



Inspection Report

Lovelace Biomedical Research Institute
2425 Ridgecrest S E
Albuquerque, NM 87108

Customer ID: **1072**

Certificate: **85-R-0003**

Site: 001

LOVELACE BIOMEDICAL RESEARCH INSTITUTE

Type: ROUTINE INSPECTION

Date: 19-JUL-2016

2.31(c)(7)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

***Changes regarding the care and use of animals in ongoing activities are not always approved by the IACUC before the changes occur. On July 8, 2016, a Sinclair pig underwent 2 CSF collections during a training session. Although an amendment had been submitted, the IACUC approved training protocol, FY15-078 Training Protocol for Procedures in Laboratory Swine, did not include approval for CSF collection. The amendment to include CSF collection was not approved until after this incident.

Unapproved significant changes to the protocol could result in unanticipated pain and distress, and put the animal's welfare at risk. Any significant changes to the approved protocol must be reviewed and approved by the IACUC prior to implementing the changes.

Correct by 7/21/16.

2.31(d)(5)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

***The IACUC did not conduct appropriate reviews of the animal activities for protocol FY14-132 to ensure that the study personnel were following the approved IACUC protocol. The animal use activity involved non-human primates.

The IACUC protocol states that the groups of animals will receive one of the following: Drug A; Drug A + B; or Drug A + C.

According to the study protocol (not reviewed and approved by the IACUC) and animal dosing records, the group 3 animals received Drug A + Drug B + Drug C. This combination of drugs was not approved in the IACUC protocol prior to dosing. An amendment has since been approved by the IACUC to include new dosing regimens. The IACUC is required to conduct continuing review of all animal activities in order to ensure that they are conducted in compliance with the approved protocol and to ensure that the animals do not experience any undue pain and suffering.

Prepared By: AARON RHYNER, D V M USDA, APHIS, Animal Care

Date:
22-JUL-2016

Title: ASSISTANT DIRECTOR 6077

Received by Title: FACILITY REPRESENTATIVE

Date:
22-JUL-2016



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The IACUC must continue reviewing all activities involving animals, in order to ensure that all animal activities are conducted as stated in the approved protocol and in compliance with these regulations.

Correct by 7/21/16

2.38(f)(1) REPEAT

MISCELLANEOUS.

***Handling of all animals was not done in a manner that did not cause trauma. On March 11, 2016, six guinea pigs expired during transportation for study related activities. The animals were held in a rat microisolator enclosure (used for transportation), for approximately 45-60 minutes before initiating transport to the exposure room. Immediately upon leaving the animal room, study personnel noted the animals had expired. An IACUC investigation revealed three contributing factors in this incident: the density of guinea pigs in the enclosure, duration they were held in the enclosure, microisolator filter top was wet (may contribute to decreased air exchange within the enclosure).

The facility has addressed the identified contributing factors, revised relevant SOP s and retrained staff. Handling of all animals shall be done as expeditiously and carefully as possible in a manner that does not cause trauma, behavioral stress, physical harm, or unnecessary discomfort.

This was a focused inspection on facility records.

Inspection was conducted on 7/19/16 with the IACUC chair, Attending Veterinarian and the Director of Scientific Support Services, along with APHIS personnel to include Dr. Aaron Rhyner and Dr. Tanya Tims.

Exit briefing was conducted on 7/20/16 with facility personnel along with APHIS personnel to include Dr. Aaron Rhyner and Dr. Tanya Tims.

Additional Inspectors

Tims Tanya, Assistant Director

Prepared By: AARON RHYNER, D V M USDA, APHIS, Animal Care

Date:
22-JUL-2016

Title: ASSISTANT DIRECTOR 6077

Received by Title: FACILITY REPRESENTATIVE

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22-JUL-2016



Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1072	85-R-0003	001	LOVELACE BIOMEDICAL RESEARCH INSTITUTE	19-JUL-16

No Animals were Inspected.

Count	Scientific Name	Common Name
000000	NONE	NONE
000000	Total	