedure and refers to the original protocol, but does not contain a rationale for doing the procedure on the animals nor for using the squirrels on this procedure. Without these narratives, the USDA inspector is unable to determine the purpose of the procedure and the appropriateness of using squirrels. The facility must ensure that all proposals and significant changes to proposals contain a rationale for involving animals and for the appropriateness of the species used.

Correct by Dec 15, 2010
2.32 (b) DIRECT NCI

PERSONNEL QUALIFICATIONS.

Training and instruction shall be made available, and the qualifications of personnel reviewed, with sufficient frequency to fulfill the research facility’s responsibilities under this section and Sec. 2.31.

A squirrel was sedated using a bell jar technique on which the animal care staff had not been previously trained. The first time the technique was administered the animal technologist was present to train the animal care staff. The second time the technique was administered the animal care staff performed it without assistance and the squirrel died. This technique can have complications of overdose as the isoflurane is not calibrated therefore lethal doses can rapidly accumulate. Also, the animals must be closely monitored and the animal care staff must be able to recognize signs of overdose. The facility must ensure that fully trained animal care staff performs proposed animal care techniques.

Correct from this point on.

2.35 (f) RECORDKEEPING REQUIREMENTS.

All records and reports shall be maintained for at least three years. Records that relate directly to proposed activities and proposed significant changes in ongoing activities reviewed and approved by the IACUC shall be maintained for the duration of the activity and for an additional three years after completion of the activity. All records shall be available for inspection and copying by authorized APHIS or funding Federal agency representatives at reasonable times.

Five squirrels had been used on Protocol #704 and the records kept on their pre- and post-procedural care were not available for review by the USDA inspector. These squirrels had a zoonotic infection and the room was decontaminated after the end of study. Without documentation to review, the inspector is unable to verify that the animals were cared for in accordance with the IACUC approved protocol and the standard of veterinary care. The facility must keep all records relating directly to proposed activities for three years after completion of the study. The facility must develop a plan to maintain records that are potentially contaminated with zoonosis and make them available for review at the time of USDA inspection.

Correct by Dec 15, 2010

Exit briefing conducted with facility representative.

Prepared By:  
TONYA HADJIS, D.V.M.  USDA, APHIS, Animal Care
Title:  VETERINARY MEDICAL OFFICER Inspector 1081

Date:  Nov-12-2010

Received By:  
(b)(6),(b)(7)(c)

Date:  Nov-12-2010