



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTHFOR 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) 402-7065

May 23, 2017

Re: Animal Welfare Assurance
A3473-01 [OLAW Case 2B]

Colonel (b)(6)
Deputy Commander
U.S. Army Medical Research Institute
of Infectious Diseases
1425 Porter Street, Bldg. 1425, (b)(6)
Fort Detrick, MD 21702-5011

Dear Colonel (b)(6),

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 16, 2017 letter reporting a noncompliance (AWI #17-03) with the PHS Policy on the Humane Care and Use of Laboratory Animals at the US Army Medical Research Institute of Infectious Disease. Your letter supplements the information provided by (b)(6) in a prompt preliminary email report on April 21, 2017. According to the information provided it is understood that on April 20, 2017 it was determined that four instances of noncompliance had occurred on a study that had closed in September 2016. Animals had met the criteria for euthanasia, but were not euthanized as required by the protocol. These animals were assigned to an NIH-funded activity.

Since the incident, post-approval monitoring, to include score sheets, has been increased with the addition of a full time compliance officer, and telemetry data is more fully utilized with the establishment of a telemetry core service. In addition, score sheets are scrutinized for vagueness that may cause confusion or misinterpretation.

OLAW believes that the corrective and preventive measures put in place by the US Army Medical Research Institute of Infectious Disease are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals. OLAW advises that this information should be disclosed by USAMRIID to the Program Official of the funding component at NIH and if data from the period of noncompliance was used for publication, the journal should also be made aware. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

(b)(6)

Brent C. Morse, DVM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES
1425 PORTER STREET
FORT DETRICK, MARYLAND 21702-5011

May 16, 2016

USAMRIID Institutional Animal Care and Use Committee (IACUC)

Axel Wolff, D.V.M.
 Director, Office of Laboratory Animal Welfare
 National Institutes of Health
 Rockledge 1, Suite 360, MSC 7982
 6705 Rockledge Drive
 Bethesda, Maryland 20892-7982

Dear Dr. Wolff:

Please reference [b)(6)] email on April 21, 2017 to Dr. Brent Morse regarding Animal Welfare Investigation (AWI) #17-03, involving noncompliance discovered on a closed protocol supported by PHS funds.

On April 20, 2017 the IACUC was notified of a noncompliance issue that was discovered during an internal audit of a nonhuman primate protocol. The study was conducted November 2014 and the protocol was closed in September 2016. Upon review of study documents, the investigative subcommittee determined that there were four instances of noncompliance where animals met criteria for euthanasia, as assessed using an approved score sheet, but were not promptly euthanized as required by protocol. Since the incident, post approval monitoring, to include score sheets, has been increased with the addition of a full time compliance officer, and telemetry data is more fully utilized with the establishment of a telemetry core service. In addition, score sheets are scrutinized for vagueness that may cause confusion or misinterpretation. The investigation was hindered by the fact that the employee that performed the assessments is no longer employed at the United States Army Medical Research of Infectious Diseases (USAMRIID). This work was supported by a National Institutes of Health grant.

If you require further information regarding this AWI, please contact LTC [b)(6)] [b)(6)] USAMRIID IACUC Chair, at [b)(6)] The Animal Welfare Assurance number is A3473-01. Please copy LTC [b)(6)] on correspondence concerning this report.

Sincerely,

[b)(6)]

Brian J. Gentile
 Colonel, US Army
 Deputy Commander

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Wednesday, May 17, 2017 10:57 AM
To: (b)(6) USARMY MEDCOM USAMRIID (US)
Cc: (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6) LTC
 USARMY MEDCOM USAMRIID (US)
Subject: RE: USAMRIID (UNCLASSIFIED)

Thank you Ms. (b)(6) I will send an official response soon.

Regards, Brent Morse

Brent C. Morse, DVM, DACLAM
 Animal Welfare Program Specialist
 Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 National Institutes of Health

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-----Original Message-----

From: (b)(6) CIV USARMY MEDCOM USAMRIID (US) [mailto:(b)(6)]
Sent: Wednesday, May 17, 2017 10:22 AM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Cc: (b)(6) COL USARMY MEDCOM USAMRIID (US) (b)(6) (b)(6) LTC
 USARMY MEDCOM USAMRIID (US) (b)(6)
Subject: USAMRIID (UNCLASSIFIED)

Classification: UNCLASSIFIED

Caveats: NONE

Dr. Morse,

The attached report is in relation to an email (b)(6) sent to your office on Friday, April, 21 2017 regarding a non-compliance issue on a closed protocol.

V/r:

(b)(6)

(b)(6) BS, CPIA

Vice-Chair, IACUC

United States Army Medical Research Institute of Infectious Diseases Bldg 1425 Porter St. (b)(6) Fort Detrick, MD 21702-5011 Tel (b)(6) Fax (b)(6) (b)(6)

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A3473-2B

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Monday, April 24, 2017 9:33 AM
To: (b)(6) USARMY MEDCOM USAMRIID (US)
Subject: RE: (UNCLASSIFIED)

Thank you. I will open a case file and await further information.

Regards, Brent Morse

Brent C. Morse, DVM, DACLAM
 Animal Welfare Program Specialist
 Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 National Institutes of Health

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-----Original Message-----

From: (b)(6) USARMY MEDCOM USAMRIID (US) [mailto:(b)(6)]
Sent: Friday, April 21, 2017 4:15 PM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Cc: (b)(6) COL USARMY MEDCOM USAMRIID (US) (b)(6) (b)(6) LTC
 USARMY MEDCOM USAMRIID (US) (b)(6) (b)(6) COL USARMY MEDCOM
 USAMRIID (US) (b)(6)
Subject: (UNCLASSIFIED)

Classification: UNCLASSIFIED
 Caveats: NONE

Brent- During a recent internal audit, we have identified a non-compliance issue on a closed protocol. This study was supported by PHS funds. The IACUC was just made aware of this issue yesterday. We will follow up with a summary of the results of our IACUC investigation. Please consider this email my preliminary report to OLAW.

Thanks and have a good weekend.

(b)(6)

(b)(6) Ph.D.
 Chair, USAMRIID IACUC

Classification: UNCLASSIFIED
 Caveats: NONE



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Facsimile: (301) 402-7065

July 27, 2017

Re: Animal Welfare Assurance
A3473-01 [OLAW Case 2C]

Colonel (b)(6)
Deputy Commander
U.S. Army Medical Research Institute
of Infectious Diseases
1425 Porter Street, Bldg. 1425, (b)(6)
Fort Detrick, MD 21702-5011

Dear Colonel Gentile,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 26, 2017 letter reporting two incidents of noncompliance (AWI #s 17-05 and 17-09) with the PHS Policy on the Humane Care and Use of Laboratory Animals at the US Army Medical Research Institute of Infectious Disease. Your letter supplements the information provided by (b)(6) and (b)(6) in prompt-report preliminary emails on May 18th and June 19th 2017. According to the information provided it is understood that on the weekend of May 6-8, 2017 a veterinary technician failed to administer two morning doses of antibiotic and one dose of anti-inflammatory to a nonhuman primate. The animal recovered uneventfully. The second event occurred on the weekend of June 10-11, 2017 when a second veterinary technician failed to administer two doses of once-a-day anti-inflammatory drug to a non-human primate. This animal also recovered uneventfully. It was not stated if these animals were assigned to NIH-funded activities.

Corrective actions included individual counseling, as well as retraining of the veterinary technician staff in utilization of treatment sheets, and roles and responsibilities of technicians and veterinarians.

OLAW believes that the corrective and preventive measures put in place by the US Army Medical Research Institute of Infectious Disease are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals. We appreciate being informed of these matters and find no cause for further action by this office.

Sincerely,

(b)(6)

Brent C. Morse, DVM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES
1425 PORTER STREET
FORT DETRICK, MARYLAND 21702-5011

July 26, 2017

USAMRIID Institutional Animal Care and Use Committee (IACUC)

Axel Wolff, D.V.M.
 Director, Office of Laboratory Animal Welfare
 National Institutes of Health
 Rockledge 1, Suite 360, MSC 7982
 6705 Rockledge Drive
 Bethesda, Maryland 20892-7982

Dear Dr. Wolff:

Please reference LTC (b)(6) email on June 19, 2017 regarding Animal Welfare Investigations' (AWI) #17-05 and #17-09, involving missed treatments by our Veterinary Medicine Division, (initial report May 18, 2017), and another similar incident occurring on June 14, 2017.

AWI #17-05, weekend of May 6-8, 2017: In the treatment of a small abscess on a nonhuman primate, a VetMed Division veterinary technician failed to administer two morning doses of a twice-a-day antibiotic, and failed to administer one dose of once-a-day anti-inflammatory. An investigation concluded that although the treatment sheets were reviewed, the technician misinterpreted the dosing schedules delineated on them. The primate recovered from the abscess uneventfully.

AWI # 17-09, weekend of June 10-11, 2017: A separate VetMed Division veterinary technician failed to administer two doses of a once-a-day anti-inflammatory drug to a nonhuman primate. The medication had been scheduled to end on June 9, but on that day treatment was extended until June 13. It was concluded the technician failed to review the revised treatment sheet documenting the new schedule, and relied on memory of the end date instead. The primate recovered uneventfully.

Corrective actions included individual counseling, as well as retraining of the veterinary technician staff in utilization of treatment sheets, and roles and responsibilities of technicians and veterinarians.

If you require further information regarding this AWI, please contact LTC (b)(6) (b)(6) USAMRIID IACUC Chair, at (b)(6) The Animal Welfare Assurance number is A3473-01. Please copy LTC (b)(6) on correspondence concerning this report.

Sincerely,

(b)(6)

(b)(6)
 Colonel, US Army
 Deputy Commander

Wolff, Axel (NIH/OD) [E]

A-3473

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, June 20, 2017 7:15 AM
To: (b)(6) LTC USARMY MEDCOM USAMRIID (US)
Subject: RE: USAMRIID AWI (UNCLASSIFIED)

Thank you for this update. I will add it to the case file.

Axel Wolff, M.S., D.V.M.
 Director, Division of Compliance Oversight OLAW

-----Original Message-----

From: (b)(6) LTC USARMY MEDCOM USAMRIID (US) [mailto:(b)(6)]
Sent: Monday, June 19, 2017 2:24 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: USAMRIID AWI (UNCLASSIFIED)

Classification: UNCLASSIFIED
 Caveats: NONE

Dear OLAW,

During the course of investigating a situation of missed treatments by our Veterinary Medicine Division, (initial report 15 May 2017), another similar incident has occurred on 14 June 2017. As the incidents are related, we would like to investigate and report them under one AWI.

(b)(6)
 Biodefense research pathologist
 (b)(6)

Classification: UNCLASSIFIED
 Caveats: NONE

A3473 - 2C

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Thursday, May 18, 2017 9:56 AM
To: (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) LTC
 USARMY MEDCOM USAMRIID (US); (b)(6) COL USARMY MEDCOM USAMRIID
 (US)
Subject: RE: USAMRIID AWI (UNCLASSIFIED)

Thank you for this report (b)(6). We will open a case file and await further information.

Regards, Brent Morse

Brent C. Morse, DVM, DACLAM
 Animal Welfare Program Specialist
 Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 National Institutes of Health

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-----Original Message-----

From: (b)(6) CIV USARMY MEDCOM USAMRIID (US) [mailto:(b)(6)]
Sent: Thursday, May 18, 2017 9:43 AM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>; (b)(6) LTC USARMY MEDCOM USAMRIID (US)
 (b)(6) (b)(6) COL USARMY MEDCOM USAMRIID (US)
 (b)(6)
Subject: USAMRIID AWI (UNCLASSIFIED)

Classification: UNCLASSIFIED
 Caveats: NONE

Dr. Morse,

Unfortunately we need to report that a veterinary technician missed weekend treatments as well as one Monday treatment. The technician is being counseled and re-trained. The animal (NHP) is doing ok. Please consider this email a preliminary report to OLAW.

Sincerely,

(b)(6)

(b)(6) BS, CPIA
 Vice-Chair, IACUC

United States Army Medical Research Institute of Infectious Diseases Bldg 1425 Porter St. (b)(6) Fort Detrick, MD
 21702-5011 Tel (b)(6) Fax (b)(6) (b)(6) This document is intended for the
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Classification: UNCLASSIFIED

Caveats: NONE



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Bethesda, Maryland 20817
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Facsimile: (301) 402-7065

August 1, 2017

Re: Animal Welfare Assurance
A3473-01 [OLAW Case 2D]

Colonel (b)(6)
Deputy Commander
U.S. Army Medical Research Institute
of Infectious Diseases
1425 Porter Street, Bldg. 1425, (b)(6)
Fort Detrick, MD 21702-5011

Dear Colonel (b)(6)

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 25, 2017 letter reporting an instance of noncompliance with institutional policy at the US Army Medical Research Institute of Infectious Diseases (USAMRIID), following up on an initial telephone notification on June 14, 2017. According to the information provided, OLAW understands that two rhesus macaques were sedated for veterinary examination and post procedural care using Telazol that had been reconstituted five days prior, contrary to the UASMRIID SOP which states that Telazol must be used within four days of reconstitution. There were no animal welfare concerns to report as a result of the noncompliance and the associated animal activity was not funded by PHS.

The corrective action consisted of all responsible personnel reviewing the relevant SOP to prevent future incidents of similar noncompliance.

Your prompt and thorough resolution of this matter is commendable and consistent with the PHS philosophy of monitored self-regulation. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

(b)(6)

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Chair



DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES
1425 PORTER STREET
FORT DETRICK, MARYLAND 21702-5011

July 25, 2017

USAMRIID Institutional Animal Care and Use Committee (IACUC)

Axel Wolff, D.V.M.
Director, Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, Maryland 20892-7982

Dear Dr. Wolff:

Please reference LTC (b)(6) telephone conversation on June 14, 2017 regarding Animal Welfare Investigation (AWI) #17-08, involving the use of expired Telazol per the United States Army Medical Research Institute of Infectious Diseases (USAMRIID) standard operating procedure (SOP).

On May 31, 2017 two nonhuman primates were sedated for veterinary observation and post procedure surgical care per USAMRIID SOP. Telazol had been reconstituted 5 days previous on May 26, 2017; per USAMRIID SOP, Telazol must be used within 4 days following reconstitution when the drug is stored at room temperature, or 14 days when refrigerated.

The expiration dates mandated by this USAMRIID SOP are more restrictive than the manufacturer recommended practices of 7 days. Based on the manufacturer's recommendations, the drug used in this instance would not have been considered expired and would have had full efficacy and safety for its prescribed use.

All personnel involved have reviewed the requirements of the SOP to ensure future compliance.

If you require further information regarding this AWI, please contact LTC (b)(6) (b)(6), USAMRIID IACUC Chair, at (b)(6). The Animal Welfare Assurance number is A3473-01. Please copy (b)(6) on correspondence concerning this report.

Sincerely,

(b)(6)

(b)(6)
Colonel, US Army
Deputy Commander



Initial Report of Noncompliance

By: Debra Guere

Date: 6-14-17

Time: 2:49 PM

Name of Person reporting: Lt (b)(6) (b)(6)
 Telephone #: (b)(6)
 Fax #:
 Email:

Name of Institution: USAMRIID
 Assurance number: A3473-01

Did incident involve PHS funded activity? Not PHS funded
 Funding component:
 Was funding component contacted (if necessary):

What happened?

Teard was administered to a NTHP 5 days after reconstituting
 contrary to approved policy/SOP of 4 days.

Species involved: Rhesus

Personnel involved:

Dates and times:

Animal deaths: None

Projected plan and schedule for correction/prevention (if known):

Projected submission to OLAW of final report from Institutional Official:

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Case #



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

August 1, 2017

Re: Animal Welfare Assurance
A3473-01 [OLAW Case 2E]

Colonel (b)(6)
Deputy Commander
U.S. Army Medical Research Institute
of Infectious Diseases
1425 Porter Street, Bldg. 1425, (b)(6)
Fort Detrick, MD 21702-5011

Dear Colonel (b)(6)

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 25, 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the US Army Medical Research Institute of Infectious Diseases, following up on an initial June 23, 2017 notification by e-mail. According to the information provided, OLAW understands that a mouse was found dead in a microisolator pan which had been autoclaved the previous day. It could not be determined whether the animal was alive or not prior to autoclaving.

The corrective action included retraining of all animal caretakers with a focus on confirming animal numbers, inspecting cages for animals and performing the aforementioned tasks.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct and prevent recurrence of the noncompliance. We appreciate being informed of these matters and find no cause for action by this Office.

Sincerely,

(b)(6)

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Chair



DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES
1425 PORTER STREET
FORT DETRICK, MARYLAND 21702-5011

July 25, 2017

USAMRIID Institutional Animal Care and Use Committee (IACUC)

Axel Wolff, D.V.M.
Director, Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, Maryland 20892-7982

Dear Dr. Wolff:

Please reference LTC (b)(6) email on June 23, 2017 regarding Animal Welfare Investigation (AWI) #17-11, involving the discovery of a mouse carcass in a previously autoclaved microisolator pan.

On June 22, 2017 an animal caretaker discovered a mouse carcass in a microisolator pan that had been autoclaved the previous day. An investigative subcommittee interviewed the animal caretaker who claimed to have checked the cage card for animal count and then checked for the actual number of animals in the cage. However, the caretaker admitted she might have been distracted at some point during the cage changing procedure. The subcommittee could not determine whether the mouse was dead or alive at the time it was placed in the autoclave.

Corrective action completed July 6, 2017 consisted of retraining of all animal caretaker personnel with emphasis on the importance of verifying animal count, checking cages for animals, and methods used to do so.

If you require further information regarding this AWI, please contact LTC (b)(6) (b)(6) USAMRIID IACUC Chair, at 801-619-1328. The Animal Welfare Assurance number is A3473-01. Please copy LTC Kreiselmeier on correspondence concerning this report.

Sincerely,

(b)(6)

(b)(6)
Colonel, US Army
Deputy Commander

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, July 27, 2017 11:38 AM
To: (b)(6) LTC USARMY MEDCOM USAMRIID (US)
Subject: RE: USAMRIID AWI final reports (UNCLASSIFIED)

Thank you for these reports. We will send responses soon.

Axel Wolff, M.S., D.V.M.
 Director, Division of Compliance Oversight OLAW

-----Original Message-----

From: (b)(6) LTC USARMY MEDCOM USAMRIID (US) [mailto:(b)(6)]
Sent: Thursday, July 27, 2017 11:12 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6) COL
 USARMY MEDCOM USAMRIID (US) (b)(6)
Subject: USAMRIID AWI final reports (UNCLASSIFIED)

Classification: UNCLASSIFIED
 Caveats: NONE

OLAW:

Please find attached three reports finalizing USAMRIID Animal Welfare Incidents 17-05/09, 17-08, and 17-11.

(b)(6) DVM, DACLAM, DACVP
 LTC, VC, USA
 Biodefense research pathologist
 IACUC Chair
 US Army Research Institute of Infectious Diseases
 1425 Porter Street, Fort Detrick, MD 21702
 Office: (b)(6)

Classification: UNCLASSIFIED
 Caveats: NONE

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, June 23, 2017 2:06 PM
To: (b)(6) LTC USARMY MEDCOM USAMRIID (US)
Subject: RE: USAMRIID AWI (UNCLASSIFIED)

Thank you for this preliminary report. We will start a new case file.

Axel Wolff, M.S., D.V.M.
 Director, Division of Compliance Oversight OLAW

-----Original Message-----

From: (b)(6) LTC USARMY MEDCOM USAMRIID (US) [mailto:(b)(6)]
Sent: Friday, June 23, 2017 1:44 PM
To: accredit@AAALAC.org; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6); (b)(6) CIV
 USARMY MEDCOM USAMRIID (US); (b)(6)
Subject: USAMRIID AWI (UNCLASSIFIED)

Classification: UNCLASSIFIED
 Caveats: NONE

OLAW and AAALAC,

This is a preliminary report of an animal welfare incident involving a mouse found dead in a rodent cage after the cage had been autoclaved during routine cage change. An investigation has been initiated. Report to follow.

(b)(6), DVM, DACLAM, DACVP
 LTC, VC, USA
 Biodefense research pathologist
 IACUC Chair
 US Army Research Institute of Infectious Diseases
 1425 Porter Street, Fort Detrick, MD 21702
 Office: (b)(6)

Classification: UNCLASSIFIED
 Caveats: NONE



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August 24, 2017

Re: Animal Welfare Assurance
A3473-01 [OLAW Case 2F]

Colonel (b)(6)
Deputy Commander
U.S. Army Medical Research Institute
of Infectious Diseases
1425 Porter Street, Bldg. 1425, (b)(6)
Fort Detrick, MD 21702-5011

Dear Colonel (b)(6)

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 14, 2017 letter reporting an incident of noncompliance (AWI #s 17-17) with the PHS Policy on the Humane Care and Use of Laboratory Animals at the US Army Medical Research Institute of Infectious Disease. Your letter supplements the information provided by LTC (b)(6) in a prompt-report preliminary email on July 26, 2017. According to the information provided it is understood that on July 21, 2017 a veterinary technician misidentified a nonhuman primate to receive cefazolin administration resulting in the animal receiving twice the calculated dose of the antibiotic. A veterinarian examined the animal and the NHP that was supposed to have received the cefazolin and found there was no impact to either NHP. It was stated that neither of these animals were assigned to PHS-funded activities.

Corrective actions included retraining of the veterinary technician on appropriate treatment delivery and NHP and cage identification methods.

OLAW believes that the corrective and preventive measures put in place by the US Army Medical Research Institute of Infectious Disease are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals. Although the activity was not PHS funded, the application of the standards of the PHS Policy across the animal care and use program reduces any potential appearance of a double standard. We appreciate being informed of these matters and find no cause for further action by this office.

Sincerely,

(b)(6)

Brent C. Morse, DVM
Acting Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES
1425 PORTER STREET
FORT DETRICK, MARYLAND 21702-5011

August 14, 2017

USAMRIID Institutional Animal Care and Use Committee (IACUC)

Axel Wolff, D.V.M.
Director, Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, Maryland 20892-7982

Dear Dr. Wolff:

Please reference LTC (b)(6) email on July 26, 2017 regarding Animal Welfare Investigation (AWI) #17-17, involving the accidental treatment of a non-human primate (NHP) with the antibiotic cefazolin.

On July 21, 2017 Veterinary Medicine Division personnel administered twice the calculated dose of antibiotic to a NHP. A veterinary technician correctly identified the patient NHP's cage tag number but mistakenly administered the antibiotic to the NHP located in the lower cage rather than the patient NHP contained in the upper cage. A veterinarian examined the overdosed NHP and found the animal to be bright, alert and responsive, and there was no impact to either NHP. The NHPs involved are not assigned to PHS funded studies.

The technician involved in this incident has been retrained on appropriate treatment delivery, and NHP and cage identification methods to prevent future recurrence.

If you require further information regarding this AWI, please contact LTC (b)(6) (b)(6) USAMRIID IACUC Chair, at (b)(6) The Animal Welfare Assurance number is A3473-01. Please copy LTC (b)(6) on correspondence concerning this report.

Sincerely,

(b)(6)
(b)(6)
Colonel, US Army
Deputy Commander

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, August 21, 2017 12:30 PM
To: (b)(6) LTC USARMY MEDCOM USAMRIID (US); OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) COL USARMY MEDCOM USAMRIID (US)
Subject: RE: USAMRIID AWI final reports (UNCLASSIFIED)

Thank you for these final reports Colonel Kreiselmeier. We will send official responses soon.

Regards, Brent Morse

Brent C. Morse, DVM, DACLAM
 Acting Director
 Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 National Institutes of Health

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

-----Original Message-----

From: (b)(6) LTC USARMY MEDCOM USAMRIID (US) [mailto:(b)(6)]
Sent: Monday, August 21, 2017 12:04 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b)(6) USARMY MEDCOM USAMRIID (US); (b)(6); (b)(6) COL USARMY MEDCOM USAMRIID (US) (b)(6)
Subject: USAMRIID AWI final reports (UNCLASSIFIED)

Classification: UNCLASSIFIED

Caveats: NONE

OLAW:

Please find attached four reports finalizing USAMRIID Animal Welfare Incidents 17-17, 17-18, 17-19, and 17-21.

(b)(6) DVM, DACLAM, DACVP
 LTC, VC, USA
 Biodefense research pathologist
 IACUC Chair
 US Army Research Institute of Infectious Diseases
 1425 Porter Street, Fort Detrick, MD 21702
 Office: (b)(6)

Classification: UNCLASSIFIED

Wolff, Axel (NIH/OD) [E]

A3473-2F

From: (b)(6) LTC USARMY MEDCOM USAMRIID (US)
 (b)(6)
Sent: Wednesday, July 26, 2017 10:32 AM
To: OLAW Division of Compliance Oversight (NIH/OD)
Cc: O Quinn, Brenda A CIV USARMY MEDCOM USAMRIID (US)
Subject: Preliminary for 3 reportable situations (UNCLASSIFIED)

Classification: UNCLASSIFIED
 Caveats: NONE

OLAW,

I am submitting preliminary reports for three situations:

1. On 21 July 2017, the IACUC was informed that VetMed Division personnel administered twice the calculated dose of antibiotic to a primate, with no untoward effects.
2. On 21 July 2017, the IACUC was informed that VetMed Division personnel failed to administer an antibiotic treatment to a primate, with no untoward effects.
3. On 24 July 2017, the IACUC was informed that a mouse carcass was discovered in a microisolator pan that had been autoclaved by an VetMed animal caretaker.

None of the animals involved were on PHS funded studies. Full reports to follow.

(b)(6) DVM, DACLAM, DACVP
 LTC, VC, USA
 Biodefense research pathologist
 IACUC Chair
 US Army Research Institute of Infectious Diseases
 1425 Porter Street, Fort Detrick, MD 21702
 Office: (b)(6)

(b)(6)
 Biodefense research pathologist
 (b)(6)

Classification: UNCLASSIFIED
 Caveats: NONE



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTHFOR 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) 402-7065

August 24, 2017

Re: Animal Welfare Assurance
A3473-01 [OLAW Case 2G]

Colonel (b)(6)
Deputy Commander
U.S. Army Medical Research Institute
of Infectious Diseases
1425 Porter Street, Bldg. 1425, (b)(6)
Fort Detrick, MD 21702-5011

Dear Colonel (b)(6),

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 14, 2017 letter reporting an incident of noncompliance (AWI #s 17-18) with the PHS Policy on the Humane Care and Use of Laboratory Animals at the US Army Medical Research Institute of Infectious Disease. Your letter supplements the information provided by LTC Kreiselmeir in a prompt-report preliminary email July 26, 2017. According to the information provided it is understood that on July 21, 2017 a veterinary technician failed to administer a scheduled antibiotic treatment to a nonhuman primate. She thought that the treatment block on the treatment sheet had been checked, but failed to confirm this with a veterinarian. A veterinarian examined the animal the next day and the treatment plan was continued. The NHP healed uneventfully. It was stated that this animal was not assigned to a PHS-funded activity.

Corrective actions included retraining of the veterinary technician to address her lack of attention to detail and to contact the veterinarian when unsure about a treatment.

OLAW believes that the corrective and preventive measures put in place by the US Army Medical Research Institute of Infectious Disease are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals. Although the activity was not PHS funded, the application of the standards of the PHS Policy across the animal care and use program reduces any potential appearance of a double standard. We appreciate being informed of these matters and find no cause for further action by this office.

Sincerely,

(b)(6)

Brent C. Morse, DVM
Acting Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES
1425 PORTER STREET
FORT DETRICK, MARYLAND 21702-5011

August 14, 2017

USAMRIID Institutional Animal Care and Use Committee (IACUC)

Axel Wolff, D.V.M.
Director, Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, Maryland 20892-7982

Dear Dr. Wolff:

Please reference LTC (b)(6) email on July 26, 2017 regarding Animal Welfare Investigation (AWI) #17-18, involving a treatment deviation of a non-human primate (NHP).

On July 21, 2017 a Veterinary Medicine Division technician failed to administer an antibiotic treatment to a NHP. The on-call technician was alerted to the fact that this animal would need a late night dose of pain medication and antibiotic at 1900 hours on July 19, 2017. The technician viewed the treatment sheets and administered the pain medication but did not administer the antibiotic because she thought the treatment block had already been lined through. Although the technician was unsure, she failed to contact the veterinarian for clarification. The missed treatment was discovered the next day. The NHP was evaluated by the veterinarian and the treatment plan was continued. The NHP healed uneventfully. The NHP is not assigned to a PHS funded study.

The technician involved in this incident will be trained to address her lack of attention to detail and when unsure about a treatment, to contact the veterinarian.

If you require further information regarding this AWI, please contact LTC (b)(6) (b)(6) USAMRIID IACUC Chair, at (b)(6) The Animal Welfare Assurance number is A3473-01. Please copy LTC (b)(6) on correspondence concerning this report.

Sincerely,

(b)(6)

Colonel, US Army
Deputy Commander

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, August 21, 2017 12:30 PM
To: (b)(6) LTC USARMY MEDCOM USAMRIID (US); OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) COL USARMY MEDCOM USAMRIID (US)
Subject: RE: USAMRIID AWI final reports (UNCLASSIFIED)

Thank you for these final reports Colonel (b)(6) We will send official responses soon.

Regards, Brent Morse

Brent C. Morse, DVM, DACLAM
 Acting Director
 Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 National Institutes of Health

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-----Original Message-----

From: (b)(6) LTC USARMY MEDCOM USAMRIID (US) [mailto:(b)(6)]
Sent: Monday, August 21, 2017 12:04 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b)(6) USARMY MEDCOM USAMRIID (US) (b)(6) |>; (b)(6) COL USARMY MEDCOM USAMRIID (US) (b)(6)
Subject: USAMRIID AWI final reports (UNCLASSIFIED)

Classification: UNCLASSIFIED

Caveats: NONE

OLAW:

Please find attached four reports finalizing USAMRIID Animal Welfare Incidents 17-17, 17-18, 17-19, and 17-21.

(b)(6) DVM, DACLAM, DACVP

LTC, VC, USA
 Biodefense research pathologist
 IACUC Chair
 US Army Research Institute of Infectious Diseases
 1425 Porter Street, Fort Detrick, MD 21702
 Office: (b)(6)

Classification: UNCLASSIFIED

Wolff, Axel (NIH/OD) [E]

A3473-26

From: (b)(6) USARMY MEDCOM USAMRIID (US)
 (b)(6)
Sent: Wednesday, July 26, 2017 10:32 AM
To: OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b)(6) CIV USARMY MEDCOM USAMRIID (US)
Subject: Preliminary for 3 reportable situations (UNCLASSIFIED)

Classification: UNCLASSIFIED

Caveats: NONE

OLAW,

I am submitting preliminary reports for three situations:

1. On 21July2017, the IACUC was informed that VetMed Division personnel administered twice the calculated dose of antibiotic to a primate, with no untoward effects.
2. On 21July2017, the IACUC was informed that VetMed Division personnel failed to administer an antibiotic treatment to a primate, with no untoward effects.
3. On 24July2017, the IACUC was informed that a mouse carcass was discovered in a microisolator pan that had been autoclaved by an VetMed animal caretaker.

None of the animals involved were on PHS funded studies. Full reports to follow.

(b)(6) DVM, DACLAM, DACVP
 LTC, VC, USA
 Biodefense research pathologist
 IACUC Chair
 US Army Research Institute of Infectious Diseases
 1425 Porter Street, Fort Detrick, MD 21702
 Office: (b)(6)

(b)(6)
 Biodefense research pathologist
 (b)(6)

Classification: UNCLASSIFIED

Caveats: NONE



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTHFOR 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) 402-7065

August 24, 2017

Re: Animal Welfare Assurance
A3473-01 [OLA W Case 2H]

Colonel (b)(6)
Deputy Commander
U.S. Army Medical Research Institute
of Infectious Diseases
1425 Porter Street, Bldg. 1425, (b)(6)
Fort Detrick, MD 21702-5011

Dear Colonel Gentile,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 14, 2017 letter reporting an incident of noncompliance (AWI #s 17-19) with the PHS Policy on the Humane Care and Use of Laboratory Animals at the US Army Medical Research Institute of Infectious Disease. Your letter supplements the information provided by LTC Kreiselmair in a prompt-report preliminary report email on July 26, 2017. According to the information provided it is understood that on July 24, 2017 a mouse carcass was found in a cage after it had been autoclaved prior to entering cage wash. The caretaker responsible for the cage changing had been present for checking for carcasses and live mice during cage changing. It was expected that the animal was dead prior to autoclaving, but this cannot be known for sure. It was stated that this animal was not assigned to a PHS-funded activity.

Corrective actions included counseling of the caretaker and suspending him for three days without pay.

OLAW believes that the corrective and preventive measures put in place by the US Army Medical Research Institute of Infectious Disease are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals. We appreciate being informed of these matters and find no cause for further action by this office.

Sincerely,

Brent C. Morse, DVM
Acting Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES
1425 PORTER STREET
FORT DETRICK, MARYLAND 21702-5011

August 14, 2017

USAMRIID Institutional Animal Care and Use Committee (IACUC)

Axel Wolff, D.V.M.
Director, Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, Maryland 20892-7982

Dear Dr. Wolff:

Please reference LTC (b)(6) email on July 26, 2017 regarding Animal Welfare Investigation (AWI) #17-19, involving a mouse carcass that was discovered in a microisolator pan that had been autoclaved.

On July 24, 2017 during a routine cage change, a mouse carcass was found in a microisolator cage after it had been autoclaved prior to entering cage wash. The animal caretaker involved indicated that he remembered checking cages by running a pair of forceps through the bedding in each cage to look for carcasses, as he was instructed to do during training. The carcass was found in a nest of cotton fiber enrichment material.

The circumstances and information collected suggest the mouse was not alive at cage change and therefore was likely deceased prior to autoclaving and subsequent delivery to cage wash, but this cannot be known for sure.

The caretaker involved in this incident was present for training that was initiated for a similar incident on June 22, 2017 that included review of the cage change standard operating procedure (SOP) and proper methods to use in screening for mice in a cage. The caretaker received counseling on the incident and was suspended for three days without pay beginning July 29, 2017.

If you require further information regarding this AWI, please contact LTC (b)(6) (b)(6) USAMRIID IACUC Chair, at (b)(6) The Animal Welfare Assurance number is A3473-01. Please copy LTC (b)(6) on correspondence concerning this report.

Sincerely,

(b)(6)

Colonel, US Army
Deputy Commander

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, August 21, 2017 12:30 PM
To: (b)(6) LTC USARMY MEDCOM USAMRIID (US); OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) COL USARMY MEDCOM USAMRIID (US)
Subject: RE: USAMRIID AWI final reports (UNCLASSIFIED)

Thank you for these final reports Colonel (b)(6). We will send official responses soon.

Regards, Brent Morse

Brent C. Morse, DVM, DACLAM
 Acting Director
 Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 National Institutes of Health

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-----Original Message-----

From: (b)(6) LTC USARMY MEDCOM USAMRIID (US) [mailto:(b)(6)]
Sent: Monday, August 21, 2017 12:04 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b)(6) CIV USARMY MEDCOM USAMRIID (US) <(b)(6)>; (b)(6) COL USARMY MEDCOM USAMRIID (US) <(b)(6)>
Subject: USAMRIID AWI final reports (UNCLASSIFIED)

Classification: UNCLASSIFIED

Caveats: NONE

OLAW:

Please find attached four reports finalizing USAMRIID Animal Welfare Incidents 17-17, 17-18, 17-19, and 17-21.

(b)(6) DVM, DACLAM, DACVP

LTC, VC, USA

Biodefense research pathologist

IACUC Chair

US Army Research Institute of Infectious Diseases

1425 Porter Street, Fort Detrick, MD 21702

Office: (b)(6)

Classification: UNCLASSIFIED

Wolff, Axel (NIH/OD) [E]

A3473-2H

From: (b)(6) LTC USARMY MEDCOM USAMRIID (US)
 (b)(6)
Sent: Wednesday, July 26, 2017 10:32 AM
To: OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b)(6) USARMY MEDCOM USAMRIID (US)
Subject: Preliminary for 3 reportable situations (UNCLASSIFIED)

Classification: UNCLASSIFIED

Caveats: NONE

OLAW,

I am submitting preliminary reports for three situations:

1. On 21July2017, the IACUC was informed that VetMed Division personnel administered twice the calculated dose of antibiotic to a primate, with no untoward effects.
2. On 21July2017, the IACUC was informed that VetMed Division personnel failed to administer an antibiotic treatment to a primate, with no untoward effects.
3. On 24July2017, the IACUC was informed that a mouse carcass was discovered in a microisolator pan that had been autoclaved by an VetMed animal caretaker.

None of the animals involved were on PHS funded studies. Full reports to follow.

(b)(6), DVM, DACLAM, DACVP
 LTC, VC, USA
 Biodefense research pathologist
 IACUC Chair
 US Army Research Institute of Infectious Diseases
 1425 Porter Street, Fort Detrick, MD 21702
 Office: (b)(6)

(b)(6)
 Biodefense research pathologist

(b)(6)

Classification: UNCLASSIFIED

Caveats: NONE

Wolff, Axel (NIH/OD) [E]

From: Wolff, Axel (NIH/OD) [E]
Sent: Wednesday, July 26, 2017 10:55 AM
To: (b)(6)
Subject: OLAW reports

Thank you for submitting the 3 preliminary reports, (b)(6) We will start new case files.

Axel Wolff, M.S., D.V.M.
Director, Division of Compliance Oversight
OLAW



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTHFOR 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) 402-7065

August 24, 2017

Re: Animal Welfare Assurance
A3473-01 [OLAW Case 2I]

Colonel (b)(6)
Deputy Commander
U.S. Army Medical Research Institute
of Infectious Diseases
1425 Porter Street, Bldg. 1425, (b)(6)
Fort Detrick, MD 21702-5011

Dear Colonel (b)(6)

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 14, 2017 letter reporting an incident of noncompliance (AWI #s 17-21) with the PHS Policy on the Humane Care and Use of Laboratory Animals at the US Army Medical Research Institute of Infectious Disease. Your letter supplements the information provided by LTC (b)(6) in a prompt-report preliminary report email on August 11, 2017. According to the information provided it is understood that on July 25, 2017 a mouse was found with its tail caught between the top of the cage and the wire lid preventing it from having access to food and water. Another pan of mice was found without food. A new caretaker being trained in the room was most likely responsible for the incidents. The animals were examined by a veterinarian and found to be bright and alert. It was stated that these animals were not assigned to a PHS-funded activity.

Corrective actions included continued training of the new caretaker on appropriate animal receipt, animal transfer and cage handling procedures.

OLAW believes that the corrective and preventive measures put in place by the US Army Medical Research Institute of Infectious Disease are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals. Although this activity was not PHS funded, the application of the standards of the PHS Policy across the animal care and use program reduces any potential appearance of a double standard. We appreciate being informed of these matters and find no cause for further action by this office.

Sincerely,

(b)(6)

Brent C. Morse, DVM
Acting Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES
1425 PORTER STREET
FORT DETRICK, MARYLAND 21702-5011

August 14, 2017

USAMRIID Institutional Animal Care and Use Committee (IACUC)

Axel Wolff, D.V.M.
 Director, Office of Laboratory Animal Welfare
 National Institutes of Health
 Rockledge 1, Suite 360, MSC 7982
 6705 Rockledge Drive
 Bethesda, Maryland 20892-7982

Dear Dr. Wolff:

Please reference LTC (b)(6) email on August 11, 2017 regarding Animal Welfare Investigation (AWI) #17-21, involving an entrapped mouse and mice without access to food.

On July 25, 2017 an animal caretaker found one mouse entrapped (tail was caught in between the top of the cage and the wire lid) preventing the mouse from gaining access to food and water overnight in one pan, and one pan of mice without food. A new employee was being trained in the animal shipment receipt and breakdown area. During shipment receipt the afternoon before, July 24, he most likely accidentally entrapped the mouse during the transfer process to its new home cage, and failed to put food in the other pan.

A veterinarian examined the entrapped mouse and the mice without food and found all animals to be bright and alert. The animals were not assigned to PHS funded studies.

The individual responsible for this incident is continuing to be trained on appropriate animal receipt, animal transfer and cage handling procedures.

If you require further information regarding this AWI, please contact LTC (b)(6) (b)(6) USAMRIID IACUC Chair, at (b)(6) | The Animal Welfare Assurance number is A3473-01. Please copy LTC (b)(6) on correspondence concerning this report.

Sincerely,

(b)(6)

Colonel, US Army
 Deputy Commander

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, August 21, 2017 12:30 PM
To: (b)(6) LTC USARMY MEDCOM USAMRIID (US); OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) COL USARMY MEDCOM USAMRIID (US)
Subject: RE: USAMRIID AWI final reports (UNCLASSIFIED)

Thank you for these final reports Colonel (b)(6). We will send official responses soon.

Regards, Brent Morse

Brent C. Morse, DVM, DACLAM
 Acting Director
 Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 National Institutes of Health

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-----Original Message-----

From: (b)(6) LTC USARMY MEDCOM USAMRIID (US) [mailto:(b)(6)]
Sent: Monday, August 21, 2017 12:04 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b)(6) USARMY MEDCOM USAMRIID (US); (b)(6); (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6)
Subject: USAMRIID AWI final reports (UNCLASSIFIED)

Classification: UNCLASSIFIED
 Caveats: NONE

OLAW:

Please find attached four reports finalizing USAMRIID Animal Welfare Incidents 17-17, 17-18, 17-19, and 17-21.

(b)(6), DVM, DACLAM, DACVP
 LTC, VC, USA
 Biodefense research pathologist
 IACUC Chair
 US Army Research Institute of Infectious Diseases
 1425 Porter Street, Fort Detrick, MD 21702
 Office: (b)(6)

Classification: UNCLASSIFIED

A 3473 - 21

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, August 14, 2017 9:46 AM
To: (b)(6) LTC USARMY MEDCOM USAMRIID (US); OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b)(6) USARMY MEDCOM USAMRIID (US)
Subject: RE: USAMRIID preliminary report AWI#17-21 (UNCLASSIFIED)

Thank you for this preliminary report (b)(6) We will open a new case file and await your final report.

Regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Acting Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

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-----Original Message-----

From: (b)(6) LTC USARMY MEDCOM USAMRIID (US) [mailto:(b)(6)]
Sent: Friday, August 11, 2017 3:27 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6)
Subject: USAMRIID preliminary report AWI#17-21 (UNCLASSIFIED)

Classification: UNCLASSIFIED

Caveats: NONE

OLAW

I am making a preliminary of an animal welfare incident. A mouse cage was discovered without food, and a mouse was found trapped by the cage lid on its tail. Both incidents involved the same animal caretaker. Final report to follow.

(b)(6), DVM, DACLAM, DACVP
LTC, VC, USA
Biodefense research pathologist
IACUC Chair
US Army Research Institute of Infectious Diseases
1425 Porter Street, Fort Detrick, MD 21702
Office: (b)(6)

Classification: UNCLASSIFIED

Caveats: NONE



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTHFOR 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) 402-7065

November 28, 2017

Re: Animal Welfare Assurance
A3473-01 [OLAW Case 2J]

Colonel (b)(6)
Deputy Commander
U.S. Army Medical Research Institute
of Infectious Diseases
1425 Porter Street, Bldg. 1425, (b)(6)
Fort Detrick, MD 21702-5011

Dear COL (b)(6)

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your September 25 and November 16, 2017 letters reporting several instances of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the US Army Medical Research Institute of Infectious Diseases, following up on an initial report on September 19, 2017. According to the information provided, OLAW understands the following about the incidents and the corresponding corrective actions:

- 1) A single clinical observation of ten nonhuman primates was missed for a biocontainment study. A problem with the electronic calendar contributed to this matter. This did not negatively impact the animals.

Corrective action: The electronic system was subsequently tested and worked correctly. A redundant procedure was added to transmit schedule changes to staff.

- 2) Six immature and/or underweight primates did not meet the maturity or weight specifications of the protocol but were used anyway. This did not impact the animals or data.

Corrective action: The Institutional Animal Care and Use Committee (IACUC) will use age ranges rather than maturity levels in future protocols.

- 3) On three separate occasions, the wrong primate was anesthetized. Also, one primate died during post-operative recovery because the technicians failed to follow monitoring procedures. Increased turnover of staff led to these problems.

Corrective action: The technician training program has been enhanced and the technicians involved have been retrained. The Veterinary Medicine Division is keeping the IACUC informed about the training program.

- 4) Two mice became dehydrated because they were too small to access the lixits.

Corrective action: The mice were euthanized and the other mice in the cage were treated and responded. The staff was trained on use of lixits and alternate hydration methods.

Page 2 – Colonel (b)(6)
November 28, 2017
OLAW Case A3473-2.J

Based on its assessment of these explanations, OLAW understands that measures have been implemented in each situation to prevent recurrence of the problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy.

Sincerely,

(b)(6)

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

cc: IACUC Chair

Wolff, Axel (NIH/OD) [E]

From: Wolff, Axel (NIH/OD) [E]
Sent: Wednesday, November 22, 2017 8:57 AM
To: (b)(6) LTC USARMY MEDCOM USAMRIID (US)
Subject: RE: OLAW reports (UNCLASSIFIED)

Thank you. Your approach makes sense.

-----Original Message-----

From: (b)(6) LTC USARMY MEDCOM USAMRIID (US) [mailto:(b)(6)]
Sent: Wednesday, November 22, 2017 8:48 AM
To: Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>
Cc: (b)(6) USARMY MEDCOM USAMRIID (US) (b)(6)
Subject: RE: OLAW reports (UNCLASSIFIED)

Classification: UNCLASSIFIED

Caveats: NONE

Dr. Wolff

The incidents of the three remaining preliminary reports are due to turnover of contract employees and rotation of military members. Although training of individuals continued as required, the turnover resulted in a larger number of newly trained/inexperienced personnel involved in veterinary support than usual. The IACUC considered this situation serious with the death of one NHP, as well as continuing with repeated anesthesia of incorrect NHPs. Because these incidents (and an additional incident of anesthesia of incorrect NHP on 29SEP17) have an identical root cause and corrective actions, I will combine them into one final report. This final report will be on your desk next week, as well as one other pending final report.

(b)(6) DVM, DACLAM, DACVP
 LTC, VC, USA
 Biodefense research pathologist
 IACUC Chair
 US Army Research Institute of Infectious Diseases
 1425 Porter Street, Fort Detrick, MD 21702
 Office: (b)(6)

-----Original Message-----

From: Wolff, Axel (NIH/OD) [E] [mailto:wolffa@od.nih.gov]
Sent: Wednesday, November 22, 2017 7:59 AM
To: (b)(6) LTC USARMY MEDCOM USAMRIID (US)
Subject: [Non-DoD Source] RE: OLAW reports (UNCLASSIFIED)

Thank you for this explanation, (b)(6) I have 2 preliminary reports addressing anesthesia and 1 regarding death of a primate during transportation. Once I receive all of these final reports, I will close out the case.
 Axel Wolff

-----Original Message-----

From: (b)(6) LTC USARMY MEDCOM USAMRIID (US) [mailto:(b)(6)]
 Sent: Tuesday, November 21, 2017 2:27 PM
 To: Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>
 Cc: (b)(6) USARMY MEDCOM USAMRIID (US) (b)(6)
 Subject: RE: OLAW reports (UNCLASSIFIED)

Classification: UNCLASSIFIED
 Caveats: NONE

Dr. Wolff
 I apologize for the confusion. Let me try to clarify-

19SEP17 email served as preliminary report for 4 incidents.
 #1 (missed observation AWI 17-23) was addressed in final report dated 25SEP17. #2, #3, #4 are addressed together in a final report you should receive next week. These three instances all deal with NHP anesthesia, have the same root cause, and the same corrective actions.

The other incident, (primates not meeting protocol requirements, AWI 17-22) incorrectly references a 19SEP17 email. At the time of anonymous IACUC notification, it was unclear if the concern was factual or reportable so a preliminary report was not generated. Upon completion of an investigation, the IACUC voted for reporting at a full committee meeting. Very shortly thereafter, the final report was drafted and sent.

I hope that helps.

-----Original Message-----

From: Wolff, Axel (NIH/OD) [E] [mailto:wolffa@od.nih.gov]
 Sent: Tuesday, November 21, 2017 7:38 AM
 To: (b)(6) LTC USARMY MEDCOM USAMRIID (US)
 Subject: [Non-DoD Source] OLAW reports

Hello (b)(6)

I am following up on a preliminary report you submitted on September 19, 2017 outlining four incidents of noncompliance. I have received two final reports (missed clinical observation, primate not meeting protocol requirements) and can match the missed observation to the preliminary but am not sure which one the second report references. Also, do you know when the remainder of the reports will be submitted? I would like to close this case before the end of the year.

Thank you.

Axel Wolff, M.S., D.V.M.

Deputy Director, OLAW

Classification: UNCLASSIFIED
 Caveats: NONE

Classification: UNCLASSIFIED

Caveats: NONE



DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES
1425 PORTER STREET
FORT DETRICK, MARYLAND 21702-5011

November 16, 2017

USAMRIID Institutional Animal Care and Use Committee (IACUC)

Axel Wolff, D.V.M.
 Director, Office of Laboratory Animal Welfare
 National Institutes of Health
 Rockledge 1, Suite 360, MSC 7982
 6705 Rockledge Drive
 Bethesda, Maryland 20892-7982

Dear Dr. Wolff:

Please reference LTC (b)(6) emails on September 19, 2017 regarding Animal Welfare Investigations (AWI) #17-25, 17-26, 17-27, and 17-30 involving non-human primates (NHP) anesthesia events. The NHPs involved are not assigned to PHS funded studies.

August 11, 18 and September 29, 2017 the IACUC office was notified of three separate instances of Veterinary Medicine Division (VMD) technicians anesthetizing the wrong NHP. No other unnecessary procedures were performed on the NHPs and there were no negative impacts to the NHPs. AWI#17-30 on 29 September was not addressed in a preliminary report.

On 15 September 2017, the IACUC was notified that an NHP had died during post-operative recovery. The cause was determined to be failure by several technicians to follow established intra- and post-anesthetic monitoring procedures.

Due to the rotational nature of division staff and recent increase in turnover of contract employees, the Veterinary Medicine Division is enhancing the technician training program in order for personnel to attain and maintain proficiency, and for consistent performance of veterinary procedures. The technicians involved in these incidents are captured by this program and have been retrained on NHP anesthesia. The Veterinary Medicine Division is providing monthly updates to the IACUC with regard to performance of the training program.

If you require further information regarding these AWIs, please contact LTC (b)(6) (b)(6) USAMRIID IACUC Chair, at (b)(6) The Animal Welfare Assurance number is A3473-01. Please copy LTC (b)(6) on correspondence concerning this report.

Sincerely,

(b)(6)

Colonel, US Army
 Deputy Commander



DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES
1425 PORTER STREET
FORT DETRICK, MARYLAND 21702-5011

November 16, 2017

USAMRIID Institutional Animal Care and Use Committee (IACUC)

Axel Wolff, D.V.M.
Director, Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, Maryland 20892-7982

Dear Dr. Wolff:

Please reference LTC (b)(6) email on November 16, 2017 regarding Animal Welfare Investigation (AWI) #17-32 involving the unexpected death of two mice. The mice involved were assigned to a PHS funded study.

On September 29, 2017 the IACUC was informed of an incident that led to the euthanasia of two mice. On September 13, 2017 the Veterinary Medicine Division received an order of mice from an approved vendor by. Some mice (one cage) were smaller than typically received, and it went unnoticed that they were unable to use the lixit watering system with subsequent dehydration and moribundity. Two mice required euthanasia, however the others responded to treatment.

Personnel were trained on evaluation of lixit use and alternate hydration strategies to prevent future recurrences.

If you require further information regarding this AWI, please contact LTC (b)(6) (b)(6) USAMRIID IACUC Chair, at (b)(6) The Animal Welfare Assurance number is A3473-01. Please copy LTC (b)(6) on correspondence concerning this report.

Sincerely,

(b)(6)

Colonel, US Army
Deputy Commander

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, November 28, 2017 9:42 AM
To: (b)(6) LTC USARMY MEDCOM USAMRIID (US)
Subject: RE: USAMRIID AWI final reports (UNCLASSIFIED)

Thank you for these reports. We'll send responses shortly.

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

-----Original Message-----

From: (b)(6) LTC USARMY MEDCOM USAMRIID (US) [mailto:(b)(6)]
Sent: Monday, November 27, 2017 3:47 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b)(6) CIV USARMY MEDCOM USAMRIID (US) (b)(6) COL
 USARMY MEDCOM USAMRIID (US) (b)(6)
Subject: USAMRIID AWI final reports (UNCLASSIFIED)

Classification: UNCLASSIFIED
 Caveats: NONE

OLAW:

Please find attached two final reports: one finalizing four individual incidents involving NHP anesthesia with the same root cause and corrective actions, and another regarding mouse watering.
 By my records USAMRIID should have no other outstanding reports due.

(b)(6), DVM, DACLAM, DACVP
 LTC, VC, USA
 Biodefense research pathologist
 IACUC Chair
 US Army Research Institute of Infectious Diseases
 1425 Porter Street, Fort Detrick, MD 21702
 Office: (b)(6)

Classification: UNCLASSIFIED
 Caveats: NONE



DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES
1425 PORTER STREET
FORT DETRICK, MARYLAND 21702-5011

September 25, 2017

USAMRIID Institutional Animal Care and Use Committee (IACUC)

Axel Wolff, D.V.M.
Director, Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, Maryland 20892-7982

Dear Dr. Wolff:

Please reference LTC (b)(6) email on Sept 19, 2017 regarding Animal Welfare Investigation (AWI) #17-22, concerning the use of non-human primates (NHP) that did not meet requirements as specified in the approved protocol.

On July 27, 2017 the IACUC received an anonymous concern that NHPs used on a study did not meet the maturity level and weight ranges specified in the protocol. An investigation found that 2 NHPs were underweight upon arrival from the sponsor and assignment to the study (2.8 and 2.9kg, 3.0kg required in protocol) and 4 NHPs were commented on as 'immature' by the pathologist at necropsy ('sexually mature adult' specified in protocol). Animal welfare and study data were determined to be uncompromised.

A GLP protocol deviation had been written to allow 2.5kg NHPs, but an IACUC addendum was not simultaneously submitted. After acclimation and rehydration, and prior to study manipulation, only one NHP was <3kg (2.95kg). The NHPs were vaccinated and held at a sponsor's vivarium prior to use at USAMRIID. The sponsor's IACUC and approved protocol defines 'adult' as >3 years, which all these NHPs were, but USAMRIID does not have a similar definition of 'sexually mature adult'.

Since the principal investigator was in constant communication with veterinarians to address challenges with this cohort of the study in order gain useful data and not waste animal lives, no disciplinary action was taken against her for failure to submit an addendum for the weights. Regarding the maturity level, USAMRIID IACUC will advise use of more easily definable age ranges rather the more difficult to determine maturity level in future protocols.

If you require further information regarding this AWI, please contact LTC (b)(6) (b)(6) USAMRIID IACUC Chair, at (b)(6) The Animal Welfare Assurance number is A3473-01. Please copy (b)(6) on correspondence concerning this report.

Sincerely,

(b)(6)

Colonel, US Army
Deputy Commander

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, October 02, 2017 9:08 AM
To: (b)(6) CIV USARMY MEDCOM USAMRIID (US); OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6) LTC USARMY MEDCOM USAMRIID (US)
Subject: RE: Reportable situations (UNCLASSIFIED)

Thank you for sending these final reports. We will send official responses soon.

Regards, Brent Morse

Brent C. Morse, DVM, DACLAM
 Acting Director
 Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 National Institutes of Health

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-----Original Message-----

From: (b)(6) CIV USARMY MEDCOM USAMRIID (US) [mailto:(b)(6)]
Sent: Wednesday, September 27, 2017 10:33 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6); (b)(6) LTC USARMY MEDCOM USAMRIID (US); (b)(6)
Subject: Reportable situations (UNCLASSIFIED)

Classification: UNCLASSIFIED

Caveats: NONE

OLAW,

Please see attached for final animal welfare incident reports.

v/r:

(b)(6), BS, CPIA
 Vice-Chair, IACUC

United States Army Medical Research Institute of Infectious Diseases Bldg 1425 Porter St. (b)(6) Fort Detrick, MD 21702-5011 Tel: (b)(6) Fax: (b)(6) (b)(6) This document is intended for the exclusive use of the recipient(s) named above. It may contain sensitive information that is protected, privileged, or confidential, and should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient(s), any dissemination, distribution, or copying is strictly prohibited. If you think you have received this document in error, please notify the sender immediately and destroy the original.



DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES
1425 PORTER STREET
FORT DETRICK, MARYLAND 21702-5011

September 25, 2017

USAMRIID Institutional Animal Care and Use Committee (IACUC)

Axel Wolff, D.V.M.
Director, Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, Maryland 20892-7982

Dear Dr. Wolff:

Please reference LTC (b)(6) email on 19 Sept 2017 regarding Animal Welfare Investigation (AWI) #17-23, concerning a missed clinical observation.

On August 4, 2017 the IACUC was notified that the biocontainment veterinary technical staff missed a clinical observation timepoint of a 10 NHP study. An investigation revealed that a glitch in the electronic sharepoint calendar (in which technical support is scheduled) due to a software update was the likely cause. Information regarding rescheduling of the observations had been properly inputted to the calendar, but did not transmit to calendar recipients. This appears to be an isolated incident since several tests of the system since then have been successful. Procedures for relaying schedule changes to the staff have also been updated, to add a layer of redundancy. The observations were at the end of the study, and there was no impact to animal welfare.

If you require further information regarding this AWI, please contact LTC (b)(6) (b)(6) USAMRIID IACUC Chair, at (b)(6) The Animal Welfare Assurance number is A3473-01. Please copy LTC (b)(6) on correspondence concerning this report.

Sincerely,

(b)(6)

Colonel, US Army
Deputy Commander

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, October 02, 2017 9:08 AM
To: (b)(6) CIV USARMY MEDCOM USAMRIID (US); OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b)(6) USARMY MEDCOM USAMRIID (US); (b)(6) LTC
 USARMY MEDCOM USAMRIID (US)
Subject: RE: Reportable situations (UNCLASSIFIED)

Thank you for sending these final reports. We will send official responses soon.

Regards, Brent Morse

Brent C. Morse, DVM, DACLAM
 Acting Director
 Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 National Institutes of Health

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-----Original Message-----

From: (b)(6) CIV USARMY MEDCOM USAMRIID (US) [mailto:(b)(6)]
Sent: Wednesday, September 27, 2017 10:33 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b)(6) COL USARMY MEDCOM USAMRIID (US) (b)(6) (b)(6) LTC
 USARMY MEDCOM USAMRIID (US) (b)(6)
Subject: Reportable situations (UNCLASSIFIED)

Classification: UNCLASSIFIED
 Caveats: NONE

OLAW,

Please see attached for final animal welfare incident reports.

v/r:

(b)(6) BS, CPIA
 Vice-Chair, IACUC

United States Army Medical Research Institute of Infectious Diseases Bldg 1425 Porter St. (b)(6) Fort Detrick, MD 21702-5011 Tel (b)(6) Fax (b)(6) (b)(6) This document is intended for the exclusive use of the recipient(s) named above. It may contain sensitive information that is protected, privileged, or confidential, and should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient(s), any dissemination, distribution, or copying is strictly prohibited. If you think you have received this document in error, please notify the sender immediately and destroy the original.

Wolff, Axel (NIH/OD) [E]

A3473-2J

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, September 19, 2017 10:30 AM
To: (b)(6) LTC USARMY MEDCOM USAMRIID (US)
Subject: RE: Preliminary for 4 reportable situations (UNCLASSIFIED)

Thank you for these reports, (b)(6). We will start a new case file.

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

-----Original Message-----

From: (b)(6) LTC USARMY MEDCOM USAMRIID (US) [mailto:(b)(6)]
Sent: Tuesday, September 19, 2017 8:33 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) COL
 USARMY MEDCOM USAMRIID (US) (b)(6)
Subject: Preliminary for 4 reportable situations (UNCLASSIFIED)

Classification: UNCLASSIFIED
 Caveats: NONE

OLAW,

I am submitting preliminary reports for four situations:

- ✓1. On 04 August 2017, the IACUC was informed that VetMed Division personnel missed a scheduled animal observation.
- ✓2. On 11 August 2017, the IACUC was informed that VetMed Division personnel misidentified, anesthetized and prepped for surgery the wrong NHP, with no untoward effects.
3. On 18 August 2017, the IACUC was informed that VetMed Division personnel misidentified, anesthetized and sampled (blood and saliva) the wrong NHP, with no untoward effects.
4. On 15 September 2017, the IACUC was informed that an NHP died post-operatively during transportation between buildings.

None of the animals involved were on PHS funded studies. Full reports to follow.

(b)(6) DVM, DAACLAM, DACVP
 LTC, VC, USA
 Biodefense research pathologist
 IACUC Chair
 US Army Research Institute of Infectious Diseases
 1425 Porter Street, Fort Detrick, MD 21702
 Office: (b)(6)

Classification: UNCLASSIFIED
 Caveats: NONE



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
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Bethesda, Maryland 20892-6910
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

January 8, 2019

Re: Animal Welfare Assurance
A3473-01 [OLAW Case 2K]

Colonel (b)(6)
Deputy Commander
U.S. Army Medical Research Institute
of Infectious Diseases
1425 Porter Street, Bldg. 1425, (b)(6)
Fort Detrick, MD 21702-5011

Dear COL (b)(6),

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 2, 2018 letter reporting an adverse event impacting research animals at the US Army Medical Research Institute of Infectious Diseases, following up on an initial telephone report on May 31, 2018. **According to the information provided, OLAW understands that flooding caused by heavy rain led to a failure of the steam sterilization plant which resulted in the shutdown of the biocontainment suites. Because effluent could no longer be decontaminated, the suites were depopulated resulting in euthanasia of 749 animals (hamsters, guinea pigs, mice).**

The Institutional Animal Care and Use Committee conducted an investigation into the decision-making process which led to the shutdown of the suites and depopulation. The findings stated that key personnel were not involved in decision-making, there was a lack of no effluent standard operating procedures (SOP), and failure to comply with the chemical effluent decontamination SOP. Following discussion by knowledgeable oversight staff, it was decided to utilize modular chemical and thermal decontamination until the Effluent Decontamination System is operable. All key personnel have been added to the incident command roster, the emergency operations plan is being revised, animal care and use SOPs were modified to address periods of modified procedures, and rehearsals were conducted to address the steps to take in the event of a failure of the decontamination system. Representatives from the Centers for Disease Control and Prevention have provided oversight in the handling of this incident.

Based on its assessment of this explanation, OLAW understands that measures are underway to correct the problem and to reduce the likelihood of a recurrence. OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. Please also inform the Public Health Service funding components about this incident. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b)(6)

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

cc: IACUC Chair



DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES
 1425 PORTER STREET
 FORT DETRICK, MARYLAND 21702-5011

January 2, 2018

Axel Wolff, M.S., D.V.M.
 Office of Laboratory Animal Welfare (OLAW)
 National Institutes of Health
 Rockledge 1, Suite 360, MSC 7982
 6705 Rockledge Drive
 Bethesda, Maryland 20892-7982

Dear Dr. Wolff:

Please reference the preliminary report to the OLAW inbox by the previous IACUC Chair, Lieutenant Colonel (b)(6) regarding Animal Welfare Investigation (AWI) #18-11. Animals were assigned across twelve (12) IACUC-approved and active protocols. Two (2) of these protocols are Public Health Service (PHS) funded.

On May 31, 2018, under the provisos of the Veterinary Medicine Division (VMD) Emergency Operations Manual, 749 animals housed in Animal Biosafety Level (ABSL) 3 and 4 containment suites were euthanized at the discretion of the Attending Veterinarian (AV) when the Fort Detrick steam sterilization plant (SSP) failed. Under the Centers for Disease Control and Prevention (CDC) requirements, laboratory effluent must be decontaminated by a proven method, preferably heat treatment, before being discharged to the sanitary sewer. USAMRIID chemically treats all effluent from the containment suites and relies on heat treatment prior to release of its laboratory effluent into the municipal sewer system. Following two incidents of back-to-back flooding from heavy rains, the stormwater flooded the SSP and effluent could not be processed under the CDC requirements.

On May 30, 2018, after discussions with the CDC, installation personnel, and key leaders in the Institute, the USAMRIID Commander ceased operations in all BSL/ABSL 3 and 4 containment suites. At the time, all current and approved animal husbandry methods produced effluent, and there were no validated, alternative procedures (where no or minimal effluent is created) in place to complete husbandry tasks. Without the option to enter suites to perform visual checks and provide food (exit requires a "shower out" procedure, producing effluent) and wash down the cages/rooms (which also produces effluent), the AV deemed there was no way to maintain the health and welfare of the animals in containment. The VMD conducted a review of all animals housed in the ABSL 3 and 4 suites and was able to bring non-exposed animals out of holding, but all remaining animals were euthanized. On June 7, 2018 the CDC issued a "cease and desist" order, stating "USAMRIID is to continue its work stoppage involving select agents and toxins in all registered laboratory areas where laboratory effluent is discharged into the SSP."

At a convened quorum of the full IACUC on June 13, 2018, the Committee voted unanimously for an investigation into the decision-making process behind the shutdown of containment suite operations. A subcommittee of two IACUC members spent over five months interviewing key personnel, specifically those at the May 30 meeting and those whose protocols were affected. The final report was presented at the November 8, 2018 IACUC meeting. The

principal findings included: identification of key personnel as missing from the May 30 discussion and decision making process, notably the IACUC Chair and personnel familiar with modified (no effluent) procedures; lack of validated, modified (no effluent) procedures in Institute standard operating procedures (SOPs) and the emergency operations plan; and noncompliance with the SOP on chemical decontamination of effluent. The IACUC felt the investigation was thorough and comprehensive. While some interviewees reported a sense of disenfranchisement from the decision making process, the IACUC recognized that even if those missing had been there to present other information at the May 30 meeting, the decision to shut down suite operations most likely would have been sustained. The IACUC voted to accept the report and its recommendations to correct the above findings.

Since this incident and concurrent with the investigation period, personnel from Emergency Operations Center, VMD, Biosecurity, members of the Science Directorate, Physical Security, Facilities, Biosafety, the Office of Animal Welfare Compliance, and others have met to discuss how best to address this type of emergency. At this time, as an interim measure and until the Institute can connect to the new Effluent Decontamination System (EDS), the Institute has contracted for modular chemical and thermal EDS (CEDS and TEDS) to support containment work. Following an extensive validation process, that work is expected to resume in January 2019. Members listed above have engaged in a talk-through rehearsal of managing a CEDS failure. The incident command roster has been updated to include the IACUC Chair and other key personnel familiar with modified BSL-3 procedures. The emergency operations plan is under review and revision to accommodate a potential containment suite shutdown, which will include use of modified procedures. The CDC has visited the Institute to review the updated procedures and has re-written some of their requirements for this type of accommodation. Institute SOPs and animal care and use protocols are being revised to reflect changes in husbandry schedules when modified procedures go into effect. The IACUC recognizes the process of document upgrades, rehearsals, validation, and steady evaluation is ongoing, and the Committee is supportive and engaged.

If you require further information regarding this AWI, please contact LTC (b)(6), USAMRIID IACUC Chair, at (b)(6) or by email at (b)(6). Our Animal Welfare Assurance number is D16-00297 (A3473-01). Please copy LTC (b)(6) on correspondence concerning this report.

Sincerely,

(b)(6)

Colonel, U.S. Army
Deputy Commander

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, January 3, 2019 11:33 AM
To: (b)(6) LTC USARMY MEDCOM USAMRIID (USA); OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b)(6) COL USARMY MEDCOM USAMRIID (USA); (b)(6) CIV USARMY MEDCOM USAMRIID (US); (b)(6) COL USARMY MEDCOM USAMRIID (US)
Subject: RE: USAMRIID: OLAW letter for AWI #18-11 - suite shut down

Thank you for providing this final report (b)(6). We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
 Director
 Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 National Institutes of Health

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

-----Original Message-----

From: (b)(6) LTC USARMY MEDCOM USAMRIID (USA) [mailto:(b)(6)]
Sent: Thursday, January 03, 2019 10:38 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b)(6) COL USARMY MEDCOM USAMRIID (USA); (b)(6); (b)(6)
 USARMY MEDCOM USAMRIID (US); (b)(6); (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6)
Subject: USAMRIID: OLAW letter for AWI #18-11 - suite shut down

Hello all --

Enclosed please find the letter to OLAW summarizing the findings of the IACUC's investigation into the decision making process to shut down containment suites due to the failure of the steam sterilization plant (SSP). Under the CDC requirements, laboratory effluent must be decontaminated by a proven method, preferably heat treatment, before being discharged to the sanitary sewer. USAMRIID chemically treats all effluent from the containment suites and relies on heat treatment prior to release of its laboratory effluent. Following two incidents of back-to-back flooding from heavy rains, the storm water flooded the SSP and effluent could not be processed. All containment animal care procedures produced effluent. With no alternative, validated methods to manage the effluent, the program could not sustain the health and welfare of the animals. 749 animals housed in ABSL3 and 4 conditions were euthanized at the discretion of the Attending Veterinarian. Animals were assigned across 12 IACUC-approved and active protocols, and two of these protocols were PHS funded. Our assurance number is : D16-00297 (A3473-01).

The IACUC felt the investigation was thorough and comprehensive. Concurrent with the investigation period, personnel from multiple divisions (Emergency Operations, Physical Security, Biosecurity, Vet Med, and this office, to name a few)

have been in regular discussions on how to best address this type of emergency. The letter provides updates on this ongoing process.

We appreciate your patience with our process to manage and review this long term investigation. Please review the letter for the complete summary of the events and the results of the investigation. Please let me know if you have questions or concerns.

Kind regards,

(b)(6)

(b)(6), DVM, MPH, DACLAM

LTC, USA

Director, Office of Animal Welfare Compliance & USAMRIID IACUC Chair (b)(6)

Mail to:

MCMR UIZ-L/LTC (b)(6)

US Army Medical Research Institute of Infectious Diseases (USAMRIID)

1425 Porter Street

Fort Detrick MD 21702

VM: (b)(6)

FAX:

Email: (b)(6)



Initial Report of Noncompliance

By: gnd

Date: 5/31/18

Time: 12:30

Name of Person reporting: (b)(6)

Telephone #: (b)(6)

Fax #:

Email:

Name of Institution: USA MARIID

Assurance number: A3473

Did incident involve PHS funded activity?

Funding component:

Was funding component contacted (if necessary):

What happened?

*BSE 3+4 effluent line broken. Exposed BSE rooms
+ euthanasia rooms*

Species involved: *monkeys, guinea pigs, mice*

Personnel involved:

Dates and times:

Animal deaths: 800

Projected plan and schedule for correction/prevention (if known):

Fix water disin line

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case #



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTHFOR 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) 402-7065

September 5, 2018

Re: Animal Welfare Assurance
A3473-01 [OLAW Case 2L]

Colonel (b)(6)
Deputy Commander
U.S. Army Medical Research Institute
of Infectious Diseases
1425 Porter Street, Bldg. 1425, (b)(6)
Fort Detrick, MD 21702-5011

Dear Colonel (b)(6)

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 31, 2018 letter reporting an incident of noncompliance (AWI # 18-14) with the PHS Policy on the Humane Care and Use of Laboratory Animals at the US Army Medical Research Institute of Infectious Disease. Your letter supplements the information provided in a prompt - preliminary report email on July 26, 2018. According to the information provided it is understood that on July 26, 2018 several issues were observed with mice used in activities on an amendment to a protocol. Some mice were not properly anesthetized; poor technique during exsanguination; poor technique during IP lavage, use of cervical dislocation as a primary method of euthanasia, though not approved in the amendment, and; inappropriate storage of controlled substances. The AV temporarily halted activities on the amendment. The IACUC subsequently voted to suspend the activities. It was stated that these animals were not assigned to a PHS-funded activity.

Corrective and preventive actions included retraining by Veterinary Medical Division (VMD) of all personnel assigned to the protocol and documentation of retraining send to the IACUC Chair. A PAM subcommittee must be present to review any remaining protocol activities. VMD personnel completed work on an improved new amendment under observation by the PAM committee. No further activities took place on the protocol which has since expired.

OLAW believes that the corrective and preventive measures put in place by the US Army Medical Research Institute of Infectious Disease are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals. Although this activity was not PHS funded, the application of the standards of the PHS Policy across the animal care and use program reduces any potential appearance of a double standard. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

(b)(6)

Brent C. Morse, DVM
Acting Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES
 1425 PORTER STREET
 FORT DETRICK, MARYLAND 21702-5011

August 31, 2018

Brent Morse, D.V.M.
 Office of Laboratory Animal Welfare (OLAW)
 National Institutes of Health
 Rockledge 1, Suite 360, MSC 7982
 6705 Rockledge Drive
 Bethesda, Maryland 20892-7982

Dear Dr. Morse:

Please reference LTC (b)(6) preliminary reports to the OLAW Inbox on July 26 and 27, 2018 regarding Animal Welfare Investigations (AWI) #18-12 and #18-14. Both of these incidents took place under the same Institutional Animal Care and Use Committee (IACUC)-approved animal care and use protocol. Activities on this protocol are not Public Health Service (PHS) funded.

For the incident known as AWI #18-12, on July 6 the Veterinary Medicine Division (VMD) veterinary medical staff observed on routine rounds that anesthetized mice were left in home cages to recover from anesthesia with no one present from the science team that anesthetized the mice. This represents failure to monitor animals post-procedurally as necessary to ensure wellbeing. The original protocol contained only non-survival procedures. A survival procedure was added by amendment (tail vein injections), but the activity was to be conducted using manual, not chemical restraint. Chemical restraint was approved for another survival procedure (added by an earlier amendment). Use of chemical restraint for the tail vein injections was not approved by the IACUC. The study personnel used (unapproved) chemical restraint for the tail vein injections and then left the mice in their cages alone to recover. The veterinary medical staff remained with the mice, provided thermal support, manual stimulation, and fluid support. They recovered all mice and no mice died from this incident. On July 12 study personnel were provided training on anesthetic recovery in mice per institute Standard Operating Procedure (SOP) and all were verified as proficient in this task. Since this incident no further activities on this protocol have taken place requiring anesthetic recovery in mice. The protocol is now expired.

For the incident known as AWI #18-14, on July 26 our Post-Approval Monitoring (PAM) committee conducted a review of activities involving mice on an amendment to the protocol. Activities included deep anesthesia of the mice, euthanasia by exsanguination using cardiocentesis, confirmation of death using thoracotomy, and post-mortem intraperitoneal (IP) lavage. The PAM subcommittee observed inappropriate depth of anesthesia in four mice, poor technique during exsanguination, poor technique during IP lavage, use of cervical dislocation as a primary method of euthanasia (not approved per addendum), and inappropriate storage of controlled substances. The Attending Veterinarian (AV) in consultation with the IACUC Chair were notified of the incidents following the PAM, and on July 26 the AV temporarily halted activities on the amendment. The IACUC met on August 9 to review the matter. The Principal Investigator (PI) and study personnel were present as guests for the initial discussion on the incident and provided information requested by the Committee. Following initial discussion the guests were asked to depart the meeting room for the remainder of the discussion and the vote

-2-

on the issue. The Committee unanimously voted to suspend activities under the amendment as written with the following sanctions:

- a. All personnel assigned to the protocol must receive retraining provided by VMD on all animal techniques and procedures.
- b. Documentation on retraining must be provided to the IACUC Chair for review.
- c. For any remaining approved activities going forward on the protocol, a PAM subcommittee must be present to review all events.
- d. For any work required to fulfill the goals of the amendment, only VMD personnel may perform the approved animal activities listed on the amendment. If activities remaining on the amendment are no longer required, utilization or reassignment of animals for ongoing work must be completed.

To fulfill (d) above, on August 13 VMD staff determined the optimal dose of ketamine-acepromazine-xylazine (KAX) cocktail for deep anesthesia in mice. VMD study support staff received proficiency training on deep anesthesia, anesthetic monitoring, exsanguination via cardiocentesis, thoracotomy, and IP lavage. The PI submitted another amendment on August 15 to clarify more specifically the activities required to complete the work on the previous amendment. Activities were conducted by trained VMD study support staff on August 16 and 17 under the approved new amendment. A PAM committee observed all activities on August 16 and there were no reportable animal welfare issues. Since this incident no further activities on this protocol have taken place and the protocol is now expired.

If you require further information regarding these AWIs, please contact LTC (b)(6), USAMRIID IACUC Chair, at (b)(6) or by email at (b)(6). Our Animal Welfare Assurance number is D16-00297 (A3473-01). Please copy LTC (b)(6) on correspondence concerning this report.

Sincerely,

(b)(6)

Colonel, U.S. Army
Deputy Commander

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, August 31, 2018 7:34 AM
To: (b)(6) LTC USARMY MEDCOM USAMRIID (US); OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6) USARMY MEDCOM USAMRIID (US); (b)(6) COL USARMY MEDCOM USAMRIID (US)
Subject: RE: USAMRIID: Reports from IO, AWI #18-12, 18-14, 18-15 (UNCLASSIFIED)

Thank you for providing these reports (b)(6). We will send official responses soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
 Director
 Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 National Institutes of Health

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-----Original Message-----

From: (b)(6) LTC USARMY MEDCOM USAMRIID (US) [mailto:(b)(6)]
Sent: Friday, August 31, 2018 7:22 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6) (b)(6) USARMY MEDCOM USAMRIID (US); (b)(6); (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6)
Subject: USAMRIID: Reports from IO, AWI #18-12, 18-14, 18-15 (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

Hi all --

Attached please find letters from our IO regarding the incidents described previously for USAMRIID. Please let me know if you have any questions.

Kind regards,

(b)(6)

(b)(6), DVM, MPH, DACLAM

LTC, USA

Deputy Director - Research Support Directorate and USAMRIID IACUC Chair (b)(6)

Mail to:

MCMR UIZ-L/LTC (b)(6)

US Army Medical Research Institute of Infectious Diseases (USAMRIID)

1425 Porter Street
Fort Detrick MD 21702

VM: (b)(6)
FAX: (b)(6)

Email: (b)(6)
CLASSIFICATION: UNCLASSIFIED

A3473 - 22
preliminary**Morse, Brent (NIH/OD) [E]**

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, July 26, 2018 3:12 PM
To: (b)(6) LTC USARMY MEDCOM USAMRIID (US); OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b)(6) USARMY MEDCOM USAMRIID (US); (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6) COL USARMY MEDCOM USAMRIID (US)
Subject: RE: USAMRIID: Report of Suspension of Activities for Protocol Noncompliance and Adverse Events (UNCLASSIFIED//FOUO)

Thank you for this preliminary report Colonel (b)(6). We will open a case file and await further information regarding the events and the suspension as noted in your report.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
 Director
 Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 National Institutes of Health

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-----Original Message-----

From: (b)(6) LTC USARMY MEDCOM USAMRIID (US) [mailto:(b)(6)]
Sent: Thursday, July 26, 2018 2:59 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b)(6) USARMY MEDCOM USAMRIID (US); (b)(6); (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6); (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6)
Subject: USAMRIID: Report of Suspension of Activities for Protocol Noncompliance and Adverse Events (UNCLASSIFIED//FOUO)
Importance: High

CLASSIFICATION: UNCLASSIFIED//FOR OFFICIAL USE ONLY

Dear sir or ma'm:

This email serves as a preliminary notification of both noncompliance and adverse events associated with one of our mouse protocols. Information was provided to the IACUC Office directly following a post approval monitoring (PAM) event today for an approved amendment to a protocol. The AV, in consultation with the IACUC Chair (undersigned), suspended all activities on this amendment. Our preliminary assessment is that this is a situation where individuals failed to follow the program, not a systemic issue within the whole program; however, because of the suspension, I am reporting these events to OLAW.

*Name and contact information of person reporting: (b)(6), IACUC Chair *Name of institution: US Army Medical Research Institute of Infectious Diseases (USAMRIID) *Assurance number: D16-00297 (A3473-01) *Funding component:

this is NOT PHS funded DOD partners provide funding - I will provide more information on specific partners asap

*Brief description of incidents: the PAM team observations included 1) four mice inadequately anesthetized for exsanguination (IC stick) and IP lavage; 2) poor exsanguination technique; 3) confirmatory method to ensure death (cervical dislocation) was not approved on the amendment, yet was still used on some of the mice (and may have served as the primary method, because exsanguination - the primary method- was done poorly); another method was approved (thoracotomy), but only used for some of the mice; 4) Thoracotomy not conducted in accordance with our institute SOP.

*Plan and schedule for correction and prevention: 1) AV has suspended activities on this amendment; 2) Retraining scheduled to take place week of August 6 for all personnel conducting activities required for this amendment; 3) documentation of training by Veterinary Medical Department staff with final approval from AV and IACUC Chair will ensure activities may re-commence; 4) PAM still in progress - collecting further documents at this time to support final report; 5) When activities are next conducted (following retraining), a new PAM will follow up on these activities.

*Timeframe for final report from the Institutional Official: NLT August 31, 2018

Please contact me for any questions or concerns. If you do not require a final report, please advise.

Kind regards,

(b)(6)

(b)(6), DVM, MPH, DACLAM

LTC, USA

Deputy Director - Research Support Directorate and USAMRIID IACUC Chair (b)(6)

Mail to:

MCMR UIZ-L/LTC (b)(6)

US Army Medical Research Institute of Infectious Diseases (USAMRIID)

1425 Porter Street

Fort Detrick MD 21702

VM: (b)(6)

FAX:

Email: (b)(6)

CLASSIFICATION: UNCLASSIFIED//FOR OFFICIAL USE ONLY

A3473
Add-to open file**Morse, Brent (NIH/OD) [E]**

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, July 30, 2018 8:30 AM
To: (b)(6) LTC USARMY MEDCOM USAMRIID (US)
Subject: RE: [Non-DoD Source] RE: USAMRIID: Report of AV halting Activities for Protocol Noncompliance and Adverse Events (UNCLASSIFIED//FOUO)

Good morning (b)(6)

Understood. I will update our file. I've also changed the email subject line to be clear. Thanks. Brent

Brent C. Morse, DVM, DACLAM
 Director
 Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 National Institutes of Health

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-----Original Message-----

From: (b)(6) LTC USARMY MEDCOM USAMRIID (US) [mailto:(b)(6)]
Sent: Friday, July 27, 2018 4:27 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b)(6) USARMY MEDCOM USAMRIID (US); (b)(6); (b)(6)
 COL USARMY MEDCOM USAMRIID (US); (b)(6); (b)(6) COL USARMY MEDCOM
 USAMRIID (US); (b)(6)
Subject: RE: [Non-DoD Source] RE: USAMRIID: Report of Suspension of Activities for Protocol Noncompliance and Adverse Events (UNCLASSIFIED//FOUO)

CLASSIFICATION: UNCLASSIFIED//FOR OFFICIAL USE ONLY

Hi Brent - as an update to this, I wanted to clarify that our actions here represent a halt (cessation) in activities on this amendment. The IACUC has not yet voted to suspend activities, but the AV has halted the activities while we move a corrective plan forward. I think I misused the word "suspend" here, which is an IACUC function. Based on the AV's authority for animal welfare in the institute, this represents a temporary cessation of activities. Please update the phrase "the AV suspended activities" to "the AV halted activities." Just want to be clear.

Kind regards,

(b)(6)

-----Original Message-----

From: (b)(6) LTC USARMY MEDCOM USAMRIID (US)
Sent: Thursday, July 26, 2018 3:38 PM
To: 'OLAW Division of Compliance Oversight (NIH/OD)' <olawdco@od.nih.gov>

Cc: (b)(6) USARMY MEDCOM USAMRIID (US) (b)(6); (b)(6)
 COL USARMY MEDCOM USAMRIID (US) (b)(6); (b)(6) COL USARMY MEDCOM
 USAMRIID (US) (b)(6)
 Subject: RE: [Non-DoD Source] RE: USAMRIID: Report of Suspension of Activities for Protocol Noncompliance and
 Adverse Events (UNCLASSIFIED//FOUO)

CLASSIFICATION: UNCLASSIFIED//FOR OFFICIAL USE ONLY

Hi Brent --

Thanks for your support and guidance - more information forthcoming.

Kind regards,

(b)(6)

-----Original Message-----

From: OLAW Division of Compliance Oversight (NIH/OD) [mailto:olawdco@od.nih.gov]

Sent: Thursday, July 26, 2018 3:12 PM

To: (b)(6) LTC USARMY MEDCOM USAMRIID (US) (b)(6); OLAW Division of Compliance
 Oversight (NIH/OD) <olawdco@od.nih.gov>

Cc: (b)(6) USARMY MEDCOM USAMRIID (US) (b)(6); (b)(6)
 COL USARMY MEDCOM USAMRIID (US) (b)(6); (b)(6) COL USARMY MEDCOM
 USAMRIID (US) (b)(6)

Subject: [Non-DoD Source] RE: USAMRIID: Report of Suspension of Activities for Protocol Noncompliance and Adverse
 Events (UNCLASSIFIED//FOUO)

Thank you for this preliminary report Colonel (b)(6). We will open a case file and await further information regarding the
 events and the suspension as noted in your report.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
 Director
 Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 National Institutes of Health

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-----Original Message-----

From: (b)(6) LTC USARMY MEDCOM USAMRIID (US) [mailto:(b)(6)]

Sent: Thursday, July 26, 2018 2:59 PM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Cc: (b)(6) USARMY MEDCOM USAMRIID (US) (b)(6); (b)(6)
 COL USARMY MEDCOM USAMRIID (US) (b)(6); (b)(6) COL USARMY MEDCOM
 USAMRIID (US) (b)(6)

Subject: USAMRIID: Report of Suspension of Activities for Protocol Noncompliance and Adverse Events
 (UNCLASSIFIED//FOUO)

Importance: High

CLASSIFICATION: UNCLASSIFIED//FOR OFFICIAL USE ONLY

Dear sir or ma'm:

This email serves as a preliminary notification of both noncompliance and adverse events associated with one of our mouse protocols. Information was provided to the IACUC Office directly following a post approval monitoring (PAM) event today for an approved amendment to a protocol. The AV, in consultation with the IACUC Chair (undersigned), suspended all activities on this amendment. Our preliminary assessment is that this is a situation where individuals failed to follow the program, not a systemic issue within the whole program; however, because of the suspension, I am reporting these events to OLAW.

*Name and contact information of person reporting: (b)(6) IACUC Chair *Name of institution: US Army Medical Research Institute of Infectious Diseases (USAMRIID) *Assurance number: D16-00297 (A3473-01) *Funding component: *this is NOT PHS funded* DOD partners provide funding - I will provide more information on specific partners asap
 *Brief description of incidents: the PAM team observations included 1) four mice inadequately anesthetized for exsanguination (IC stick) and IP lavage; 2) poor exsanguination technique; 3) confirmatory method to ensure death (cervical dislocation) was not approved on the amendment, yet was still used on some of the mice (and may have served as the primary method, because exsanguination - the primary method- was done poorly); another method was approved (thoracotomy), but only used for some of the mice; 4) Thoracotomy not conducted in accordance with our institute SOP.
 *Plan and schedule for correction and prevention: 1) AV has suspended activities on this amendment; 2) Retraining scheduled to take place week of August 6 for all personnel conducting activities required for this amendment; 3) documentation of training by Veterinary Medical Department staff with final approval from AV and IACUC Chair will ensure activities may re-commence; 4) PAM still in progress - collecting further documents at this time to support final report; 5) When activities are next conducted (following retraining), a new PAM will follow up on these activities.
 *Timeframe for final report from the Institutional Official: NLT August 31, 2018

Please contact me for any questions or concerns. If you do not require a final report, please advise.

Kind regards,

(b)(6)

(b)(6) DVM, MPH, DACLAM

LTC, USA

Deputy Director - Research Support Directorate and USAMRIID IACUC Chair (b)(6)

Mail to:

MCMR UIZ-L/LTC (b)(6)

US Army Medical Research Institute of Infectious Diseases (USAMRIID)

1425 Porter Street

Fort Detrick MD 21702

VM: (b)(6)

FAX:

Email: (b)(6)

CLASSIFICATION: UNCLASSIFIED//FOR OFFICIAL USE ONLY

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DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTHFOR 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) 402-7065

September 5, 2018

Re: Animal Welfare Assurance
A3473-01 [OLAW Case 2M]

Colonel (b)(6)
Deputy Commander
U.S. Army Medical Research Institute
of Infectious Diseases
1425 Porter Street, Bldg. 1425, (b)(6)
Fort Detrick, MD 21702-5011

Dear Colonel (b)(6)

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 31, 2018 letter reporting an incident of noncompliance (AWI # 18-12) with the PHS Policy on the Humane Care and Use of Laboratory Animals at the US Army Medical Research Institute of Infectious Disease. Your letter supplements the information provided in a preliminary report email on July 27, 2018. According to the information provided it is understood that on July 6, 2018 Veterinary Medical Division (VMD) staff observed anesthetized mice in home cages left to recover from anesthesia with no one present from the science team to provide proper post-procedural monitoring. Chemical restraint was not approved for the procedure being conducted. All mice recovered after supportive care by the veterinary medical staff. It was stated that these animals were not assigned to a PHS-funded activity.

Corrective and preventive actions included training of study personnel on anesthetic recovery in mice. No further activities on this protocol have taken place requiring anesthetic recovery in mice and the protocol has since expired.

OLAW believes that the corrective and preventive measures put in place by the US Army Medical Research Institute of Infectious Disease are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals. Although this activity was not PHS funded, the application of the standards of the PHS Policy across the animal care and use program reduces any potential appearance of a double standard. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

(b)(6)

Brent C. Morse, DVM
Acting Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES
 1425 PORTER STREET
 FORT DETRICK, MARYLAND 21702-5011

August 31, 2018

Brent Morse, D.V.M.
 Office of Laboratory Animal Welfare (OLAW)
 National Institutes of Health
 Rockledge 1, Suite 360, MSC 7982
 6705 Rockledge Drive
 Bethesda, Maryland 20892-7982

Dear Dr. Morse:

Please reference LTC (b)(6) preliminary reports to the OLAW Inbox on July 26 and 27, 2018 regarding Animal Welfare Investigations (AWI) #18-12 and #18-14. Both of these incidents took place under the same Institutional Animal Care and Use Committee (IACUC)-approved animal care and use protocol. Activities on this protocol are not Public Health Service (PHS) funded.

This case only { For the incident known as AWI #18-12, on July 6 the Veterinary Medicine Division (VMD) veterinary medical staff observed on routine rounds that anesthetized mice were left in home cages to recover from anesthesia with no one present from the science team that anesthetized the mice. This represents failure to monitor animals post-procedurally as necessary to ensure wellbeing. The original protocol contained only non-survival procedures. A survival procedure was added by amendment (tail vein injections), but the activity was to be conducted using manual, not chemical restraint. Chemical restraint was approved for another survival procedure (added by an earlier amendment). Use of chemical restraint for the tail vein injections was not approved by the IACUC. The study personnel used (unapproved) chemical restraint for the tail vein injections and then left the mice in their cages alone to recover. The veterinary medical staff remained with the mice, provided thermal support, manual stimulation, and fluid support. They recovered all mice and no mice died from this incident. On July 12 study personnel were provided training on anesthetic recovery in mice per institute Standard Operating Procedure (SOP) and all were verified as proficient in this task. Since this incident no further activities on this protocol have taken place requiring anesthetic recovery in mice. The protocol is now expired.

For the incident known as AWI #18-14, on July 26 our Post-Approval Monitoring (PAM) committee conducted a review of activities involving mice on an amendment to the protocol. Activities included deep anesthesia of the mice, euthanasia by exsanguination using cardiocentesis, confirmation of death using thoracotomy, and post-mortem intraperitoneal (IP) lavage. The PAM subcommittee observed inappropriate depth of anesthesia in four mice, poor technique during exsanguination, poor technique during IP lavage, use of cervical dislocation as a primary method of euthanasia (not approved per addendum), and inappropriate storage of controlled substances. The Attending Veterinarian (AV) in consultation with the IACUC Chair were notified of the incidents following the PAM, and on July 26 the AV temporarily halted activities on the amendment. The IACUC met on August 9 to review the matter. The Principal Investigator (PI) and study personnel were present as guests for the initial discussion on the incident and provided information requested by the Committee. Following initial discussion the guests were asked to depart the meeting room for the remainder of the discussion and the vote

-2-

on the issue. The Committee unanimously voted to suspend activities under the amendment as written with the following sanctions:

- a. All personnel assigned to the protocol must receive retraining provided by VMD on all animal techniques and procedures.
- b. Documentation on retraining must be provided to the IACUC Chair for review.
- c. For any remaining approved activities going forward on the protocol, a PAM subcommittee must be present to review all events.
- d. For any work required to fulfill the goals of the amendment, only VMD personnel may perform the approved animal activities listed on the amendment. If activities remaining on the amendment are no longer required, utilization or reassignment of animals for ongoing work must be completed.

To fulfill (d) above, on August 13 VMD staff determined the optimal dose of ketamine-acepromazine-xylazine (KAX) cocktail for deep anesthesia in mice. VMD study support staff received proficiency training on deep anesthesia, anesthetic monitoring, exsanguination via cardiocentesis, thoracotomy, and IP lavage. The PI submitted another amendment on August 15 to clarify more specifically the activities required to complete the work on the previous amendment. Activities were conducted by trained VMD study support staff on August 16 and 17 under the approved new amendment. A PAM committee observed all activities on August 16 and there were no reportable animal welfare issues. Since this incident no further activities on this protocol have taken place and the protocol is now expired.

If you require further information regarding these AWIs, please contact LTC (b)(6) USAMRIID IACUC Chair, at (b)(6) or by email at (b)(6). Our Animal Welfare Assurance number is D16-00297 (A3473-01). Please copy LTC (b)(6) on correspondence concerning this report.

Sincerely,

(b)(6)

Colonel, U.S. Army
Deputy Commander

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, August 31, 2018 7:34 AM
To: (b)(6) LTC USARMY MEDCOM USAMRIID (US); OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6) USARMY MEDCOM USAMRIID (US); (b)(6) COL USARMY MEDCOM USAMRIID (US)
Subject: RE: USAMRIID: Reports from IO, AWI #18-12, 18-14, 18-15 (UNCLASSIFIED)

Thank you for providing these reports (b)(6). We will send official responses soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
 Director
 Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 National Institutes of Health

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-----Original Message-----

From: (b)(6) LTC USARMY MEDCOM USAMRIID (US) [mailto:(b)(6)]
Sent: Friday, August 31, 2018 7:22 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6); (b)(6) CTR USARMY MEDCOM USAMRIID (US); (b)(6); (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6)
Subject: USAMRIID: Reports from IO, AWI #18-12, 18-14, 18-15 (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

Hi all --

Attached please find letters from our IO regarding the incidents described previously for USAMRIID. Please let me know if you have any questions.

Kind regards,

(b)(6)

(b)(6) DVM, MPH, DACLAM
 LTC, USA

Deputy Director - Research Support Directorate and USAMRIID IACUC Chair (b)(6)

Mail to:

MCMR UIZ-L/LTC (b)(6)

US Army Medical Research Institute of Infectious Diseases (USAMRIID)

1425 Porter Street
Fort Detrick MD 21702

VM: (b)(6)
FAX: (b)(6)

Email: (b)(6)
CLASSIFICATION: UNCLASSIFIED

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, July 30, 2018 8:34 AM
To: (b)(6) LTC USARMY MEDCOM USAMRIID (US); OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6) COL USARMY MEDCOM USAMRIID (US)
Subject: RE: USAMRIID: Report of noncompliance and AE (UNCLASSIFIED)

Thank you for this report LTC (b)(6). Yes, please consolidate this with the July 26th report and respond with one final letter. Thank you again.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
 Director
 Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 National Institutes of Health

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-----Original Message-----

From: (b)(6) LTC USARMY MEDCOM USAMRIID (US) [mailto:(b)(6)]
Sent: Friday, July 27, 2018 4:58 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6); (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6)
Subject: USAMRIID: Report of noncompliance and AE (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

Dear sir or madam:

My apologies for the lateness of this preliminary report.

*Name and contact information of person reporting: (b)(6) IACUC Chair

*Name of institution: US Army Medical Research Institute of Infectious Diseases (USAMRIID)

*Assurance number: D16-00297 (A3473-01)

*Funding component: *this is NOT PHS funded* DOD partners provide funding - I will provide more information on specific partners asap

*Brief description of incident: on July 6 our veterinary medical staff observed on routine rounds that anesthetized mice were left in home cages to recover from anesthesia with no one present from the science team that anesthetized the

mice. This represents failure to monitor animals post-procedurally as necessary to ensure wellbeing. The original protocol contained only non-survival procedures. A survival procedure was added by amendment (tail vein injections), but the activity was to be conducted using manual, not chemical restraint. Chemical restraint was approved for another survival procedure (added by an earlier amendment). Use of chemical restraint for the tail vein injections was not approved by the IACUC. The study personnel used (unapproved) chemical restraint for the tail vein injections and then left the mice in their cages alone to recover. The veterinary medical staff remained with the mice, provided thermal support, manual stimulation, and fluid support. They recovered all mice and no mice died from this incident.

*Plan and schedule for correction and prevention: The science team received corrective training the week of July 9 on anesthetic monitoring and recovery, which was documented. An amendment was submitted to update the protocol, stating the procedures to be followed for anesthetic monitoring and recovery. Other features of the amendment included adding language to clarify that anesthetic will be used for chemical restraint for the survival procedure of tail vein injections. To date, no other activities have gone forward on the amendment. When activities resume, our office plans a Post Approval Monitoring session to oversee the activities.

*Timeframe for final report from the Institutional Official: This represents the second infraction on the same protocol within the last three weeks. Two different, unrelated amendments supported the work for July 6 and July 26. The second infraction was sent to your office on July 26, 2019 as we learned about it. As we resolve these two events on the same protocol, we can provide a consolidated report from our IO NLT August 31, 2018. If you would prefer separate reports for each incident, please advise. If you do not require a final report for this particular incident, please advise.

Please contact me for any questions or concerns.

Kind regards,

(b)(6)

(b)(6) DVM, MPH, DACLAM
LTC, USA

Deputy Director - Research Support Directorate and USAMRIID IACUC Chair (b)(6)

Mail to:

MCMR UIZ-L/LTC (b)(6)
US Army Medical Research Institute of Infectious Diseases (USAMRIID)
1425 Porter Street
Fort Detrick MD 21702

VM: (b)(6)

FAX:

Email: (b)(6)

CLASSIFICATION: UNCLASSIFIED



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTHFOR 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) 402-7065

September 5, 2018

Re: Animal Welfare Assurance
A3473-01 [OLAW Case 2N]

Colonel (b)(6)
Deputy Commander
U.S. Army Medical Research Institute
of Infectious Diseases
1425 Porter Street, Bldg. 1425, (b)(6)
Fort Detrick, MD 21702-5011

Dear Colonel (b)(6),

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 31, 2018 letter reporting an incident of noncompliance (AWI # 18-15) with the PHS Policy on the Humane Care and Use of Laboratory Animals at a satellite facility for the US Army Medical Research Institute of Infectious Disease. Your letter supplements the information provided in a prompt - preliminary report email on August 6, 2018. According to the information provided it is understood that between the evening of July 30, 2018 and the morning of July 31st two rhesus macaques escaped their caging due to an unsecured pan flap. The two animals fought and sustained extensive injuries. They were captured on the morning of July 31st and treated. The cage was welded such as to prevent such an escape and the animals have both recovered from their injuries. It was stated that these animals were not assigned to a PHS-funded activity.

OLAW believes that the corrective and preventive measures put in place by the US Army Medical Research Institute of Infectious Disease are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals. Although this activity was not PHS funded, the application of the standards of the PHS Policy across the animal care and use program reduces any potential appearance of a double standard. We appreciate being informed of this unfortunate matter and find no cause for further action by this office.

Sincerely,

(b)(6)

Brent C. Morse, DVM
Acting Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES
 1425 PORTER STREET
 FORT DETRICK, MARYLAND 21702-5011

August 31, 2018

Brent Morse, D.V.M.
 Office of Laboratory Animal Welfare (OLAW)
 National Institutes of Health
 Rockledge 1, Suite 360, MSC 7982
 6705 Rockledge Drive
 Bethesda, Maryland 20892-7982

Dear Dr. Morse:

Please reference LTC (b)(6) preliminary report to the OLAW Inbox on August 6, 2018 regarding Animal Welfare Incident (AWI) #18-15. This incident took place under an Institutional Animal Care and Use Committee (IACUC)-approved animal care and use protocol. Activities on this protocol are not Public Health Service (PHS) funded, but the incident took place at the National Institutes of Health (NIH)-Poolesville MD facility, a satellite facility for our program.

Our program maintains a holding protocol for nonhuman primates (NHPs) with a USAMRIID Principal Investigator (PI). NHPs are held at the satellite facility. The PI received a report from the NIH-Poolesville facility manager that two Rhesus macaques, male and female, assigned to her protocol escaped a C-shaped quad cage between Monday July 30 evening rounds and Tuesday July 31 morning rounds. The pan flap that typically is secured to prevent the bottom pan from moving was left unsecured. The animals opened the pan flap and kicked the bottom floor out of the quad cage. They escaped and had a fight where both sustained extensive injuries requiring surgery and follow up care. NIH-Poolesville personnel found the escaped monkeys on Tuesday morning (July 31), captured them, and treated the animals.

The satellite facility staff removed the cage from circulation and welded the floor to the cage such that it will no longer be removable. The monkeys finished their course of treatment the week of August 20 and the clinical veterinarian at NIH-Poolesville reported on August 30 both animals are completely healed. No further action is required by our program on this matter.

If you require further information regarding this AWI, please contact LTC (b)(6), USAMRIID IACUC Chair, at (b)(6) or by email at (b)(6). Our Animal Welfare Assurance number is D16-00297 (A3473-01). Please copy LTC (b)(6) on correspondence concerning this report.

Sincerely,

(b)(6)

Colonel, U.S. Army
 Deputy Commander

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, August 31, 2018 7:34 AM
To: (b)(6) LTC USARMY MEDCOM USAMRIID (US); OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6) USARMY MEDCOM USAMRIID (US); (b)(6) COL USARMY MEDCOM USAMRIID (US)
Subject: RE: USAMRIID: Reports from IO, AWI #18-12, 18-14, 18-15 (UNCLASSIFIED)

Thank you for providing these reports (b)(6). We will send official responses soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
 Director
 Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 National Institutes of Health

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-----Original Message-----

From: (b)(6) USARMY MEDCOM USAMRIID (US) [mailto:(b)(6)]
Sent: Friday, August 31, 2018 7:22 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6); (b)(6) USARMY MEDCOM USAMRIID (US); (b)(6); (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6)
Subject: USAMRIID: Reports from IO, AWI #18-12, 18-14, 18-15 (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

Hi all--

Attached please find letters from our IO regarding the incidents described previously for USAMRIID. Please let me know if you have any questions.

Kind regards,

(b)(6)

(b)(6), DVM, MPH, DACLAM
 LTC, USA
 Deputy Director - Research Support Directorate and USAMRIID IACUC Chair (b)(6)

Mail to:
 MCMR UIZ-L/LTC (b)(6)
 US Army Medical Research Institute of Infectious Diseases (USAMRIID)

1425 Porter Street
Fort Detrick MD 21702

VM: (b)(6)

FAX:

Email: (b)(6)

CLASSIFICATION: UNCLASSIFIED

A3473-2N

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, August 06, 2018 1:15 PM
To: (b)(6) LTC USARMY MEDCOM USAMRIID (US); OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b)(6) USARMY MEDCOM USAMRIID (US)
Subject: RE: USAMRIID: Report of Noncom and AE at satellite facility (UNCLASSIFIED//FOUO SENSITIVE)

Thank you for this preliminary report (b)(6). Yes, we will require a final report due to the injuries sustained by the animals. We will open a case file and await further information.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
 Director
 Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 National Institutes of Health

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-----Original Message-----

From: (b)(6) LTC USARMY MEDCOM USAMRIID (US) [mailto:(b)(6)]
Sent: Monday, August 06, 2018 12:22 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b)(6) USARMY MEDCOM USAMRIID (US) (b)(6)
Subject: USAMRIID: Report of Noncom and AE at satellite facility (UNCLASSIFIED//FOUO SENSITIVE)

CLASSIFICATION: UNCLASSIFIED//FOR OFFICIAL USE ONLY SENSITIVE

Hi all --

This is a new preliminary report of events that took place July 30 at our satellite facility, NIH Poolesville. We have a holding protocol at USAMRIID and monkeys in holding are in residence at this facility. This represents a noncompliance with local SOP and the NRC Guide ("...the primary enclosure should provide a secure environment that does not permit animal escape..." - p. 51) leading to an adverse event.

*Name and contact information of person reporting: LTC (b)(6), see signature block below for contact information

*Name of institution: US Army Medical Research Institute of Infectious Diseases (USAMRIID)

*Assurance number: D16-00297 (A3473-01)

*Funding component and if contacted (for situations related to PHS-supported activities): DOD funded, not PHS funded.

*Brief description of incident (e.g., species, category of personnel involved, dates, times, animal deaths): On Friday August 3 we received this report from the PI (summarized here): At our satellite facility, NIH-Poolesville, two Rhesus macaques (M and F) escaped a C-shaped quad cage between Monday July 30 evening rounds and Tuesday July 31 morning rounds. The pan flap that typically is secured to prevent the bottom pan from moving was left unsecured. The animals opened the pan flap and kicked the bottom floor out of the quad. They escaped and had a fight where both sustained extensive injuries requiring surgery and follow up care. Personnel found the escaped monkeys on Tuesday morning (July 31), captured them, and treated the animals. The animals are still under treatment.

*Plan and schedule for correction and prevention (if known): 1) NHPs will follow treatment plan per AV at Poolesville; 2) The cage has been removed from circulation and the floor will be welded to the cage so that it is no longer removable; 3) I have asked the RIID PI to confirm if further training on securing pan flaps will be provided; if so, they will provide us documentation of the training.

*Timeframe for final report from the Institutional Official: If OLAW requires a final report, we can provide NLT August 31, 2018. Please advise if you require this report from the IO.

Thanks, all!

Kind regards,

(b)(6)

(b)(6), DVM, MPH, DACLAM

LTC, USA

Deputy Director - Research Support Directorate and USAMRIID IACUC Chair (b)(6)

Mail to:

MCMR UIZ-L/LTC (b)(6)

US Army Medical Research Institute of Infectious Diseases (USAMRIID)

1425 Porter Street

Fort Detrick MD 21702

VM: (b)(6)

FAX:

Email: (b)(6)

CLASSIFICATION: UNCLASSIFIED//FOR OFFICIAL USE ONLY SENSITIVE



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTHFOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
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
Rockledge One, Suite 360
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

October 10, 2018

Re: Animal Welfare Assurance
A3473-01 [OLAW Case 20]

Colonel (b)(6)
Deputy Commander
U.S. Army Medical Research Institute
of Infectious Diseases
1425 Porter Street, Bldg. 1425, (b)(6)
Fort Detrick, MD 21702-5011

Dear COL (b)(6)

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your September 28, 2018 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at the US Army Medical Research Institute of Infectious Diseases, following up on an initial report on September 7, 2018. According to the information provided, OLAW understands that an anesthetized hamster being used to feed mosquitoes, awoke and escaped from the enclosure. The animal fell to the ground and sustained an inoperable mandible fracture. There had been no communication between research and veterinary staff prior to the feeding procedure.

The immediate action taken upon discovery consisted of euthanizing the hamster. The Principal Investigator will now manage the insectary, will review all mosquito feeding procedures, will write a standard operating procedure on mosquito feeding, and will modify the enclosure to prevent escape. A post-approval monitoring visit will occur in the laboratory after the modifications to the procedures have been made.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and 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 V. Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair

A3473 -
Final

DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES
1425 PORTER STREET
FORT DETRICK, MARYLAND 21702-5011

September 28, 2018

Axel Wolff, M.S., D.V.M.
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, Maryland 20892-7982

Dear Dr. Wolff:

Please reference LTC (b)(6) preliminary reports to the OLAW Inbox on September 7, 2018 regarding Animal Welfare Investigation (AWI) #18-17. This incident took place under an Institutional Animal Care and Use Committee (IACUC)-approved animal care and use protocol. Activities on this protocol are not Public Health Service (PHS) funded.

An anesthetized hamster used for mosquito feeding awoke during the feeding and managed to escape from the commercial feeding net located on top of the six foot high mosquito enclosure. For optimal conditions for the mosquitoes, feedings are done in the dark. Veterinary Medicine Division (VMD) staff conducting the activity were monitoring the hamster's anesthesia every 2-3 minutes, entering the dark room each time to check. On the last check, staff discovered the hamster was out of the feeding net. They located the hamster on the ground. A subsequent physical exam showed the animal had sustained an inoperable fracture of his mandible. The veterinarian on duty euthanized the hamster. The Principal Investigator (PI) confirmed all staff performing activities were trained to do so, and all activities and anesthetic doses were conducted IAW the approved protocol and institute SOPs.

Despite the company's assertion this feeding net is "escape proof," the animal escaped and sustained injury. While the study staff and VMD staff are trained on providing this procedure, the PI has learned there was no coordinated effort in communication between study staff and VMD staff prior to this particular feeding, and he is typically informed when all feedings take place. In this case, he was never informed.

The PI has been named the new manager of the insectary. He is engaged in thorough review of all mosquito feeding procedures, to include evaluating which mosquito species require live animals for feeding. He plans to write a standard operating procedure (SOP) for the institute on the procedure of mosquito feeding. It will include use of anesthesia as required for animals involved in the procedure, plus

-2-

appropriate anesthetic monitoring in the dark room. He will update his protocol with a later modification referencing the SOP. If the commercial netting is included in the new SOP, he will have a custom made cover placed over the net, either fabricated from plexiglass or fabric, weighted down so a hamster cannot move it. He will continue feedings with the hamster placed inside the cage, a procedure also approved on the protocol. In this manner there will be no risk of falling to the hamster.

At the September 20, 2018 IACUC meeting, the committee requested a post-approval monitoring (PAM) review take place once any modification has been made to the feeding procedures and the protocol itself. Pending these events, no further action is required by our program on this matter.

If you require further information regarding this AWI, please contact LTC (b)(6) USAMRIID IACUC Chair, at (b)(6) or by email at (b)(6). Our Animal Welfare Assurance number is D16-00297 (A3473-01). Please copy LTC (b)(6) on correspondence concerning this report.

Sincerely,

(b)(6)

Colonel, U.S. Army
Deputy Commander

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, October 01, 2018 9:16 AM
To: (b)(6) LTC USARMY MEDCOM USAMRIID (US); OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b)(6) USARMY MEDCOM USAMRIID (US); (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6) COL USARMY MEDCOM USAMRIID (US)
Subject: RE: USAMRIID Report of Serious Animal Welfare Incident (UNCLASSIFIED)

Thank you for providing this final report (b)(6) We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
 Director
 Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 National Institutes of Health

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-----Original Message-----

From: (b)(6) LTC USARMY MEDCOM USAMRIID (US) [mailto:(b)(6)]
Sent: Friday, September 28, 2018 3:07 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b)(6) USARMY MEDCOM USAMRIID (US); (b)(6); (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6); (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6)
Subject: RE: USAMRIID Report of Serious Animal Welfare Incident (UNCLASSIFIED)

Hey Axel --

Attached is our letter from the IO regarding the incident reported below. Please let me know if you have any other concerns.

Kind regards,

(b)(6)

-----Original Message-----

From: OLAW Division of Compliance Oversight (NIH/OD) [mailto:olawdco@od.nih.gov]
Sent: Monday, September 10, 2018 6:14 AM
To: (b)(6) LTC USARMY MEDCOM USAMRIID (US); (b)(6)
Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: [Non-DoD Source] RE: USAMRIID Report of Serious Animal Welfare Incident (UNCLASSIFIED)

Thank you for this preliminary report. [REDACTED] We will start a new case file and would like a copy of the final report from the IO after the IACUC has completed its investigation.

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

-----Original Message-----

From: [REDACTED] LTC USARMY MEDCOM USAMRIID (US) [mailto:[REDACTED]]
Sent: Friday, September 07, 2018 4:04 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: [REDACTED] USARMY MEDCOM USAMRIID (US) [REDACTED] [REDACTED] COL
USARMY MEDCOM USAMRIID (US) [REDACTED]
Subject: USAMRIID Report of Serious Animal Welfare Incident (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

Hi all --

This is a new preliminary report of events that took place September 6, 2018. This represents an animal welfare incident (loss of life due to equipment design failure) NOT due to noncompliance.

*Name and contact information of person reporting: LTC [REDACTED], see signature block below for contact information

*Name of institution: US Army Medical Research Institute of Infectious Diseases (USAMRIID)

*Assurance number: D16-00297 (A3473-01)

*Funding component and if contacted (for situations related to PHS-supported activities): DOD funded, not PHS funded.

*Brief description of incident (e.g., species, category of personnel involved, dates, times, animal deaths): On Friday September 7 we received this report from the PI (summarized here): An anesthetized hamster used for mosquito feeding awoke during the feeding and managed to escape from the commercial feeding net located on top of the six foot high mosquito enclosure. For optimal conditions for the mosquitoes, feedings are done in the dark. Vet Med staff conducting the activity were monitoring the hamster's anesthesia every 2-3 minutes, entering the dark room each time to check. On the last check, staff discovered the hamster was out of the feeding net. They located the hamster on the ground. A subsequent physical exam showed the animal has sustained an inoperable fracture of his mandible. The veterinarian on duty euthanized the hamster. The PI confirmed all staff performing activities were trained to do so, and all activities and anesthetic doses were conducted IAW the approved protocol and institute SOPs. This is the first known incident of the feeding net failing to restrain a hamster.

*Plan and schedule for correction and prevention (if known): Despite the company's assertion this feeding net is "escape proof," the animal escaped and sustained injury. The PI plans to order a custom made cover to place over the net, either fabricated from plexiglass or fabric, weighted down so a hamster can't move it. He is submitting a modification to the protocol to cover anesthetic monitoring during the procedure and also update the use of the new cover. The ALT AV has halted mosquito feedings using the current feeding net, but feedings may continue with the hamster placed inside the cage (also approved on the protocol), where there is no risk of falling to the hamster. The IACUC will meet on September 13 to discuss the incident and determine if other remediation is required.

*Timeframe for final report from the Institutional Official: We can provide NLT September 30, 2018. Please advise if you require this report from the IO.

Thanks, all!

Kind regards,

(b)(6)

(b)(6), DVM, MPH, DACLAM

LTC, USA

Deputy Director - Research Support Directorate and USAMRIID IACUC Chair (b)(6)

Mail to:

MCMR UIZ-L/LTC (b)(6)

US Army Medical Research Institute of Infectious Diseases (USAMRIID)

1425 Porter Street

Fort Detrick MD 21702

VM: (b)(6)

FAX:

Email: (b)(6)

CLASSIFICATION: UNCLASSIFIED



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTHFOR 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) 402-7065

December 6, 2018

Re: Animal Welfare Assurance
#A3473-01 (OLAW Case 2P)

Colonel (b)(6)
Deputy Commander
U.S. Army Medical Research Institute
of Infectious Diseases
1425 Porter Street, Bldg. 1425, (b)(6)
Fort Detrick, MD 21702-5011

Dear Colonel (b)(6)

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 30, 2018 letter reporting an incident of noncompliance (AWI # 18-18) with the PHS Policy on the Humane Care and Use of Laboratory Animals at the US Army Medical Research Institute of Infectious Disease. Your letter supplements the information provided in a prompt - preliminary report email on September 19, 2018. According to the information provided it is understood that on 29 September 2018 three mice escaped from a shipping container during receipt and breakdown of the box. Two of the mice were recaptured without issue. The third animal was fatally injured during recapture. It was stated that these animals were not assigned to a PHS-funded activity.

It was determined that no revisions to the relevant SOPs were required at this time. The Veterinary Medical Division will continue to closely monitor the activity.

OLAW believes that the preventive measures in place by the US Army Medical Research Institute of Infectious Disease are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals. Although this activity was not PHS funded, the application of the standards of the PHS Policy across the animal care and use program reduces any potential appearance of a double standard. We appreciate being informed of this unfortunate matter and find no cause for further action by this office.

Sincerely,

(b)(6)

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES
1425 PORTER STREET
FORT DETRICK, MARYLAND 21702-5011

November 30, 2018

Brent C. Morse, M.S., D.V.M.
 Office of Laboratory Animal Welfare (OLAW)
 National Institutes of Health
 Rockledge 1, Suite 360, MSC 7982
 6705 Rockledge Drive
 Bethesda, Maryland 20892-7982

Dear Dr. Morse:

Please reference LTC (b)(6) preliminary report to the OLAW Inbox on September 19, 2018 regarding Animal Welfare Investigation (AWI) #18-18. This incident took place under an Institutional Animal Care and Use Committee (IACUC)-approved animal care and use protocol. Activities on this protocol are not Public Health Service (PHS) funded.

On 19 September 2018, 67 C3H/HeN mice were received by the Veterinary Medical Division (VMD) for the assignment to an approved protocol. During receipt and breakdown of the shipping box, three of the mice jumped out of the transport crate. Two of the mice were immediately captured and were returned to the shipping box without issues. The third one jumped on the technician's lab coat and was fatally injured during recapture. Following the incident the veterinarian was called and confirmed death had occurred by unintentional cervical dislocation.

The VMD reviewed the current relevant standard operating procedures (SOPs) for breakdown of animal shipping crates. Over the last two months, all procedures were reviewed by the Deputy Director, VMD Operations and the Small Animal Veterinarian. No incidents took place for any shipment of mice. At this time, no SOP updates will take place and VMD will continue to monitor the activity closely. The investigators for this study were informed of the incident and a new mouse was ordered to replace the one lost. The IACUC was informed of the incident at the October 11, 2018 full committee meeting.

If you require further information regarding this AWI, please contact LTC (b)(6), USAMRIID IACUC Chair, at (b)(6) or by email at (b)(6). Our Animal Welfare Assurance number is D16-00297 (A3473-01). Please copy LTC (b)(6) on correspondence concerning this report.

Sincerely,

(b)(6)

Colonel, U.S. Army
 Deputy Commander

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, December 04, 2018 3:08 PM
To: (b)(6) LTC USARMY MEDCOM USAMRIID (USA); OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6)
Subject: USARMY MEDCOM USAMRIID (US)
 RE: USAMRIID Report of Serious Animal Welfare Incident

Thank you for this final report Colonel (b)(6). We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
 Director
 Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 National Institutes of Health

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-----Original Message-----

From: (b)(6) LTC USARMY MEDCOM USAMRIID (USA) [mailto:(b)(6)]
Sent: Tuesday, December 04, 2018 2:54 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6); (b)(6)
 USARMY MEDCOM USAMRIID (US); (b)(6)
Subject: RE: USAMRIID Report of Serious Animal Welfare Incident

Hi Brent --

Attached is the letter from the IO summarizing our review of this incident. Please let me know if you have any questions and thanks!

Kind regards,

(b)(6)

-----Original Message-----

From: OLAW Division of Compliance Oversight (NIH/OD) [mailto:olawdco@od.nih.gov]
Sent: Wednesday, October 31, 2018 2:45 PM
To: (b)(6) LTC USARMY MEDCOM USAMRIID (US); (b)(6); OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b)(6) COL USARMY MEDCOM USAMRIID (US); (b)(6); (b)(6)
 USARMY MEDCOM USAMRIID (US); (b)(6)
Subject: [Non-DoD Source] RE: USAMRIID Report of Serious Animal Welfare Incident

Thank you for this update (b)(6). I will add it to the case file and await the final report.

Best regards, Brent

Brent C. Morse, DVM, DACLAM
 Director
 Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 National Institutes of Health

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-----Original Message-----

From: (b)(6) LTC USARMY MEDCOM USAMRIID (US) [mailto:(b)(6)]
 Sent: Wednesday, October 31, 2018 1:48 PM
 To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
 Cc: (b)(6) COL USARMY MEDCOM USAMRIID (US) (b)(6) (b)(6)
 USARMY MEDCOM USAMRIID (US) (b)(6)
 Subject: RE: USAMRIID Report of Serious Animal Welfare Incident

Hi Brent --

This is a just an email update reporting this incident is still under review for appropriate remedial action; we don't have our final report to send to you yet. The Vet Med Division is still discussing appropriate ways to best address repeat issues of this event. We should have our final report to you NLT November 30, 2018, and I'm hoping much sooner than that.

Please let me know if you have any questions and thanks!

Kind regards,

(b)(6)

-----Original Message-----

From: OLAW Division of Compliance Oversight (NIH/OD) [mailto:olawdco@od.nih.gov]
 Sent: Wednesday, September 19, 2018 1:05 PM
 To: (b)(6) LTC USARMY MEDCOM USAMRIID (US) (b)(6) (b)(6); OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
 Cc: (b)(6) S CTR USARMY MEDCOM USAMRIID (US) (b)(6) (b)(6) COL USARMY MEDCOM USAMRIID (US) (b)(6)
 Subject: [Non-DoD Source] RE: USAMRIID Report of Serious Animal Welfare Incident

Thank you for this preliminary report (b)(6). We will open a case file and await further information.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
 Director
 Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 National Institutes of Health

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-----Original Message-----

From: (b)(6) LTC USARMY MEDCOM USAMRIID (US) [mailto:(b)(6)]
 Sent: Wednesday, September 19, 2018 1:00 PM
 To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
 Cc: (b)(6) USARMY MEDCOM USAMRIID (US) (b)(6); (b)(6)
 USARMY MEDCOM USAMRIID (US) (b)(6)
 Subject: USAMRIID Report of Serious Animal Welfare Incident

Hi all --

This is a new preliminary report of events that took place September 19, 2018. This represents an animal welfare incident - loss of life due to lack of awareness and preparation regarding accommodating a unique behavioral feature of the mouse strain (hyperactivity), not accounted for earlier. Loss of life was NOT due to noncompliance.

*Name and contact information of person reporting: LTC (b)(6) see signature block below for contact information

*Name of institution: US Army Medical Research Institute of Infectious Diseases (USAMRIID)

*Assurance number: D16-00297 (A3473-01)

*Funding component and if contacted (for situations related to PHS-supported activities): DOD funded, not PHS funded.

*Brief description of incident (e.g., species, category of personnel involved, dates, times, animal deaths): On 19 September 2018, 67 C3H/HeN mice were received by the Veterinary Medical Division (VMD) for the assignment to an approved protocol. During receipt and breakdown of the shipping box, three of the mice jumped out of the transport crate. Two of the mice were immediately captured and were returned to the shipping box without issues. The third one jumped on the technician's lab coat and was fatally injured during recapture. Following the incident the veterinarian was called and confirmed death had occurred by unintentional cervical dislocation.

*Plan and schedule for correction and prevention (if known): This strain of mice is known to be hyperactive which makes transfers especially difficult. To minimize this type of incident in the future, VMD will review the current relevant standard operating procedures (SOPs). Once SOP(s) are modified, appropriate personnel will be trained. The investigators for this study have been informed of the incident. The protocol will still be able to proceed once a new mouse is ordered. The IACUC will review the incident no later than the next full committee meeting October 11.

*Timeframe for final report from the Institutional Official: We can provide NLT October 31, 2018. Please advise if you require this report from the IO.

Thanks, all!

Kind regards,

(b)(6)

(b)(6) DVM, MPH, DACLAM

LTC, USA

Deputy Director - Research Support Directorate and USAMRIID IACUC Chair (b)(6)

Mail to:

MCMR UIZ-L/LTC (b)(6)

US Army Medical Research Institute of Infectious Diseases (USAMRIID)

1425 Porter Street

Fort Detrick MD 21702

VM: (b)(6)

FAX: (b)(6)

Email: (b)(6)