



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

July 1, 2019

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

(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 June 19, 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 seventeen rats were given a lower dose of an anesthetic drug than described in the protocol. The lower dose was used to better meet the scientific goals of the study involving neuroprotection.

The corrective action consisted of amending the protocol.

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.

Sincerely,

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

cc: IACUC Chair



A4528-2G

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

June 19, 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 #AOD18013-001-00000.

ANIMAL WELFARE CONCERN. During a recent review of a publication, our Institutional Animal Care and Use Committee (IACUC) Chair discovered that an investigator added a new dose of midazolam without prior approval of the IACUC. The investigator added 1 mg/kg dose due to the overwhelmingly protective effect of 3 mg/kg midazolam in histopathology and survival studies. Seventeen rats received the 1 mg/kg dose of midazolam. The investigator stated that decreasing the amount of midazolam would allow other neuroprotective pathways to be revealed by manipulation with specific CBR modulators.

CORRECTIVE ACTION. Upon discovery, the investigator immediately submitted an amendment to the IACUC for review and approval.

Since this addition of a dose group was a protocol noncompliance on a protocol 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 Institutional Animal Care and Use Committee 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
Association for the Assessment and Accreditation of Laboratory Animal Care,
International

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, June 27, 2019 6:58 AM
To: (b) (6) USARMY MEDCOM USAMRICD (USA)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: USAMRICD Noncompliance Letters (Assurance #D16-00776)

Thank you for these reports, (b) (6) We will respond soon.

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

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

From: (b) (6) USARMY MEDCOM USAMRICD (USA) <(b) (6)>
Sent: Wednesday, June 26, 2019 1:24 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: USAMRICD Noncompliance Letters (Assurance #D16-00776)

Good afternoon.

Attached are two letters of non-compliances that were recently reported to our IACUC office.

If you have any questions on this please contact (b) (6) (b) (6)

Thank you.

(b) (6)

(b) (6)

IACUC Coordinator
8350 Ricketts Point Road

(b) (6)

Aberdeen Proving Ground, MD 21010-5400

(b) (6)