



Inspection Report

INTERNATIONAL INSTITUTE FOR BIOMEDICAL RESEARCH

Customer ID: **22152**

Certificate: **58-R-0137**

Site: 001

220 - 108TH AVE STE 501

INTERNA INSTIT FOR BIOMEDICAL RESEARCH

Type: ROUTINE INSPECTION

Date: Aug-20-2009

TREASURE ISLAND, FL 33706

No non-compliances identified during this inspection.

No regulated animals present.

Prepared By:

MARY E MOORE, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1044

Aug-20-2009

Received By:

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

Date:

Title:

Aug-20-2009



Inspection Report

INTERNATIONAL INSTITUTE FOR

Customer ID: **22152**

220 - 108TH AVE STE 501

Certificate: **58-R-0137**

Site: 001

INTERNA INSTIT FOR BIOMEDICAL

TREASURE ISLAND, FL 33706

Type: ROUTINE INSPECTION

Date: Mar-10-2009

No non-compliances identified during this inspection.

Prepared By:

MARY E MOORE, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1044

Mar-10-2009

Received By:

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

Date:

Title:

Mar-10-2009



Inspection Report

INTERNATIONAL INSTITUTE FOR BIOMEDICAL RESEARCH

Customer ID: **22152**

Certificate: **58-R-0137**

Site: 001

INTERNA INSTIT FOR BIOMEDICAL RESEARCH

220 - 108TH AVE STE 501

Type: ROUTINE INSPECTION

Date: Jul-29-2008

TREASURE ISLAND, FL 33706

2.33 (b)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

(b) Each research facility shall establish and maintain programs of adequate veterinary care that include:

(1) The availability of appropriate facilities, personnel, equipment, and services to comply with the provisions of this subchapter;

(2) The use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries.

Several bags of sodium chloride used for fluid administration were stored in the laboratory. One bag was hanging on the IV stand in the treatment room. All were expired with a May 2008 dating. The use of expired agents for therapeutic purposes does not meet acceptable veterinary care standards. Expired pharmaceuticals and fluids should be discarded; their use is not permitted in regulated animals under the Animal Welfare Act.

Correct by: This non-compliance was corrected during this inspection.

Prepared By:

MARY E MOORE, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1044

Jul-29-2008

Received By:

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

Date:

Title:

Jul-29-2008



Inspection Report

INTERNATIONAL INSTITUTE FOR

Customer ID: **22152**

220 - 108TH AVE STE 501

Certificate: **58-R-0137**

Site: 001

INTERNA INSTIT FOR BIOMEDICAL

Type: ROUTINE INSPECTION

TREASURE ISLAND, FL 33706

Date: Apr-21-2008

2.38 (b) **REPEAT**
MISCELLANEOUS.

(b) Access and inspection of records and property.

(1) Each research facility shall, during business hours, allow APHIS officials:

(i) To enter its place of business;

(ii) To examine records required to be kept by the Act and the regulations in this part;

(iii) To make copies of the records;

Documentation to verify the appointment of the facility's IACUC members by the Institutional Official was not available during this inspection. Verification of the appointments was not contained in the IACUC minutes. The IACUC chair was contacted by phone by another IACUC member during this inspection and a message was relayed to this inspector that the documentation was thought to be in the form of a memo/electronic transmission. A copy of this record was to be transmitted to this inspector by the close of business April 22, 2008 but was not received.

This is an amended inspection report correcting the omission of the registration certificate on the following inspection (22152, 356085, 49706)

Prepared By:

MARY E MOORE, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1044

Sep-30-2008

Received By:

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

Date:

Title:

Sep-30-2008



Inspection Report

INTERNATIONAL INSTITUTE FOR BIOMEDICAL RESEARCH

Customer ID: **22152**

Certificate: --

Site: 001

IBR (CLASS B)

220 - 108TH AVE STE 501

Type: ROUTINE INSPECTION

Date: Apr-21-2008

TREASURE ISLAND, FL 33706

2.38 (b) REPEAT

MISCELLANEOUS.

(b) Access and inspection of records and property.

(1) Each research facility shall, during business hours, allow APHIS officials:

- (i) To enter its place of business;
- (ii) To examine records required to be kept by the Act and the regulations in this part;
- (iii) To make copies of the records;

Documentation to verify the appointment of the facility's IACUC members by the Institutional Official was not available during this inspection. Verification of the appointments was not contained in the IACUC minutes. The IACUC chair was contacted by phone by another IACUC member during this inspection and a message was relayed to this inspector that the documentation was thought to be in the form of a memo/electronic transmission. A copy of this record was to be transmitted to this inspector by the close of business April 22, 2008 but was not received.

Prepared By:

MARY E MOORE, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1044

Apr-21-2008

Received By:

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

Date:

Title:

Apr-21-2008



Inspection Report

INTERNATIONAL INSTITUTE FOR BIOMEDICAL RESEARCH

Customer ID: **22152**

Certificate: **58-R-0137**

Site: 001

INTERNA INSTIT FOR BIOMEDICAL RESEARCH

220 - 108TH AVE STE 501

Type: ROUTINE INSPECTION

Date: Jul-06-2007

TREASURE ISLAND, FL 33706

2.30 (c)

REGISTRATION.

(c) Notification of change of operation.

(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.

The facility mailing address changed prior to the last inspection conducted June 6, 2007. The eastern regional office has not been notified in writing of the address change. Any change in operations affecting the status of a research facility, including address changes, must be reported to the AC Regional Director by certified mail within 10 days of such change. Timely notification of changes is required to ensure appropriate communication can be maintained between the facility and regional office.

Correct by: July 19, 2007.

2.31 (a)

REPEAT

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(a) The Chief Executive Officer of the research facility shall appoint an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members to assess the research facility's animal program, facilities, and procedures.

The Institutional Official states that the appointment of an IACUC has not been finalized but is imminent. The facility intends to utilize an IACUC sharing dual appointments and dual function with another facility which holds a registration at this same physical location.

Establishment of a functioning IACUC is essential for maintenance of a research registration under the Animal Welfare Act and to ensure the well being of all regulated animals held under that registration.

Prepared By:

MARY E MOORE, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1044

Jul-09-2007

Received By:

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

Date:

Title:

Jul-09-2007



Inspection Report

2.33 (a) REPEAT

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

(a) Each research facility shall have an attending veterinarian who shall provide adequate veterinary care to its animals in compliance with this section:

(1) Each research facility shall employ an attending veterinarian under formal arrangements.

Formal arrangements for the employment of an attending veterinarian have not been finalized. A contract is pending with a veterinarian which will provide not only the current routine oversight of veterinary services but establish the additional services and functions required by an attending veterinarian and as defined by the Animal Welfare Act.

An attending veterinarian must be formally engaged by the facility to provide all services and functions as required under the Animal Welfare Act.

Exit interview conducted with IO by telephone.

Prepared By:

MARY E MOORE, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1044

Jul-09-2007

Received By:

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

Date:

Title:

Jul-09-2007



Inspection Report

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Site: 001

INTERNA INSTIT FOR BIOMEDICAL RESEARCH

220 - 108TH AVE STE 501

Type: ROUTINE INSPECTION

TREASURE ISLAND, FL 33706

Date: Jun-04-2007

2.31 (a)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(a) The Chief Executive Officer of the research facility shall appoint an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members to assess the research facility's animal program, facilities, and procedures.

The Institutional Official for this facility states that his IACUC committee membership appointments are identical to those appointments of an IACUC committee belonging to another research registration which is concurrently held at this same physical location. However, key IACUC members of the other IACUC committee, including the attending veterinarian and chair, as well as the President of the business currently housing all concerned regulated animals deny dual appointments and dual IACUC function.

Establishment of a functioning IACUC committee is paramount for maintenance of a research registration under the Animal Welfare Act and essential to ensure the well being of any regulated animal held under that registration.

Correct by: July 04, 2007.

2.33 (a)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

(a) Each research facility shall have an attending veterinarian who shall provide adequate veterinary care to its animals in compliance with this section:

(1) Each research facility shall employ an attending veterinarian under formal arrangements. In the case of a part-time attending veterinarian or consultant arrangements, the formal arrangements shall include a written program of veterinary care and regularly scheduled visits to the research facility;

The facility currently has no formal arrangement for the employment of an attending veterinarian. Provisions are in place for routine husbandry and basic veterinary care of facility animals in their current

Prepared By:

MARY E MOORE, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1044

Jun-06-2007

Received By:

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

Date:

Title:

Jun-07-2007



Inspection Report

housing situation. However, this oversight specifically excludes interpreting the veterinary services as formal retention of an attending veterinarian for the research facility according to the company providing these services. Additionally, the IO for this facility stated in a telephone message that the facility did not have a "personal" veterinarian.

The responsibilities of an attending veterinarian for a research facility include (but are not limited to) consultation and development of guidelines for principal investigators and other personnel on all animal related activities, determining the research policy on necropsies and developing policies on expired drug use and/or disposal. It was apparent during this inspection that the clinical veterinary services provided to the facility animals do not include the above described responsibilities.

An attending veterinarian must be formally engaged by the facility to ensure adequate veterinary service and function as required under the Animal Welfare Act.

Correct by: July 04, 2007

2.38 (b) REPEAT
MISCELLANEOUS.

(b) Access and inspection of records and property.

(1) Each research facility shall, during business hours, allow APHIS officials:

- (i) To enter its place of business;
- (ii) To examine records required to be kept by the Act and the regulations in this part;
- (iii) To make copies of the records;

No records related to IACUC function were available for review during this inspection. Missing documentation included IACUC meeting minutes, biannual facility inspections and program review, as well as the subsequent evaluations required to be submitted to the Institutional Official. To ensure appropriate IACUC oversight and function all records required to be kept by the Animal Welfare Act must be available during APHIS inspections.

This non-compliant item was cited on the August 11, 2006 inspection report under certificate 52-R-0109. That registration was cancelled for non-renewal on August 16, 2006. On September 1, 2006, certificate 58-R-0137 was issued under the same federal tax identification number and corporate officers as the previously issued certificate. The research facility site address remained the same under both certificates but the registrant permanent mailing address has changed.

Prepared By:

MARY E MOORE, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1044

Jun-06-2007

Received By:

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

Date:

Title:

Jun-07-2007



Inspection Report

Prepared By:

MARY E MOORE, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1044

Jun-06-2007

Received By:

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

Date:

Title:

Jun-07-2007