



Inspection Report

FORSYTH DENTAL INFIRMARY FOR

Customer ID: **131**

140 THE FENWAY

Certificate: **14-R-0186**

Site: 001

FORSYTH INSTITUTE

BOSTON, MA 02115

Type: ROUTINE INSPECTION

Date: Dec-02-2008

Facility is in compliance with AWA Standards and Regulations at the time of inspection.

Prepared By:

TONYA HADJIS, V.M.O. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1081

Dec-02-2008

Received By:

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

Date:

Title:

Dec-02-2008



Inspection Report

FORSYTH DENTAL INFIRMARY FOR CHILDREN

Customer ID: 131

Certificate: 14-R-0186

Site: 001

FORSYTH INSTITUTE

140 THE FENWAY

Type: ROUTINE INSPECTION

BOSTON, MA 02115

Date: Jun-12-2008

2.30 (c) (1)

REGISTRATION.

2.30 (c) (1) - "A research facility shall notify the AC Regional Director by certified mail of any change in the name, address, or ownership, or other change in operations affecting its status as a research facility, within 10 days after making such change."

1. It was learned during the inspection that a new IO was appointed as of 1/1/08, but the facility did not notify USDA/APHIS/AC of the change. The updated information should be sent to the Animal Care Eastern Regional Director, USDA/APHIS/Animal Care at 920 Main Campus Drive, Suite 200, Raleigh, NC 27606. Correct by 7/11/08.

Prepared By:

PAULA S GLADUE, V M D USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1054

Jun-12-2008

Received By:

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

Date:

Title:

Jun-12-2008



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FORSYTH DENTAL INFIRMARY FOR CHILDREN

Customer ID: 131

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140 THE FENWAY

Type: ROUTINE INSPECTION

BOSTON, MA 02115

Date: Dec-05-2007

This was a focused inspection based on the non-compliant items that were identified during the last inspection. Facility has successfully corrected all of the non-compliant items from the last inspection.

Prepared By:

PAULA S GLADUE, V M D USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1054

Dec-05-2007

Received By:

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

Date:

Title:

Dec-05-2007



Inspection Report

FORSYTH DENTAL INFIRMARY FOR CHILDREN

Customer ID: 131

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140 THE FENWAY

Type: ROUTINE INSPECTION

BOSTON, MA 02115

Date: Jul-11-2007

2.31 (b) (3) (ii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31 (b) (3) (ii) - "IACUC Membership. (3) Of the members of the Committee: (ii) At least one shall not be affiliated in any way with the facility other than as a member of the Committee, and shall not be a member of the immediate family of a person who is affiliated with the facility. The Secretary intends that such person will provide representation for general community interests in the proper care and treatment of animals."

1. The sole Non-affiliated community member of the facility's IACUC resigned in June 2006. The IACUC continued to hold convened meetings and conduct business following the departure of the Non-affiliated Committee member. A replacement Non-affiliated member has not been appointed by the Institutional Official (IO) as of the date of this inspection.

The Non-affiliated member of an IACUC provides representation for general community interests in the proper care and treatment of animals at a research facility. The IO needs to appoint a Non-affiliated community member to the facility's IACUC in order to have a duly constituted IACUC in place. Correct immediately.

2.31 (c) (3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31 (c) (3) - "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 (IO) of the research facility.....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.....The reports must distinguish significant deficiencies from minor deficiencies..... If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule with dates for correcting each deficiency."

1. Review of Semi-annual Report to the IO dated 6/30/07:

Prepared By:

PAULA S GLADUE, V M D USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1054

Jul-11-2007

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- a. The Report states that a minor deficiency was noted during the Facility Inspection. The Report does not identify what the deficiency was and there is no schedule for correction given.
- b. The Report states that the IACUC does not have a Non-affiliated community member. The Report also states that this is an ongoing unresolved issue. This deficiency was not graded as being significant or minor, and there is no schedule for correction given.
- c. The Report was not signed by a majority of the members of the IACUC before it was sent to the IO.

The IACUC is responsible for conducting semi-annual evaluations of the animal facilities and the program for humane care and use of animals. The Semi-annual Report to the IO should contain a description of any deficiencies identified, distinguish significant from minor deficiencies, give a correction schedule, and be signed by a majority of the IACUC. The IACUC needs to make the necessary corrections and re-submit the 6/30/07 Report to the IO. Correct by 10/1/07.

2.31 (e) (3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31 (e) (3) - "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 #07-001:

- a. It was learned from personnel that the antibiotic Streptomycin is administered to the Guinea Pigs but the use of Streptomycin (dose, frequency and route of administration) is not described in the protocol.
- b. It was learned from personnel that Ketamine and Xylazine are administered to the Guinea Pigs but the use of these drugs (dose, frequency and route of administration) is not described in the protocol.
- c. The method used for intravenous administration of test substance to the Guinea Pigs is not described.
- d. The method of sedation used prior to euthanasia of the Guinea Pigs is not described.

A proposal for animal use must contain a complete description of the proposed use of the animals. The IACUC must address these items identified for this protocol. Correct by 8/15/07.

NOTE - This was the first inspection of this newly registered research facility.

Prepared By:

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