



Inspection Report

UNIVERSITY OF CALIFORNIA, DAVIS

Customer ID: 9192

Certificate: 93-R-0433

Site: 001

UNIVERSITY OF CALIFORNIA, DAVIS

ONE SHIELDS AVE

Type: ROUTINE INSPECTION

DAVIS, CA 95616

Date: Feb-13-2013

2.31 (c) (7)

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.

A significant change to protocol 16573 was not approved by the IACUC prior to implementation. As approved in this protocol, the investigator states that " Infants will be raised in the nursery for postnatal studies and paired with animals of a similar age within the same study groups..." Later in the document "On the day of gene transfer, animals that are housed with another animal will be temporarily separated (~7 to 10 days)..." The protocol specifically states (under the Social Enrichment section) "Pairing conditions from which subjects are to be exempt...Duration of exemption: 7 10 Day(s).

Two NHPs born on 5/29/12 and 5/25/12 were assigned to the above protocol. According to their records, the animals were not paired until either 9/24/12 or 9/26/12 (records conflict), and thus were housed individually for approximately four months. There was no explanation in the animal 's records as to why they were housed separately for the extended period of time.

Protocol changes of this type can have a significant impact on animal well-being and require approval by the IACUC prior to being instituted. 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.

Correction date: Corrected.

Prepared By:

MARCY ROSENDALE, D.V.M.

MARCY E ROSENDALE, D.V.M. USDA, APHIS, Animal Care

Date:

Title:

VETERINARY MEDICAL OFFICER Inspector 5039

Mar-11-2013

Received By:

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

Date:

Title:

Mar-11-2013



Inspection Report

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:

IACUC approved protocol 16562 titled " CNPRC Herd/Breeding/Colony Management" includes provisions to use colony NHPs for training during either survival procedures or prior to euthanasia. The protocol does not state any maximum number of procedures that may be performed on individual animals during these training procedures. Seven SOPs are specifically listed in the protocol (blood draw, catheter placement, IM, ID, IV, or SQ injections, nasogastric or orogastric intubation, CSF tap, stereotaxic placement, cystocentesis, anesthesia monitoring, bronchoscopy) as well as a general statement "or other clinical procedures requiring training."

Additionally, the protocol does not describe any use of euthanized animals for training. The protocol specifically states that "...once the training procedures are complete, the animal is immediately euthanized with... and a routine necropsy is performed." The necropsy report of a NHP found during a record review describes an animal that was presented for necropsy "...presented in good flesh subsequent to practice experimental surgical procedure... surgeries involving head, abdomen, and limbs." The animal's individual record did not contain any documentation regarding the final use of the animal, thus it was initially unclear if the procedures were performed prior to or after the death of the animal. Additional records were located showing that the procedures were performed after euthanasia.

The IACUC is responsible for reviewing all aspects of animal care and use in order to ensure compliance with the Animal Welfare Act. In order to properly accomplish this function, a complete description of activities using regulated species is necessary. Protocol 16562 places no limits on the number of training procedures that may be performed on colony NHPs. It is the responsibility of the IACUC to ensure that protocols include a complete description of proposed activities that involve the use of regulated species in order that those activities may be adequately reviewed and determined to be in accordance with the Animal Welfare Act.

Correct by May 11, 2013.

An exit briefing was conducted with a facility representative.
Accompanied by Dr. J. Lee and Dr. P. Smith.

Prepared By:

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