



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

July 12, 2018

Re: Animal Welfare Assurance
A3338-01 [OLAW Case P]

Dr. Vittorio Gallo
Chief Research Officer and Scientific Director
Children's National Medical Center
111 Michigan Avenue NW
Washington, DC 20010

Dear Dr. Gallo,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 9, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Children's National Medical Center. According to the information provided, it is understood that on April 19, 2018 your institution became aware that a PI had used a greater number of mice than that for which the protocol was approved. The number of extra mice was not noted. It was not noted if this activity was funded by the PHS.

Corrective actions included informing the Principal Investigator to submit a protocol modification to increase the animal numbers for the protocol. In addition, a letter of reprimand was sent to the PI requiring a response to be reviewed by the IACUC. The response was reviewed by the IACUC and one member requested additional actions. A primary member on the protocol was invited to the next IACUC meeting to address these concerns regarding the disposition of excess animals on the protocol and informed the committee that the numbers of animals that would be slated for euthanasia due to wrong genotype were significantly lower than had been expected by the IACUC. Further requirements by the committee included: a report to the IACUC every 6 months for one year stating the number of animals euthanized and the reason for euthanasia; a meeting with the RAF Director within 14 days to review breeder logs to confirm animal waste is kept to a minimum, and; the PI will provide excess animals to the RAF for transfer to the RAF training protocol whenever possible.

The prompt consideration of this matter by the Children's National Medical Center was consistent with the philosophy of institutional self-regulation. Similarly, the actions taken to resolve the issue and prevent recurrence were appropriate. For future reports, please include if the activity was PHS or NSF funded and the approximate animal numbers involved. We appreciate being informed of this 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

(b) (6)



July 09, 2018

Re: Assurance D16-00219 (A3338-01)

Brent Morse, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Dear Dr. Morse:

In accordance with the Guidance on prompt reporting to OLAW under IV.F.3 of the PHS Policy and as the Institutional Official representing the Children's National Medical Center (CNMC), I respectfully submit this letter regarding a recent incident requiring investigation by the CNMC IACUC. Please note that this institution is self-reporting the events that transpired, as well as the actions that we have taken to rectify the problem and to prevent its recurrence.

The investigation was related to a greater number of mice being used than the protocol was approved for.

The IACUC followed the CNMC IACUC Policy, "Investigating and Reporting Animal Care and Use Concerns by the IACUC" regarding the investigation, and the issues surrounding the investigation were as follows:

- 4/19/18 The IACUC Office received an automated Protocol Usage e-mail from the protocol management system alerting them that a greater number of mice were used than the protocol was approved for.
- 4/20/18 The IACUC Office sent an e-mail to the PI requesting clarification of the animal numbers in the automated Protocol Usage e-mail. The PI responded the same day confirming the overage and provided an explanation and factors that contributed to their lab using more mice than they were initially approved for.
- 4/23/18 The IACUC Chair reviewed the response e-mail and determined that; no further investigation was required at this time, the response would be sent to the IACUC members for review and discussion at the May monthly IACUC meeting. An e-mail was sent to the PI notifying him that the issue would be discussed at the next monthly meeting in May 2018 along with a request for an amendment to increase animal numbers to be submitted to the IACUC immediately for review. The IACUC notified the IO about the investigation and that the issue would be discussed at the next IACUC meeting.
- 4/27/18 Amendment submitted by PI to increase animal numbers along with scientific justification for the increase.

- 5/10/18 The Chair convened the monthly meeting of the IACUC which included a review and discussion of the outcome of the investigation. Following a thorough discussion at the IACUC meeting, the members agreed that although no animals were harmed, the researchers showed a lack of adherence to the approved protocol and implemented a significant change in animal (mouse) numbers without prior IACUC approval. Therefore, the members decided that the incident was reportable to OLAW and a letter of reprimand would be sent to the PI, requiring that the PI provide a written response regarding: details for reason of overage and difficulties breeding, along with their success rate; explanation if all animals that were bred would be used. The PI's response would be reviewed by the members. If the members were satisfied by the PI's response, the report to OLAW would be sent. If the members had further comments/concerns, the matter would return to the next convened meeting of a quorum for further discussion and decisions.
- 05/14/18 The letter of reprimand was sent to the PI and a response was required.
- 05/16/18 The PI responded and addressed the two issues presented by the IACUC. The PI's response was sent to the IACUC members for review. The IACUC Office also requested confirmation from all IACUC members that the PI's response was satisfactory and no additional actions were recommended.
- 5/22/18 A committee member requested two additional actions to be recommended to the PI. Due to Children's policy, the additional recommended actions required a full vote so this was placed on the agenda for the following month's meeting in June 2018.
- 5/29/2018 The modification to increase animal numbers received final approval after DMR following FCR.
- 6/14/2018 The Chair convened the monthly meeting of the IACUC which included a review and discussion of the additional actions recommended by a committee member. The Chair asked the Regulatory Specialist to present an update regarding the incident involving an unapproved animal overage. The Regulatory Specialist reported that the Modification that the PI had submitted related to the overage matter had been approved by the IACUC. Also, the PI had addressed in writing the issues presented by the IACUC in the letter of reprimand. Following the review by the members of the PI's response to the letter of reprimand, one of the members still had concerns about the number of animals that might be euthanized and not used for experiments. The IACUC invited a primary researcher on the protocol to come to the meeting and address the members regarding numbers of animals in the protocol and to answer several questions/concerns including the concern of excessive numbers of unused animals being euthanized. The members learned from the researcher that the numbers of animals that would be slated for euthanasia due to wrong genotype, without being used for experiments, were significantly lower than the number that had been expected by the IACUC. After the researcher left the meeting, the members determined that additional actions would be required from the PI; an e-mail requiring a response would be sent to the PI requiring that the following be addressed:



- i. The number of animals euthanized and the reason for euthanasia must be reported to the IACUC every 6 months for a year (1st report due 6 months from date of the e-mail for two reports total)
- ii. Within 14 days of the date of the e-mail, the PI or PI's designee must meet with the RAF Director to review breeder logs to confirm animal waste is kept to a minimum
- iii. The PI will provide excess animals to the RAF for transfer to the RAF "Training in Current Biotechnology" protocol whenever possible

6/18/2018 A follow up e-mail was sent to the PI with the additional actions required.

6/29/2018 The PI responded, acknowledging the requirements that had to be met. The IACUC Chair verified that the PI had addressed all of the IACUC's requirements.

7/09/2018 The IACUC notified the PI that the IACUC's requirements had been addressed and accepted, so the investigation was completed.

Please accept this report as an indication of our institution's commitment to comply with all PHS policies and regulations on research animal care and to ensure that situations affecting research animal welfare are deliberately addressed and corrected.

Sincerely,

(b) (6)

Vittorio Gallo, PhD
Chief Research Officer, CNHS
Scientific Director, CRI Institutional Official, IACUC

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Cc: (b) (6)
Chair, IACUC

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, July 10, 2018 8:35 AM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b) (6) Gallo, Vittorio; (b) (6)
Subject: RE: Assurance D16-00219 (A3338-01)

Thank you for providing this 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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From: (b) (6)@childrensnational.org]
Sent: Tuesday, July 10, 2018 8:23 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)@childrensnational.org>; Gallo, Vittorio <VGallo@childrensnational.org>; (b) (6)
(b) (6)@childrensnational.org>
Subject: Assurance D16-00219 (A3338-01)

Dear Dr. Morse,

This e-mail is regarding a recent internal investigation of possible non-compliance in the Children's Research Institute of the Children's National Medical Center.
Please find an attached letter of self-reporting from the Institutional Official.

Thank you,

(b) (6)

