



## Inspection Report

Alcon Research Ltd.  
6201 South Freeway; R3-12  
Fort Worth, TX 76134

Customer ID: **1382**  
Certificate: **74-R-0011**  
Site: 001  
ALCON RESEARCH, LTD

Type: ROUTINE INSPECTION  
Date: 22-AUG-2017

### 2.31(d)(1)

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

An adverse event resulting in the death of an animal occurred in Dec 2016 under protocol 2016-100051. Although this protocol had been approved by the IACUC, it was a blanket protocol that appeared to cover all procedures the investigator might want to do with animals. There were at least 7 different procedures listed, ranging from delivering topical eye drops to awake animals to multiple procedures requiring anesthesia. There was a list of multiple anesthetics and analgesics but no specific anesthetic protocols linked to specific procedures.

Per the facilities' SOP's, prior to beginning a project a study design outlining in detail specifically what is to be done is supposed to be submitted and approved by the IACUC. A study design was not submitted or approved by the IACUC prior to the start of this project.

The IACUC is responsible for reviewing those components of the activities related to the care and use of animals and determining that the proposed activities are in accordance with regulations prior to those activities occurring.

Had a study design been submitted for IACUC and attending veterinarian approval new animal welfare concerns introduced by new variables may have been identified. At least the veterinary staff and the post approval monitoring staff would have known this project was being done and would have had the opportunity to ensure activities were being conducted according to protocol.

The facility has since revised their protocol format requiring protocols to be project specific and retrained personnel involved in the adverse event.

The facility needs to ensure study designs and/or protocols with specific details for each procedure are reviewed and approved by the IACUC prior to the procedure beginning.

To be corrected by Aug 28, 2017

Prepared By: DIGESUALDO CYNTHIA, D V M USDA, APHIS, Animal Care

Date:  
13-OCT-2017

Title: VETERINARY MEDICAL OFFICER 5055

Received by Title: SENT BY EMAIL

Date:  
13-OCT-2017



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This inspection and exit interview were conducted with facility representatives.

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**Date:**  
13-OCT-2017

**Title:** VETERINARY MEDICAL OFFICER   5055

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## Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1382	74-R-0011	001	ALCON RESEARCH, LTD	22-AUG-17

Count	Scientific Name	Common Name
000067	<i>Macaca fascicularis</i>	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000200	<i>Oryctolagus cuniculus</i>	DOMESTIC RABBIT / EUROPEAN RABBIT
000011	<i>Sus scrofa domestica</i>	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
<b>000278</b>	<b>Total</b>	