



Inspection Report

National Jewish Health
1400 Jackson Street, M211
Denver, CO 80206

Customer ID: **1080**
Certificate: **84-R-0001**
Site: 001
NATIONAL JEWISH HEALTH

Type: ROUTINE INSPECTION
Date: 17-APR-2018

2.31(c)(7) CRITICAL

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

***Significant changes regarding the use of animals in protocol #AS2836-11-20, involving guinea pigs, were not approved by the Institutional Animal Care and Use Committee (IACUC).

APHIS inspector discovered that the PI deviated from the IACUC approved protocol regarding the duration of guinea pig exposure to cigarette smoke and initial exposure to nebulization. The protocol states that 8 guinea pigs would be exposed to cigarette smoke in a smoking machine for "2 hours/day for 5 days for the first week, 3 hours/day for 5 days for the second week, and 5 hours for the third week." A flow chart in the protocol also depicts this timeline. Facility records indicate that four guinea pigs from group 1 were exposed to cigarette smoke for 5 hours/day for a total of 6 days. The PI had planned to continue to smoke exposure for 4 more days, however this group's final smoke exposure occurred on 03/19/18 due to the adverse reaction of a guinea pig. As the guinea pigs were removed from the smoking machine, one female guinea pig, microchip # 052-550-022, was observed to have "bloody discharge from nose," and displayed "vocalization" and "open mouth breathing." The guinea pig received medical treatment, however she was euthanized that same day due to continued respiratory distress. Guinea pig #051-774-537, also from group 1, was noted to have "serosanguinous discharge on both nares" when removed from the smoking machine on 03/19/18.

The IACUC approved protocol states that medications "will be administered via nebulization to guinea pigs during exposure to cigarette smoke." The protocol does not state during which week of smoke exposure the nebulization will actually begin. The PI informed the APHIS inspector that due to difficulty in obtaining the medication, she did not begin nebulization until 04/16/18, by which time the smoke exposure had ended for both groups. The cigarette smoke exposure ended for group 1 guinea pigs on 03/19/18 and ended for group 2 guinea pigs on 04/13/18. The PI did not submit an amendment informing the IACUC of the change in procedure.

Unapproved significant changes to a protocol can result in unanticipated pain and distress, and put the animal's welfare at risk. All activities involving animals must adhere to those in the IACUC-approved protocols and amendments. This conformance to protocol is necessary to ensure that the IACUC has the authority to assure the proper care and use of animals in research projects. Any significant changes to the approved protocol must be reviewed and approved by the IACUC prior to implementing the changes.

Prepared By: ENGEL D.V.M DOMINIQUE, D V M USDA, APHIS, Animal Care

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To be corrected from this date forward.

This inspection and exit interview were conducted with facility representatives.

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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1080	84-R-0001	001	NATIONAL JEWISH HEALTH	17-APR-18

Count	Scientific Name	Common Name
000021	<i>Cavia porcellus</i>	DOMESTIC GUINEA PIG
000011	<i>Oryctolagus cuniculus</i>	DOMESTIC RABBIT / EUROPEAN RABBIT
000032	Total	