



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

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

FOR EXPRESS MAIL:

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

December 12, 2019

Re: Animal Welfare Assurance
A4528-01 [OLAW Case 2H]

(b) (6)

Commander
US Army Medical Research Institute of
Chemical Defense
3100 Ricketts Point Road
Aberdeen Proving Ground, MD 21010-5400

Dear (b) (6),

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 18, 2019 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 Chemical Defense.

According to the information provided, OLAW understands that two groups of 80 male mice were ordered on a protocol only approved for female mice. On October 18, 2019, a laboratory technician working with the animals realized she was working with males instead of females after already working with approximately 50 mice. Work was stopped and the investigator and the IACUC was notified. The investigator stated that sex is not an issue when it comes to response to intoxication and there is no reason to believe it will impact antitoxin treatments. The investigator also stated that the spreadsheet used for animal orders defaults automatically to males. This study is supported by PHS funding.

As a corrective measure, the investigator stopped shipments of male mice and submitted a protocol amendment to include male mice on the study that was later approved. The spreadsheet enabling ordering of female mice corrected.

OLAW appreciates the prompt consideration of this matter by US Army Medical Research Institute of Chemical Defense which is consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident and prevent recurrence. We appreciate being informed of this matter and please contact us with any further questions or concerns.

Sincerely,

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



A4528-2H

DEPARTMENT OF THE ARMY
U.S. ARMY MEDICAL RESEARCH INSTITUTE OF CHEMICAL DEFENSE
8350 RICKETTS POINT ROAD
ABERDEEN PROVING GROUND, MD 21010-5400

November 18, 2019

Office of the Commander

Division of Compliance Oversight Office
of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Drive
Suite 2500, MSC 6910
Bethesda, MD 20892

Dear Sir:

Please reference the Office of Laboratory Animal Welfare Assurance number D16-00776. The incident described below occurred on a protocol funded by the National Institutes of Health, grant #5R01AI125704.

ANIMAL WELFARE CONCERN. Two groups of 80 male mice each were ordered for a protocol which was approved for only female mice. The study was conducted on the first group of 80 male mice on October 18, 2019, by a laboratory technician who was approximately 50 mice into the study when she realized she was working with males instead of females. She immediately stopped work and alerted the investigator. The laboratory manager notified the Institutional Animal Care and Use Committee (IACUC) of the mix-up the next business day. The investigator stated that the spreadsheet they use for animal orders defaults to males. The investigator stated that sex is not an issue when it comes to response to intoxication. There is no reason to believe it will impact antitoxin treatments.

CORRECTIVE ACTION. Upon discovery and notification the investigator stopped the future shipments of male mice and submitted a protocol amendment to include males. They have corrected their spreadsheet to order females going forward and have also received approval to use both sexes. Therefore, this error should not be repeated.

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Since this was a failure to adhere to the IACUC approved protocol and it is funded by the National Institutes of Health, the IACUC determined it needed to be reported to the Office of Laboratory Animal Welfare.

My point of contact for this matter is (b) (6), our IACUC Chairman, at
(b) (6)

Sincerely,

(b) (6)

Institutional Official/Commanding

cc:

U.S. Army Medical Research and Development Command, Animal Care and Use
Review Office
AAALAC, International

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, November 20, 2019 8:13 AM
To: USARMY APG MEDCOM USAMRICD Mailbox IACUC
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: OLAW Assurance # D16-00776

Thank you for this report, (b) (6). We will respond soon.

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

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

From: USARMY APG MEDCOM USAMRICD (b) (6)
Sent: Tuesday, November 19, 2019 5:14 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: USARMY APG MEDCOM USAMRICD (b) (6)
Subject: OLAW Assurance # D16-00776

Please find attached a recent noncompliance found on a NIH funded protocol and the corrective actions taken.

Regards,

(b) (6)
IACUC Chair/Statistician
USAMRICD
8350 Ricketts Point Rd.
APG, MD 21010

(b) (6)