



INSPECTION REPORT

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SOUTHWEST FOUNDATION FOR
BIOMEDICAL RESEARCH

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SOUTHWEST FOUNDATION FOR

P. O. BOX 760549
SAN ANTONIO, TX 78245 0549

Inspection
Type: ROUTINE INSPECTION
Date: APR-03-2007

- 2.31 (c) (3) DIRECT
- 2.31 (c) (4)
- 2.31 (d) (1) (ii)
- 2.31 (d) (1) (x) REPEAT NCI
- 2.31 (d) (1) (xi)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31 c) IACUC Functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall:

3) Prepare reports of its evaluations conducted as required by paragraphs (c)(1) and (2) of this section, and submit the reports to the Institutional Official of the research facility; Provided, however, That the IACUC may determine the best means of conducting evaluations of the research facility's programs and facilities; and Provided, further, That no Committee member wishing to participate in any evaluation conducted under this subpart may be excluded. The IACUC may use subcommittees composed of at least two Committee members and may invite ad hoc consultants to assist in conducting the evaluations, however, the IACUC remains responsible for the evaluations and reports as required by the Act and regulations. The reports shall be reviewed and signed by a majority of the IACUC members and must include any minority views. The reports shall be updated at least once every six months upon completion of the required semiannual evaluations and shall be maintained by the research facility and made available to APHIS and to officials of funding Federal agencies for inspection and copying upon request. The reports must contain a description of the nature and extent of the research facility's adherence to this subchapter, must identify specifically any departures from the provisions of title 9, chapter I, subchapter A--Animal Welfare, and must state the reasons for each departure. The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, with reference to Subchapter A, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule with dates for correcting each deficiency. Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the Institutional Official, to APHIS and any Federal agency funding that activity;

APR 16 2007

Prepared By: Elizabeth Pannill V.M.O.
ELIZABETH PANNILL, V.M.O., USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER, Inspector ID: 4018

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Date:
APR-09-2007

Title:



INSPECTION REPORT

A male baboon was presented for necropsy and tissue collection on August 28,2006 .The animal had been sedated and then injected with euthanasia solution prior to necropsy , however the animal was actually in a deep state of anesthesia and not deceased at the time the necropsy began. The pathologist detected a faint femoral pulse approximately 10 minutes after the necropsy and tissue harvest was started. Failure to determine the death of an animal prior to necropsy beginning is a significant program deficiency. The IACUC did not identify this departure from adherence to the regulations in any of its semiannual reports to the Institutional Official. A plan must be developed to identify departures from adherence to the regulations and they must be included in the semi annual report to the Institutional Official.

Correct By: 5-25-07

2.31 (c) (4) Review, and, if warranted, investigate concerns involving the care and use of animals at the research facility resulting from public complaints received and from reports of noncompliance received from laboratory or research facility personnel or employees;

The attending veterinarian was notified of the necropsy incident regarding the baboon that was not deceased prior to necropsy. Facts concerning the incident were gathered by the attending veterinarian but there was no further investigation into the incident by the IACUC. There is no record that the full IACUC was notified of the incident. The IACUC must review and if warranted investigate all concerns involving care and use of animals at the facility. A plan must be in place to assure that when an incident is reported the full IACUC is notified that a report has been made.

Correct By: 5-25-07

2.31(d)(1) (ii) The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources used to determine that an alternative was not available.

The PI did not consider alternatives to giving only the minimum dose of euthanasia agent used on this protocol. The use of an alternative may have prevented the occurrence of this incident. The PI must consider alternatives or provide a written narrative description of the methods and sources used to determine that an alternative was not available.

Correct By 5-25-07

2.31 (d) (1) (x) No animal will be used in more than one major operative procedure from which it is allowed to recover, unless: (C) In other special circumstances as determined by the Administrator on an individual basis. Written requests and supporting data should be sent to the Western Regional Office.

This was identified as a non compliant item of 7-13-06 with a correction date of 8-13-06. The letter requesting a variance to the regulation was sent to the Western Regional Office on 2-13-07. The regional animal care specialist has requested additional information from the facility prior to granting a variance. The protocol is on going and at least one animal involved in this protocol has had a second survival surgery since 7-13-06.

Prepared By:

Elizabeth Pannill
ELIZABETH PANNILL, V.M.O. , USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER , Inspector ID: 4018

Received By:

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2.31 (d) (1) (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.

Euthanasia means the humane destruction of an animal accomplished by a method that produces rapid unconsciousness and subsequent death without evidence of pain or distress. The euthanasia of one baboon was not accomplished as described above as it was not dead prior to the start of the necropsy procedure. There was no scientific justification for a deviation in this case. The method of euthanasia must produce rapid unconsciousness and subsequent death or the Investigator must provide a scientific justification for a deviation.

Correct By: 5-25-07

2.32 (c) (4)

PERSONNEL QUALIFICATIONS.

2.32 (c) (4) Training and instruction of personnel must include guidance in at least the following areas:

(4) Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility. No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act;

New employee training SOP does not address the method of reporting deficiencies in animal care. The SOP has recently been updated and now does include the statement that any IACUC member may be contacted by employees regarding animal care concerns. Signs with IACUC members contact information are posted in many locations around the facility. The SOP is in draft form only and has not yet been approved by the IACUC. The SOP needs to be approved by the IACUC and adopted by the facility. All personnel must be aware of the SOP regarding the proper reporting of animal care and treatment concerns.

Correct By 5-25-07

Prepared By:

Elizabeth Pannill V.M.O.
ELIZABETH PANNILL, V.M.O., USDA, APHIS, Animal Care

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**2.33 (b) DIRECT
ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.**

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, immobilization, anesthesia, analgesia, tranquilization, and euthanasia;
- (5) Adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedure

Records indicate that the male baboon presented for necropsy and tissue harvest was first sedated with Ketamine and then given an IV injection of 5.7 mls of euthanasia solution. The dose of 5.7 mls, is the minimal dosage that would be required for an animal of this weight. Individual animals may require different amounts of drug to be effective and should be dosed accordingly. The fact that the animal was still alive as indicated by a femoral pulse detected at necropsy indicates that the dosage of euthanasia solution was inadequate to assure a quick, humane death .Performing a necropsy on a living animal even when it is anesthetized does not constitute adequate veterinary care.

The incident regarding the male baboon presented for necropsy and tissue harvest in a deep state of anesthesia rather than properly euthanized indicates that further guidance must provided regarding euthanasia methods and methods to determine death of an animal following injection of euthanasia solution . Guidance must be provided to all involved in animal euthanasia and necropsy to ensure that such incidents never occur again and to ensure that adequate veterinary care is maintained . Additional training and updated euthanasia and necropsy SOPs may provide such guidance.

Correct By: 5-25-07

This inspection was of records only and conducted April 3-5 2007 with Drs. Pannill, Kjos and Johnson of USDA Animal Care and the attending veterinarian and 2 IACUC members of SWFBR.

Prepared By: Elizabeth Pannill V.M.O.
ELIZABETH PANNILL, V.M.O. , USDA, APHIS, Animal Care

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