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:

(6) Review and approve, require modifications in (to secure approval), or withhold approval of those components of proposed activities related to the care and use of animals, as specified in paragraph (d) of this section.

An IACUC approved activity called for the removal of surgically implanted hardware within a proscribed period of time. Some of the hardware was not removed from one animal as called for in that research protocol. The animal subsequently developed complications at the surgical site and required extensive additional treatment beyond what was necessary for the initially approved activity.

The IACUC should review proposed significant changes to activities involving animals prior to the implementation of the activity. After reviewing the activities, the IACUC may approve the changes, require modifications to the activities, or withhold their approval. A system should be in place which would ensure that proposed significant changes to activities involving the care and use of animals are reviewed and approved by the IACUC prior to their implementation.

Correct on all current and future protocols by April 3, 2011.

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; Further, the IACUC shall determine that the proposed activities or significant changes in ongoing activities

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Date: Jan-21-2011

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

Date: Mar-03-2011
meet the following requirements:
(i) Procedures involving animals will avoid or minimize discomfort, distress, and pain to the animals.

A nonhuman primate (NHP) was kept on study despite having multiple health issues following a surgical procedure that was a part of an IACUC approved protocol. The NHP was kept on study for over 23 months after developing complications to a surgical procedure. During this time repeated surgical procedures and medical treatments for complications from the activity were performed. According to the staff at the facility, other animals on the same study had minimal or no complications resulting from their use in the activity.

Allowing an animal to remain on a study for almost two years while undergoing repeated invasive treatments for chronic complications of the study is not consistent with the intent of this section of the Animal Welfare Act. Keeping an animal on study under these circumstances does not avoid or minimize discomfort, distress, or pain to that animal. The IACUC should determine that the ongoing activities at the facility involving animals will avoid or minimize discomfort, distress, and pain to the animals under their review.

Correct by April 3, 2011.

2.31  
(e)  (3)  
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:
(3) A complete description of the proposed use of the animals.

An IACUC approved protocol described an activity using animals but did not provide details regarding the use of those animals at a different facility. One portion of the approved activity, including surgical procedures, was being performed at a second institution but the description of the activity in the protocol did not include any details regarding this arrangement, such as which parts of the procedure were to take place at the second facility.

The IACUC is responsible for reviewing all aspects of animal care and use, and for evaluating protocols in order to ensure compliance with the Animal Welfare Act. In order to properly accomplish this function, the IACUC must be made aware of all procedures being conducted. It is the responsibility of the IACUC to ensure that the investigator provides a complete description of proposed activities that involve the use of animals in order that those activities may be adequately reviewed and determined to be in accordance with the Animal Welfare Act.

This non-compliant item was corrected by the time of the exit interview.

Note:
An exit briefing was conducted with a facility representative.

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Date: Mar-03-2011