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: 07-APR-2026

2.31(c)(7) **Repeat**

Institutional Animal Care and Use Committee (IACUC).

A significant change to an ongoing IACUC approved protocol was implemented by investigator staff without prior review and approval of the IACUC. A pig was anesthetized on 10/1/25 for an IACUC approved ophthalmic injection procedure under Protocol 25-03. During the surgical prep, the investigator performed a lateral canthotomy bilaterally to widen the palpebral fissure to better access the injection site. However, the IACUC approved protocol did not include the surgical procedure of lateral canthotomy and the investigator did not contact veterinary staff prior to performing the surgical procedure.

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. 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. This incident was identified by the research facility as a protocol deviation and corrective measures were implemented prior to this inspection.

2.31(e)(2)

Institutional Animal Care and Use Committee (IACUC).

IACUC approved Protocol #26-02 was reviewed. Although the approved protocol includes a rationale for using animals and includes the number of animals requested for the study, there is no rationale for the number of animals requested. The approved protocol contains the following as the rationale for the number of animals requested: “The number of animals anticipated to be used over the course of 3 years.”

Per this Section, a proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain a rationale for: involving animals, the appropriateness of the species, and the number of animals to be used. Complete information must be provided in a proposal for animal use for the IACUC to review the proposed animal use activities and determine that the proposed activities are in accordance with the requirements in this subchapter of the Animal Welfare Act. The IACUC needs to address this item. Correct by 5/8/26.

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Date: 10-APR-2026

Title: VETERINARY MEDICAL OFFICER

Received by Title: Facility Representative

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2.38(f)(1) **Critical** **Repeat**

Miscellaneous.

Sixteen nonhuman primates (NHPs) were not handled as carefully as possible by research facility staff as specified below.

(1) On 11/18/25 an NHP was sedated for an IACUC approved surgical procedure and was connected to the anesthesia machine for administration of gas anesthetic. The anesthesia technician had tested the anesthesia machine for leaks prior to connecting the NHP to the machine. Research technicians noted prior to initiation of the surgical procedure that the NHP had developed whole body distention and veterinary staff were immediately contacted. The responding veterinarian assessed the animal and determined: that the distention observed in the NHP was due to the collection of air in subcutaneous tissues; the condition of the NHP was consistent with hypoxemia and poor perfusion; and due to the poor prognosis, made the decision to euthanize the animal. A necropsy was performed that revealed marked tissue emphysema along the ventrum of the animal from the neck to inguinal area, and trauma to the lung. The cause of death was determined to be barotrauma and lung trauma with secondary subcutaneous emphysema caused by the incomplete opening of the pop-off valve on the anesthesia machine by the anesthesia technician.

(2) Four NHPs sustained injuries to their hands during routine cage cleaning on four different dates when they received bite wounds from an NHP housed in an adjacent enclosure. In each instance, the injury occurred when husbandry staff removed the pan underneath the top enclosure in the rack in order to clean it. Despite the insertion of a clear plexiglass panel between the top and bottom enclosures when the pan was removed, the NHPs housed in the top and bottom enclosures in the rack managed to move the panel that created a gap that allowed the NHPs to contact each other and inflict bite wounds. In each instance, veterinary staff were immediately contacted, the NHPs were sedated and the wounds evaluated/surgically prepped. Each of the four NHPs underwent amputation of a portion of a digit of their hands, received antibiotics and analgesics, and were closely monitored by veterinary staff until healed.

(3) Two NHPs sustained injuries to their hands during routine cage cleaning on two separate dates when husbandry technicians placed the NHP cage racks too close to each other. As a result, NHPs in different cage racks could make contact and inflict bite wounds to an NHP housed in a different cage rack. In each instance, veterinary staff were immediately contacted, the NHPs were sedated and the wounds evaluated/surgically prepped. Both NHPs underwent amputation of a portion of a digit of their hands, received antibiotics and analgesics, and were closely monitored by veterinary staff until healed

(4) On 8/30/25 one 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 immediately 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 and closely monitored until recovered. The research facility determined that the door latch was not in the fully locked position that allowed the NHP to raise the cage 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.

(5) Seven NHPs on an IACUC approved protocol received an injection of a test article on study day 1, serial cerebral spinal fluid (CSF) collections were scheduled, and the analgesic meloxicam was to be administered following the CSF

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collections. According to the IACUC approved protocol, meloxicam was to be administered daily on study days 4 through 12. The study day 7 dose of meloxicam was not administered to the seven NHPs. It was determined that the failure to administer the study day 7 dose of meloxicam was due to miscommunication and technician error.

(6) On 12/23/25 one NHP was fasted and sedated for an IACUC approved procedure. The animal was moved to the procedure prep room where prep staff discovered that the sedated NHP had been misidentified and had been sedated in error. The NHP was returned to its enclosure to recover from the sedation, was provided food when fully recovered, and experienced no adverse effects from the sedation. The research facility could not determine when the misidentification occurred, or which staff member was responsible. Multiple staff members were involved in the different phases of the process that included facility staff who separated the pair housed NHPs the afternoon prior for the overnight fast, husbandry staff transferred all NHPs in the room to a clean cage the morning of the procedure, and the technician administering the sedation may have misread the NHP's tattoo cage side.

Per this Section, the handling of animals by all personnel should be done as carefully as possible in a manner that does not cause trauma, physical harm, behavioral stress, or unnecessary discomfort. The sixteen NHPs were not handled as carefully as possible by facility staff resulting in death of one NHP during anesthesia, hand injuries in seven NHPs, misidentification of one NHP that was unnecessarily sedated, and seven NHPs did not receive one dose of an analgesic. All of these incidents were identified by the research facility and appropriate corrective measures were implemented prior to this inspection. No additional handling incidents have occurred.

This inspection was conducted with facility representatives on 4/7/26 and 4/8/26. The exit briefing was held on 4/8/26.

END OF REPORT

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United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 23918
Inspection Date: 07-Apr-2026

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
23918	14-R-0192	003	BIOMEDICAL RESEARCH MODELS INC	07-APR-2026

Count	Scientific Name	Common Name
000548	*Macaca fascicularis*	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000034	*Oryctolagus cuniculus*	DOMESTIC RABBIT / EUROPEAN RABBIT
000002	*Papio anubis*	OLIVE BABOON
000584	**Total**	