



Inspection Report

Novus Biologicals
8100 Southpark Way, Unit #A8
Littleton, CO 80120

Customer ID: **331569**
Certificate: **84-R-0089**
Site: 001
Novus Biologicals

Type: ROUTINE INSPECTION
Date: 27-MAR-2017

2.31(d)(2)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

The umbrella rabbit antibody production protocol was submitted to the IACUC by the principal investigator and the same individual (PI) approved the protocol as the current IACUC chair on 9/22/2014 and 4/13/2016.

With respect to activities involving animals, the IACUC, as an agent of the research facility, shall review protocols and amendments to protocols prior to approval. No member may participate in the IACUC review or approval of an activity in which that member has a conflicting interest (e.g., is personally involved in the activity).

Correct by 30 April, 2017.

2.31(d)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

The IACUC approved umbrella rabbit antibody production protocol states that "Rabbit bleeds will consist of 30-40 mls of whole blood...No more than 1% body weight will be taken during any 2 week period and if bleeds are done more than 4 times the hematocrit will be checked at least monthly or before each bleed."

During inspection, rabbits were observed during bleed procedures, and 50 mls of blood were being taken from each animal, which exceeds the amount approved in the protocol. There are no weight records for the animals to confirm the amount of blood drawn does not exceed 1% body weight. There are no records of hematocrit available and no way to measure hematocrit onsite before each bleed.

Two representative animals were weighed at 9.8 & 9.9 lbs, which is 4.45 kgs and 4.5 kgs. 1% of body weight for these animals is 44-45 mls, so the amount drawn (50 mls) still exceeds the approved protocol.

The IACUC has not sufficiently reviewed the activities involving animals and departures from the protocol have occurred without approval. The activity is not being conducted in accordance with the description of that activity

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provided by the principal investigator and approved by the Committee. The IACUC has the responsibility to ensure evaluation of procedures that may cause more than momentary pain or distress. The increase in blood volume taken could result in a serious impact on the health of the animals. After approving a protocol, the IACUC should determine that procedures involving animals are conducted in accordance with the protocol and will avoid or minimize discomfort, distress, and pain to the animals unless acceptable justification for the departure is provided in writing.

Correct by 30 April, 2017.

Exit interview conducted with facility representative by phone on 3 April, 2017

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