



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive - MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-2803

September 19, 2017

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

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 September 18, 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at MRIGlobal, following up on an initial report on August 22, 2017. According to the information provided, OLAW understands that a study was initiated using cats although the activity had not been approved by both designated member reviewers.

The immediate action taken upon discovery consisted of taking the cats off study and placing them on a training protocol. The Principal Investigator (PI) consulted with the designated member who required additional information, the changes were made, and the protocol was subsequently approved by both reviewers. The PI assured the Institutional Animal Care and Use Committee (IACUC) that such an incident would not recur. The IACUC coordinator will now notify the chair of any outstanding approvals past five business days, the IACUC chair will contact the designated reviewers and PI if there is a problem with protocol approval, and (as required by PHS Policy), if the designated reviewers cannot unanimously approve the protocol it will be referred to the full IACUC.

OLAW understands that the protocol involved was not PHS-supported, but concurs that the incident was serious and supports the actions taken by the IACUC. The establishment and application of policies and practices that are consistent with the provisions of the PHS Policy at MRIGlobal are commendable and avoid the perception of a double standard. Thank you for keeping OLAW apprised on this matter.

Sincerely,

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

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

September 18, 2017



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 a feline safety study, an Animal Use Statement (AUS) not reviewed and approved by the Designated Member Review (DMR) on behalf of the IACUC in a Principal Investigator's (PI) animal study protocol, AUS17-09 "Safety Evaluation of ZTS-00507082 and ZTS-00084768 in Laboratory Cats". This incident was first reported to OLAW, on August 22, 2017 via an email by Mr. Eric R Jeppesen, RBP, CBSP, Manager ESH Office and IACUC Chair.

On August 15, 2017, Mr. Jeppesen, was reviewing AUS's related to a routine USDA inspection conducted on Friday August 11, 2017 and Monday August 14, 2017. During this review it was discovered that one Designated Member (DM) has not approved AUS17-09 "Safety Evaluation of ZTS-00507082 and ZTS-00084768 in Laboratory Cats" while the other DM had granted approval. Since MRIGlobal utilizes two DM's for review, both are required to review and approve the AUS prior to initiating any animal study. At the time of the discovery of the incident, with consultation with the Attending Veterinarian (AV), the animals were immediately taken off study and transferred to the feline training AUS. None of the animals in the study needed to be euthanized due to this oversight.

The PI described immediately reached out to the DM that had not granted approval and made the recommended changes to the AUS to gain approval. Approval was granted on the afternoon of August 15, 2017. The IACUC discussed the incident and requested corrective actions from the PI.

The PI spoke to the IACUC Chair and both DM's that this was an unfortunate incident and took responsibility for the noncompliance. The PI assured the entire IACUC by email that an incident of such nature would not occur again. The IACUC determined that this was an isolated incident and not a programmatic failure.

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

The following action plan was implemented after the incident:

1. The IACUC Coordinator will notify the IACUC Chair of outstanding approvals past 5 business days.
2. The IACUC Chair will contact the PI and the DM's to resolve issues that would inhibit approval.
3. If the DM's do not grant approval the IACUC will meet to review the AUS.

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,

A handwritten signature in black ink, appearing to read "Thomas Sack", written in a cursive style.

Thomas Sack, PhD
President and CEO
Institutional Official

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, September 19, 2017 12:58 PM
To: 'Jeppesen, Eric'
Subject: RE: MRIGlobal D16-00309 Notification

Thank you for this report. We will respond soon.
Axel Wolff

From: Jeppesen, Eric [mailto:ejepesen@mriglobal.org]
Sent: Tuesday, September 19, 2017 11:57 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Sack, Tom <tsack@mriglobal.org>; Secondary Individual @mriglobal.org; Secondary Individual @MRIGLOBAL.ORG
Subject: RE: MRIGlobal D16-00309 Notification

Please see the attached final report.

Should you have any questions please don't hesitate to contact me.

Eric R Jeppesen
Manager, ESH Office
RSO
MRIGlobal

From: OLAW Division of Compliance Oversight (NIH/OD) [mailto:olawdco@od.nih.gov]
Sent: Thursday, August 24, 2017 6:42 AM
To: Jeppesen, Eric <ejepesen@mriglobal.org>
Subject: RE: MRIGlobal D16-00309 Notification

Thank you for this preliminary report. We will start a new case file and look forward to receiving the final report upon completion.

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

From: Jeppesen, Eric [mailto:ejepesen@mriglobal.org]
Sent: Tuesday, August 22, 2017 9:42 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Sack, Tom <tsack@mriglobal.org>; Secondary Individual @mriglobal.org
Subject: MRIGlobal D16-00309 Notification

Dear OLAW,

During a recent audit by the IACUC chair, it was discovered that a study was being conducted without full IACUC approval. The study in question was AUS17-09 "Safety Evaluation of ZTS-00507082 and ZTS-00084768 in Laboratory Cats". The PI/SD was immediately notified, the study was put on hold, and an investigation was undertaken.

Per our approval process MRIGlobal uses the Designated Member review to facilitate Animal Use Statements (AUS). This can be found in our program description that was recently submitted and approved. MRIGlobal's approval number is D16-00309 (formerly A3494-01).

The investigation revealed the following:

- The PI/SD thought the AUS was approved as did the animal care staff.
- The IACUC reviewed the list of active protocols from the July 2017 meeting and did not realize the AUS was not approved.

In reviewing the paperwork, one Designated Member (DM) approved the AUS, while the other DM had clarifications to be addressed.

The PI/SD immediately reached out to the DM who had not granted approval with an updated AUS. The updated AUS addressed the DM's questions to their satisfaction. AUS17-09 was approved and the cats allowed back on study.

MRIGlobal is currently developing options to ensure this does not occur again. Once these measure are in place a follow on report with corrective actions will be provided.

If you have further questions please do not hesitate to contact me.

Eric R Jeppesen, RBP, CBSP, SM(NRCM)
Manager, ESH Office
Radiation Safety Officer
MRIGlobal
425 Volker Boulevard
Kansas City, MO 64110
Phone Number Office
Phone Number Fax

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