



Inspection Report

Sinclair Research Center L L C
Post Office Box 658
Columbia, MO 65205

Customer ID: 45331

Certificate: 43-R-0122

Site: 001

SINCLAIR RESEARCH CENTER, L L C

Type: ROUTINE INSPECTION

Date: Jul-27-2015

2.36 (b) (3)

ANNUAL REPORT.

***In May 2014, a protocol (S12929) which proposed food fasting diabetic pigs up to 36 hours for purposes of the study was approved by a designated IACUC member. The protocol stated, "In the case of test materials intended to have PK/PD activity for up to 24 hours, animals may be fasted for up to 36 hours". This exception to the standards of the Animal Welfare Act (AWA) was not acknowledged as an exception in the protocol nor was it attached to the facility's 2014 Annual Report. The Principal Investigator (PI) stated within the protocol that there were "No exceptions" to the standards and regulations promulgated under the AWA for the care and use of warm-blooded animals. According to the AWA, animals such as pigs must be fed at least once a day. The registrant must ensure that exceptions to the standards and regulations of the AWA are justified by the PI, approved by the IACUC, and included with the Annual Report so the Administrator can ensure that minimal standards not being met are scientifically justified. To be corrected by: August 29, 2015

The inspection was conducted on July 27-29, 2015 by Dr. Erika Leisner (VMO) and Dr. Amanda Owens (VMO) with facility representatives. The exit interview was conducted on July 29, 2015 with facility representatives.

Prepared By:

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Date:

Jul-31-2015

Received By:

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

Title:

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