



## Inspection Report

PRINCETON UNIVERSITY

Customer ID: 176

Certificate: 22-R-0022

Site: 001

MOLECULAR/EVOLUTIONARY BIOLOGY

P O BOX 36

Type: ROUTINE INSPECTION

Date: Jun-23-2010

PRINCETON, NJ 08544

### 2.31 (c) (3)

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

Section 2.31 (c) (3) states - "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.....The reports shall be updated at least once every six months upon completion of the required semiannual evaluations."

1. The Semi-annual Reports to the Institutional Official (IO) from the IACUC were reviewed during the inspection beginning with the 6/30/09 report for the reviews conducted by the IACUC in April 2009. The next Semi-annual Report from the IACUC to the IO was submitted 11 months later on 5/21/10 for the reviews conducted by the IACUC in October 2009.

The IACUC is required to submit a Report to the IO at least once every 6 months upon completion of the required semi-annual evaluations of the Animal Facility Inspection and the Program for the Humane Care and Use of Animals. Correct from this date forward for all semi-annual evaluations conducted by the IACUC.

### 2.31 (c) (7)

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

Section 2.31 (c) (7) states - "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."

1. Pertaining to Protocol #1724: The PI used a method to induce anesthesia in NHP #P on 4/30/10 that was not described in his/her IACUC approved protocol.

The IACUC must review and approve any proposed significant changes to ongoing research activities before the proposed change(s) can be implemented by the investigator. The IACUC needs to address the deviation that was identified for the proposal. Correct by 7/26/10.

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## Inspection Report

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2.31 (d) (1) (ii)

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

Section 2.31 (d) (1) (ii) states - "The IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements: (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 alternatives were not available."

1. Review of Protocol #1724: The protocol describes the use of water scheduling/fluid restriction in NHPs. The water control as described in the protocol could be expected to result in more than momentary distress in the NHPs due to any unrelieved thirst experienced during the time without access to fluids, and a consideration of alternatives would be required. The written narrative of the methods and sources used to determine that alternatives were not available to the potentially painful or distressful procedures described in the proposal for animal use does not include the procedure of water scheduling/fluid restriction.

In order to approve proposed animal use activities, the IACUC is required to determine that all proposed activities meet the requirement that a principal investigator has considered alternatives to the potentially painful and distressful procedures described in a proposal for animal use. The IACUC needs to: (1) address this item as identified for this protocol and (2) ensure that all active proposals comply with Section 2.31 (d) (1) (ii). Correct (1) by 7/26/10 and (2) by 3/26/11.

2.31 (d) (1) (iii)

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

Section 2.31 (d) (1) (iii) states - "The IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements: (iii) The principal investigator has provided written assurance that the activities do not unnecessarily duplicate previous experiments."

1. Pertaining to Protocol #1724 that was approved 7/9/08: There was no written assurance by the principal investigator that the proposed activities do not unnecessarily duplicate previous experiments as is required per this Section.

In order to approve proposed animal use activities, the IACUC is required to determine that all proposed activities meet the requirement that the principal investigator has provided written assurance that the proposed activities do not unnecessarily duplicate previous experiments. The IACUC needs to: (1) address this item as identified for this protocol and (2) ensure that all active proposals comply with Section 2.31 (d) (1) (iii). Correct (1) by 7/26/10 and (2) by 3/26/11.

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**2.31** (d) (1) (x) (A)

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

Section 2.31 (d) (1) (x) (A) states - "The IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements: (x) No animal will be used in more than one major operative procedure from which it is allowed to recover, unless: (A) Justified for scientific reasons by the principal investigator, in writing."

1. Protocol #1724 describes the placement of 2 recording chambers during a single major survival surgery. The protocol includes a statement that no animal will undergo more than one major survival surgical procedure. NHP #1 had undergone surgery prior to 2009 to place one recording chamber. The same NHP had surgery on 2/10/09 to place a second recording chamber in a different anatomic location.

No animal will be used in more than one major operative procedure from which it is allowed to recover unless the principal investigator has justified in writing the scientific reasons for performing more than one major operative procedure. The IACUC needs to: (1) address this item as identified for this protocol and (2) ensure that all active proposals comply with Section 2.31 (d) (1) (x) (A). Correct (1) by 7/26/10 and (2) by 3/26/11.

**2.31** (d) (5)

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

Section 2.31 (d) (5) states - " IACUC review of activities involving animals. (5) The IACUC shall conduct continuing reviews of activities covered by this subchapter at appropriate intervals as determined by the IACUC, but not less than annually."

1. Protocol #1724 was reviewed and approved by the IACUC 7/9/08. It underwent its first annual review on 4/24/09. The next annual review was conducted 14 months later on 6/22/10.

The IACUC should conduct continuing reviews of all animal use proposals no less than annually. The IACUC needs to ensure that all animal use proposals undergo continuing reviews no less than annually. Correct for all protocols from this date forward.

**2.31** (e) (3)

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

Section 2.31 (e) (3) states - "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."

1. Review of Protocol #1724: There were inconsistencies or incomplete descriptions provided in the IACUC approved protocol for each of the following proposed uses of the animals.

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- a. There were insufficient details provided for the water scheduling/fluid restriction/controlled access to water and EMG procedures.
- b. The list of medications to be administered to the NHPs does not include the frequency of administration.
- c. The protocol states that 2 recording chambers and 1 head post will be placed at a single surgery. NHP #B and NHP #P had no recording chambers and 2 head posts placed at surgery in 12/09.
- d. The protocol describes 2 possible methods to attach recording chambers and head post. A conversation with the investigator revealed that a 3rd method was used in NHP #B and NHP #P in 12/09. The 3rd method is not described in the approved protocol.
- e. The protocol includes an exemption to social housing and states that a plan is being developed to try to pair each NHP with a different animal. A conversation with the investigator revealed that there have not been any attempts to re-pair the NHPs.

A proposal for animal use must contain a complete description of the proposed use of the animals. The IACUC needs to: (1) address this item as identified for this protocol and (2) ensure that all active proposals comply with Section 2.31 (e) (3). Correct (1) by 7/26/10 and (2) by 3/26/11.

### 2.31 (e) (4)

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

Section 2.31 (e) (4) states - "A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain the following: (4) A description of procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research, including provision for the use of analgesic, anesthetic, and tranquilizing drugs where indicated and appropriate to minimize discomfort and pain to animals."

- 1. Protocol #1724 contains the major survival surgical procedure of craniotomy and includes the administration of analgesic "X" at the conclusion of the surgery, and then "as needed". A craniotomy would reasonably be expected to cause more than slight or momentary pain and/or distress for which the administration of an analgesic post-operatively would be needed routinely. The administration of an analgesic following a craniotomy on an "as needed" basis is not appropriate to minimize discomfort and pain.

A proposal to conduct activity in animals must contain a description of procedures designed to limit discomfort and pain to the animals. The IACUC and AV need to: (1) address this item identified for this protocol and (2) ensure that all active proposals comply with Section 2.31 (e) (4). Correct (1) by 7/26/10 and (2) by 3/26/11.

### 2.33 (b) (2)

#### REPEAT

#### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Section 2.33 (b) (2) states - "Each research facility shall establish and maintain programs of adequate veterinary care that include: (2) The use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries."

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1. The following outdated medications were identified during the inspection: Emergency kit in IE-14 - 20 ml bottle Potassium chloride, #1 bottle, exp date 5/10; Cart in OE-12B - one bottle of Acidophilus capsules, exp date 5/10.

The use of outdated medications may not be safe or efficacious and is not considered to be an acceptable practice. The outdated medications were immediately discarded by facility personnel.

### 2.33 (b) (3)

#### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Section 2.33 (b) (3) states - "Each research facility shall establish and maintain programs of adequate veterinary care that include: (3) Daily observation of all animals to assess their health and well-being; Provided, however, That daily observation of animals may be accomplished by someone other than the attending veterinarian; and Provided, further, That a mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian."

1. NHP #B underwent a surgical procedure on 12/10/09. The 12/13/09 entry in the medical record at 8 AM by laboratory personnel states that the NHP was not interested in eating fruit or treats, appeared agitated, and was grinding his teeth. An animal exhibiting these clinical signs can indicate that the animal is experiencing pain. There was no documentation in the medical record that the Attending Veterinarian was contacted by laboratory personnel to convey the clinical signs observed in the NHP.

The daily observation of all animals to assess their health and well-being to identify any problems of animal health and behavior should be done by all personnel involved with animal care. The research facility needs to ensure that accurate and timely information on problems of animal health are communicated to the AV by all personnel involved with animal care to ensure the provision of adequate veterinary care to the animals. Correct from this date forward.

### 2.33 (b) (5)

#### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Section 2.33 (b) (5) states - " Each research facility shall establish and maintain programs of adequate veterinary care that include: (5) Adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedures."

1. Protocol #1724 includes water scheduling/fluid restriction and states that one of the primary daily criteria used to assess the health status of the NHPs is the animals' weight. The June 2010 monitoring records for NHP #P were reviewed. The NHP was on study for 11 days; the NHP's weight was recorded by the investigator for only 5 of the 11 study days.

Research facilities should provide adequate pre and post procedural care to maintain the animals' health. The AV and IACUC need to address this deviation from the approved protocol. Correct by 7/2/10.

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## Inspection Report

2.36 (b) (3)

### ANNUAL REPORT.

Section 2.36 (b) (3) states - "The annual report shall.....(3) Assure that the facility is adhering to the standards and regulations under the Act, and that it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the IACUC. A summary of all such exceptions must be attached to the facility's annual report. In addition to identifying the IACUC-approved exceptions, this summary must include a brief explanation of the exceptions, as well as the species and number of animals affected."

1. Protocol #1724 describes the use of water scheduling and fluid restriction in NHPs. After reviewing the protocol, animal records, and having a conversation with the investigator, it was determined that at times the NHPs are offered water on a schedule that is less than the minimum required per Section 3.83 Watering. The Annual Report submitted by the research facility for FY 2009 did not include this exception to the watering standards.

The annual report should provide a summary of all exceptions to the standards that have been approved by the IACUC including a brief explanation of the exception, the species and number of animals affected. The IACUC needs to submit a revised copy of the FY 2009 Annual Report to the Eastern Regional Office. Correct by 7/26/10.

3.75 (e)

### HOUSING FACILITIES, GENERAL.

Section 3.75 (e) states - "Substances that are toxic to the nonhuman primates but that are required for normal husbandry practices must not be stored in food storage and preparation areas, but may be stored in cabinets in the animal areas."

1. There was a cutting board and knife used to prepare fruit for NHPs on the top shelf of the cart in OE12B. There was a spray bottle containing the disinfectant Virkon and a spray bottle containing Alcohol located on the cart next to the cutting board and knife. Facility personnel immediately moved the bottles.

Substances that are toxic to nonhuman primates but that are required for normal husbandry practices must not be stored in food storage and preparation areas in order to avoid contamination of food. The Registrant needs to ensure that all personnel are familiar with this requirement for the health of the animals. Correct by 7/2/10.

NOTE - This was a full facility inspection conducted from 6/23/10 through 6/24/10. Exit interview held with facility personnel on 6/24/10. Inspection report delivered for signature 6/25/10. END OF REPORT.

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