



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

June 6, 2019

Re: Animal Welfare Assurance
A3114-01 [OLAW Case 4H]

Dr. Rebecca Cunningham
Vice President for Research and
Institutional Official
University of Michigan
(b) (4) Victor Vaughan Building
1111 Catherine Street
Ann Arbor, MI 48109-2054

Dear Dr. Cunningham,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 21, 2019 letter responding to my May 28, 2019 request for information regarding a whistleblower complaint alleging unsafe use of chemicals in mice at the University of Michigan. According to the information provided, OLAW understands the following:

- The message to OLAW and the University of Michigan Animal Care and Use Office was made by an individual using the alias (b) (6). The real (b) (6) had not made the reports.
- Campus police investigated and determined that someone else had submitted the reports under the alias.
- The Institutional Animal Care and Use Committee (IACUC) investigated to determine if a toxic chemotherapeutic drug was being used.
- Use of the drug was confirmed and cages containing mice that had been given the drug were isolated in a chemical containment facility and the Environmental Health and Safety Office (EHS) was notified.
- EHS determined that seven mice had received the drug at a very low dose which posed no human risk. Animal care staff was wearing personal protective equipment which further reduced any risk to humans.
- The complainant was notified by email that the matter had been resolved and that the IACUC would be glad to meet with him but there was no further comment.
- The Principal Investigator was counseled to ensure that all safety practices are followed, something which had not always been done as required.
- The laboratory will be subject to post-approval monitoring visits to confirm compliance.

Based on its assessment of this explanation, OLAW has a better understanding of the facts surrounding the complaint. OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. Because the complainant has been informed of the outcome and has not made any additional complaints, OLAW will not attempt to inform him of the findings. Thank you for your prompt and thorough response.

Sincerely,

(b) (6)

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

cc: IACUC Chair
Director Animal Care and Use Office



INSTITUTIONAL ANIMAL CARE & USE COMMITTEE

UNIVERSITY OF MICHIGAN

June 21, 2019

Axel Wolff, MS, DVM
Deputy Director, Office of the Director
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health (NIH)
BG 6700B Rm 2528
6700B Rockledge Drive
Bethesda, MD 20817

Dear Dr. Wolff:

The University of Michigan (U-M), in accordance with Assurance D16-00072 and the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy), provides this follow-up report with reference to an email sent from an anonymous individual with the alias of (b) (6) to OLAW on May 14, 2019.

On May 2, 2019, the IACUC received through the Animal Care and Use Office (ACUO) an email from (b) (6) Believing (b) (6) was a known University of Michigan laboratory technician, the IACUC contacted him to discuss the matter and learned he did not make the report. As a result, the matter was investigated through police services, and it was discovered that an unknown individual established a Gmail account using the name (b) (6) to make the report. Nevertheless, the IACUC considered the matter serious and conducted an investigation.

The report alleged a toxic dose of a chemotherapeutic drug (Docetaxel) was used in a manner that would negatively affect the health of laboratory technicians and animals housed in close proximity to treated animals. The email stated the allegation was confirmed through lab results, but tests were never conducted. The IACUC took the following steps: 1) the Attending Veterinarian (AV) was notified and the affected cages of animals were immediately moved to a chemical containment facility; and 2) a member of the Environmental Health and Safety Office was notified to assess the circumstances.

The risk assessment conducted by the EHS Manager was extremely thorough. In summary, the dose of Docetaxel was an insignificant human dose and administered to seven mice as a 100 uL subcutaneous injection. In addition, it was noted that the risk of exposure was even further mitigated since animal handlers use gloves and gowns as standard forms of personal protective equipment (PPE), which would prevent direct skin contact.

On May 3, 2019, (b) (6) was thanked for providing the report, and he was informed that the IACUC, the AV and EHS worked together and immediately resolve the issue. Members of the IACUC offered to meet with him directly. The committee considered the immediate concern resolved.

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acuoffice@umich.edu

On May 7, 2019, (b) (6) emailed the IACUC and asked if the animal rooms were safe to use. The IACUC reaffirmed the matter was resolved.

On May 14, 2019, (b) (6) again emailed the IACUC and copied OLAW. The U-M IACUC responded to (b) (6) by saying, *"Thank you for your note. We have assessed the issue, and it has been resolved. I extend to you for the second time the opportunity to meet to discuss the matter and any concerns."* Since that correspondence, (b) (6) has not emailed the IACUC.

The IACUC also communicated directly with the principal investigator (PI), and noted that animal activities were conducted under her supervision without total adherence to the required safety precautions. The IACUC asked that she stress the importance of maintaining a compliant quality and safe program to the members of her research team. In addition, members of the Quality Assurance team were tasked with performing follow up inspections of her lab to ensure the required standards are followed.

The University of Michigan is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance by OLAW in this regard. Should you have any questions regarding this report, please contact William G. Greer (wggreer@umich.edu; (b) (6)).

Sincerely,
(b) (6)

Rebecca Cunningham
IO and Vice President for Research

Cc: William Greer, Assistance Vice President for Research and Director of ACUO
Daniel D. Myers, Jr., DVM, MPH, DACLAM, IACUC Chair
William King, Assistant Vice President for Research and Attending Veterinarian
AAALAC International

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, June 27, 2019 7:07 AM
To: Greer, William
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: OLAW - Chemo Drug Use-6.21.19.pdf

Thanks for this report, Bill. I'll send a response soon.
Axel

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

From: Greer, William <wggreer@med.umich.edu>
Sent: Wednesday, June 26, 2019 3:23 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) <wggreer@umich.edu>; King, Bill <wwking@med.umich.edu>; Myers, Daniel <ddmyers@med.umich.edu>
Subject: OLAW - Chemo Drug Use-6.21.19.pdf

Good afternoon Axel,

Please find attached the formal report regarding the (b) (6) report you received on the use of Chemo-Drugs at U-M.

Best regards,

Bill

Electronic Mail is not secure, may not be read every day, and should not be used for urgent or sensitive issues



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May 28, 2019

Re: Animal Welfare Assurance
A3114-01 [OLAW Case 4H]

Dr. S. Jack Hu
Vice President for Research, and
University of Michigan
(b) (4) Victor Vaughan Building
1111 Catherine Street
Ann Arbor, MI 48109-2054

Dear Dr. Hu,

The Office of Laboratory Animal Welfare (OLAW) has received two notices (May 2, 14, 2019) from (b) (6) at the University of Michigan alleging unsafe use of a chemical in mice. Specifically, staff in the (b) (6) laboratory were using Docetaxel in a regular animal housing room (NCRC Building 36, (b) (4)). The complainant stated that using the drug in this room jeopardizes the health of other staff members.

Please instruct the Institutional Animal Care and Use Committee, avoiding any conflicts of interest, to determine whether any protocol or chemical safety violations have occurred. If any deficiencies are identified, please provide reasonable and specific corrective and preventive actions. Please provide the requested information by **June 28, 2019**. Feel free to contact me should you have any questions.

Sincerely,

(b) (6)

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

cc: IACUC Chair
Director Animal Care and Use Office

Wolff, Axel (NIH/OD) [E]

A3114-4H

From: Ward, Joan (NIH/OD) [E] on behalf of Laboratory Animal Welfare, Office of (NIH/OD)
Sent: Wednesday, May 15, 2019 9:12 AM
To: Wolff, Axel (NIH/OD) [E]
Subject: FW: Report Animal Concerns

FYI: I checked back to see if we had a prior e-mail and could not find one.

From: (b) (6)
Sent: Tuesday, May 14, 2019 8:42 AM
To: acuoffice@umich.edu; attending-veterinarian@umich.edu; animal-io@umich.edu; compliancehotline@umich.edu; wggreer@umich.edu; Jack Hu <jackhu@umich.edu>; (b) (6) Laboratory Animal Welfare, Office of (NIH/OD) <OLAW@OD.NIH.GOV>
Subject: Re: Report Animal Concerns

Dear all,

This is the third week that I am waiting for your update to make us sure that we are safe in our working place. However, It seems that ULAM tries to cover this serious issue due to the probably some relation. So, I email you again before bringing this to the public to take action, check all the staff and student that worked in the chemo drug contaminated room. Also, I highly recommend suspending the animal protocol of the lab, due to placing other students and staffs in health issue and carelessness of them about public health.

Thanks

(b) (6)

On Thu, May 2, 2019 at 9:30 AM (b) (6) wrote:

Dear all,

Last Tuesday during my usual animal care, I found one of the (b) (6) lab members using the chemical compound in the regular animal housing room as she explained her study to other lab members (perhaps protocol number 8192, 200A, H-N. 2 to 3). At first, I was not sure, but during this weekend after finding some unusual/dead mice, I asked one of my vet friends, to check the mice, and she found that they affected by chemo drug (Docetaxel) and today I received Lab results. The ULAM policy stated that all the chemical and drug specifically chemo drug should not use in regular animal housing room. This is not safe, jeopardize other lab experiments and affect the health of other users of NCRC-Building 36- (b) (4)

I believe that this happened without ULAM permission. So, I email you to inform you and ask you to take action, check all the mice in (b) (4) and maybe euthanize contaminated mice. Also, I highly recommend you test your staffs and students, specifically pregnant, to make sure that they do not affect.

In the case of the student/students, if she/ they did this without her/their supervisor approval, she/they should suspend from the animal protocol, due to placing other students and staffs in health issue. Also, if this happened by supervisor approval, then this is the ULAM job to check with the protocol supervisor to avoid such a serious issue in the future.

Thanks,

(b) (6)