



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

January 8, 2021

Re: Animal Welfare Assurance
A3494-01 [OLAW Case E]

Dr. Thomas Sack
President and Chief Executive Officer
Midwest Research Institute
425 Volker Boulevard
Kansas City, MO 64110

Dear Dr. Sack,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 7, 2021 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at MRIGlobal, following up on an initial report on December 16, 2020. According to the information provided, OLAW understands that four nonhuman primates used for training had not been observed or provided husbandry for two consecutive days. This occurred due to a problem with scheduling and coordinating the movement of the animals between facilities.

The immediate action taken upon discovery consisted of having the veterinarian examine the monkeys, which were found to be healthy. The corrective actions consisted of revising the standard operating procedure for the transfer of animals to ensure that appropriate staff is informed of animal movements. Also, a spreadsheet will be used to record animal observations and provision of husbandry.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair
Robert Gibbens, D.V.M., USDA-APHIS-AC

January 7, 2021



Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360
6705 Rockledge Drive
Bethesda, MD 20892

Dear OLAW:

MRIGlobal, in accordance with Assurance D16-00309 (formerly A3494-01) and PHS Policy IV.F.3., provides this report of noncompliance regarding non-human primate (NHP) husbandry and observations. The NHPs were not on any study at this time and were training animals. This incident was first reported to OLAW, on December 16, 2020 via an email by Mr. Eric R Jeppesen, RBP, CBSP, Manager ESH Office and IACUC Chair.

On December 13, 2020, Mr. Jeppesen, was notified by the Study Director (SD) that 4 NHP had not been observed or provided husbandry for the dates of December 11 and December 12, 2020. The Attending Veterinarian (AV) was also notified on December 13, 2020 and examined the animals. The AV performed a cage-side assessment and found the animals were physically healthy.

The noncompliance occurred related to a scheduling issue. The NHPs were to be moved from an upper floor room to our conventional animal facility to complete training. During the scheduling meeting the scheduler was attempting to update the scheduling spreadsheet to make this change real time; unfortunately, the spreadsheet had an issue and would not allow the scheduler to edit the document. The scheduler was going to update after the issue was corrected. The schedule correction did not happen, and this change was not communicated to the staff.

A review of the records associated with the AUS indicate that this project is internally funded and no government funds were used.

The following action plan was implemented after the incident:

1. The transfer SOP will be revised to include that once the transfer of animals is complete, the schedulers, Study Director, and technical staff will be alerted via formal email. If the transfer of animals does not occur, then the schedulers, Study Director and other technical staff must review the schedule and update animal locations.
2. Implementing a spreadsheet where the technical staff confirm they have observed and provided animal husbandry for all animals on each active AUS. The schedule will be reviewed by the Study Director/Study Coordinator to ensure no activities are missed.

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425 Volker Blvd., Kansas City, Missouri 64110-2241 Phone: 816-753-7600, Fax: 816-753-8420 www.mriglobal.org

MRIGlobal is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact Eric R. Jeppesen, IACUC Chair.

Thank you for your consideration of this matter.

Sincerely,

 (b) (6)

Thomas Sack, PhD
President and CEO
Institutional Official

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, January 8, 2021 7:45 AM
To: Jeppesen, Eric
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: MRIGlobal incident report

Thank you for this report, Mr. Jeppesen. We will send a response soon.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: Jeppesen, Eric <ejepesen@mriglobal.org>
Sent: Thursday, January 7, 2021 3:41 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Sack, Tom <tsack@mriglobal.org>; (b) (6)
(b) (6)
Subject: MRIGlobal incident report

OLAW,

Please see the attached final report for MRIGlobal.

Eric R. Jeppesen, RBP, CBSP, SM(NRCM)
Manager, Environment, Safety & Health Office
IACUC Chair
MRIGlobal
425 Volker Boulevard
Kansas City, MO 64110
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ejepesen@mriglobal.org

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Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, December 21, 2020 7:11 AM
To: Jeppesen, Eric
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: MRIGlobal incident

Thank you for this preliminary report, Mr. Jeppesen. We will open a new case file and look forward to receiving the final report from the IO after the IACUC has completed its investigation.

Axel Wolff, M.S., D.V.M.
 Deputy Director, OLAW

From: Jeppesen, Eric <ejepesen@mriglobal.org>
Sent: Wednesday, December 16, 2020 1:02 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Sack, Tom <tsack@mriglobal.org>; (b) (6)
 (b) (6)
Subject: MRIGlobal incident

Dear OLAW,

Eric R. Jeppesen, IACUC Chair ejepesen@mriglobal.org, Office phone (b) (6), Mobile phone (b) (6)
 (b) (6)

MRIGlobal

D16-00309 (A3494-01)

Funding component: NA, internally funded

Four (4) NHP's did not have observations or husbandry for a period of two (2) days' time; 12/11/2020 and 12/12/2020. After the Study Director (SD) discovered the situation the morning of 12/13/2020 they immediately contacted the IACUC Chair and the Attending Veterinarian (AV). The AV performed a cage side check of the animals the same day; 12/13/2020. NHP's were found to be healthy. The NHP's were given food and water. There were no deaths reported.

IACUC members have started an investigation of this incident along with the SD and animal care staff.

MRIGlobal expects to complete the corrections and prevention prior to January 1, 2021.

The final report from our Institutional Official will be emailed on January 8th, 2021.

Should you have any questions please do not hesitate to contact me.

Sincerely,

Eric R. Jeppesen, RBP, CBSP, SM(NRCM)
 Manager, Environment, Safety & Health Office
 IACUC Chair
 MRIGlobal
 425 Volker Boulevard

Kansas City, MO 64110

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ejeppesen@mriglobal.org

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