



Inspection Report

Biomedical Research Models Inc
57 Union Street
Worcester, MA 01608

Customer ID: **23918**

Certificate: **14-R-0192**

Site: 003

BIOMEDICAL RESEARCH
MODELS INC

Type: FOCUSED INSPECTION

Date: 01-JUL-2025

2.31(c)(7)

Institutional Animal Care and Use Committee (IACUC).

Significant changes to ongoing IACUC approved protocols were implemented by investigator/research staff without prior review and approval of the IACUC as specified below.

(1) Pertaining to IACUC approved protocol 25-03: A pig was anesthetized for an IACUC approved ophthalmic procedure. During the surgical prep, the investigator observed a cataract was present in the eye that obscured visualization of the back of the eye. The investigator performed a lensectomy to clearly visualize the back of the eye. However, the IACUC approved protocol did not include the surgical procedure of lensectomy, and the investigator did not contact veterinary staff prior to performing the procedure.

(2) A total of eight NHPs on two separate IACUC approved protocols did not receive the post procedure analgesics as described in the protocols. Each of the protocols required that analgesics were to be administered to the NHPs for three days post procedure. Six NHPs on Protocol 24-09 underwent a procedure on 2/22/25 and did not receive their dose of analgesic on post procedure day one. Two NHPs on Protocol #15-03 underwent a procedure on 12/7/24 and did not receive their dose of analgesic on post procedure day three. The research facility determined in each instance that the analgesic was not administered to the NHPs due to technician error.

Per this Section, with respect to activities involving animals, the IACUC shall review and approve, require modifications to secure approval, or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities prior to implementation by the investigator. Principal investigators are to follow the IACUC approved proposals and any proposed changes shall be reviewed and approved by the IACUC prior to implementation. In (1) above, performing a surgical procedure that is not described in an IACUC approved protocol is a significant change in an ongoing activity that was implemented without prior review and approval by the IACUC. In (2) above, altering the IACUC approved post procedure schedule of analgesic administration to the NHPs is a significant change in an ongoing activity that was implemented without prior review and approval of the IACUC.

These two incidents were identified by the research facility and corrective measures were implemented prior to this inspection, which included IACUC approval of a modification to add lensectomy to Protocol 25-03, implementation of a treatment verification system to ensure all treatments are administered as described in the IACUC approved protocol, and refresher training of staff on following IACUC approved protocols. To remain corrected from this date 7/1/25 forward.

Prepared By: PAULA GLADUE

USDA, APHIS, Animal Care

Date:

09-JUL-2025

Title: VETERINARY MEDICAL
OFFICER

Received by Title: Facility Representative

Date:

09-JUL-2025



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2.36(b)(3)

Annual report.

The Semi-annual Report to the Institutional Official dated 10/23/24 included a departure from the provisions of the AWA under Subpart D Nonhuman Primates Feeding. This exception to the feeding standards under the AWA that affected 15 non-human primates was not reported by the research facility on their USDA FY 24 Annual Report.

Per this Section, the annual report shall assure that the research facility is adhering to the standards and regulations under the Act, and that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the IACUC. A summary of all such IACUC-approved exceptions must be attached to the facility's annual report that includes a brief explanation of the exceptions, as well as the species and number of animals affected. Correct by (1) submitting a corrected FY 24 Annual Report to USDA that includes a summary of the exception with number of animals affected by 8/10/25 and (2) including any IACUC approved departures on future USDA annual reports from this date 7/1/25 forward.

2.38(f)(1)

Miscellaneous.

Three nonhuman primates were not handled as carefully as possible by research facility staff as specified below.

(1) On 10/21/24 a non-human primate (NHP) was found to have its hand caught between the top of the cage door and the top of the cage during morning health check. Staff lifted the cage door, and the animal was able to free its hand. Staff noted swelling of the animal's hand and immediately contacted veterinary staff. The animal was assessed and treated by veterinary staff. The research facility determined that facility staff had left the cage door latch in the open position that allowed the NHP to raise the door enough to create a gap that the animal placed its hand into, and the hand became trapped in the gap when the NHP released the cage door.

(2) On 10/12/24 two NHPs were not fed their ration of biscuits; they did receive produce on that day. The animals were being transitioned to a new diet over several days and had fully transitioned to the new diet by 10/6/24. The research facility determined that the room technician had mistakenly thought that veterinary staff would be responsible for feeding the two animals that day.

Per this Section, the handling of animals by all personnel should be done as carefully as possible in a manner that does not cause physical harm, behavioral stress, or unnecessary discomfort. The NHPs were not handled as carefully as possible by facility staff resulting in a hand injury to one NHP and two other NHPs not being fed one day's ration. These two incidents were identified by the research facility and corrective measures were implemented prior to this inspection, which included the retraining of staff on methods for securing the types of NHP caging and retraining on feeding instructions. To remain corrected from this date 7/1/25 forward.

This inspection and exit briefing were conducted with facility representatives.

END OF REPORT

Prepared By: PAULA GLADUE

USDA, APHIS, Animal Care

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Additional Inspectors:

Tonya Hadjis, Supervisory Animal Care Specialist

Prepared By: PAULA GLADUE

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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
23918	14-R-0192	003	BIOMEDICAL RESEARCH MODELS INC	01-JUL-2025

Count	Scientific Name	Common Name
000531	<i>Macaca fascicularis</i>	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000004	<i>Papio anubis</i>	OLIVE BABOON
000000	<i>Sus scrofa domestica</i>	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000535	Total	