



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR 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

January 5, 2018

Re: Animal Welfare Assurance
A3148-01 [OLAW Case A]

Dr. Margot LaPointe
Vice President for Research
Henry Ford Health System
Research Administration, 2F86
1 Ford Place
Detroit, MI 48202

Dear Dr. LaPointe,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 22, 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Henry Ford Medical Group, following up on an initial report on October 2, 2017. According to the information provided, OLAW understands that several live neonatal mice were found in the carcass cooler room due to a failure to ensure death with a secondary physical method of euthanasia following exposure to CO₂.

The immediate action taken upon discovery consisted of appropriately euthanizing the mice. The laboratory staff was directed not to conduct further euthanasia until retraining was completed. The Principal Investigator and the laboratory staff were retrained on euthanasia procedures and evaluated for proficiency. Additional training was taken, the laboratory was placed under enhanced post-approval monitoring, and no further problems were identified. Ongoing training in euthanasia will be provided to current and new staff.

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 having been informed about this matter and find no cause for further action by this Office.

Sincerely,

Signature

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

cc: IACUC Chair



HENRY FORD MEDICAL GROUP

Margot C. LaPointe, Ph.D.

Vice President for Research
Henry Ford Hospital/HFHS
Department of Research Administration - OFP-2F86
1 Ford Place
Detroit, MI 48202

December 22, 2017

Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360
6705 Rockledge Drive
Bethesda, MD 20892

To Whom It May Concern:

The Henry Ford Health System (HFHS), in accordance with Assurance D16-00090 (A3148-01) and PHS Policy IV.F.3., provides this report of noncompliance regarding an incident of improper euthanasia of neonatal mice pertaining to grants R01AI119041-02 and R01AR069681-02. This incident was initially sent as a preliminary report submitted to Dr. Brent Morse, OLAW, on October 3rd, 2017 via e-mail by [REDACTED] IACUC Administrator and Pamela Harding, PhD, IACUC Chair.

On Thursday, 21 September 2017, a bag of improperly euthanized neonatal mice was found in the refrigerated disposal room at One Ford Place by Bioresources technical staff. Several of these mice were conscious and in a distressed state. The Bioresources technicians immediately examined all of the mice in the bag and humanely euthanized those that were conscious. Bioresources technical staff also alerted the Bioresources Supervisor, who immediately reached out to the PI to notify him of the concern and re-issued the IACUC policy manual, which includes the policy on euthanasia. Additionally, the PI and all of his staff were informed that euthanasia retraining was immediately required.

On Sept 22, the incident was reported to the IACUC and an IACUC subcommittee was formed (consisting of the AV, Chair, Vice-Chair, Scientist Member and Coordinator) and met on 9/27. This subcommittee determined that the incident should be reported as a noncompliant event to the Office of Laboratory Animal Welfare (OLAW) at the NIH, and to inform the PI that recurrence could lead to the suspension of all of the PI's approved protocols. The PI was immediately informed by the IACUC that there was a temporary halt of euthanasia performed by all staff members in the laboratory until everyone was retrained and the investigation completed. The PI and his staff were informed that if euthanasia was needed before this training could commence, Bioresources and/or a Bioresources technician should be notified to complete the task.



On Sept 28th, the PI and all members of his laboratory were retrained in all aspects of rodent euthanasia, with specific emphasis placed on the use of CO₂ followed by decapitation (neonate) and cervical dislocation and/or induced pneumothorax (post weanling) as appropriate secondary methods to assure death. The PI and each member of his laboratory attended the training and demonstrated proficiency in CO₂ euthanasia followed by the above mentioned secondary methods. This training session was conducted and documented by the Bioresources Supervisor and the AV.

An urgent full board constituted IACUC meeting was convened on September 28th, 2017, and at this time the subcommittee informed the rest of the IACUC committee of the animal welfare concern and the IACUC committee voted to report the event to OLAW.

While the IACUC was aware that this situation was resolved immediately and all of the PI's staff were retrained in appropriate euthanasia by September 28th, 2017, to avoid any further incidents, the committee required the following items to be completed by PI/staff:

- 1) Repeat Citi Training ("Working with Mice in Research" module). PI and all lab personnel must complete by October 6th, 2017.
- 2) Evaluate all of the PI's approved IACUC protocols via the IACUC's Post Approval Monitoring (PAM) program for the duration of the protocols.

PI and staff completed all required training by September 28th and records were documented and on file with Bioresources and the IACUC.

Post-Approval-Monitoring was completed on November 16th and December 19th, 2017. Individuals from the IACUC (including the AV) performed PAM visits at the One Ford Place location including the PI's laboratory and breeding room. Procedures observed included: CO₂ euthanasia of 1-6 week old mice; Decapitation after CO₂ euthanasia of 1 week old mice; and harvesting of the thymus of 5-6 week old mice.

Throughout the procedures, two dermatology staff members explained the procedure of euthanasia and decapitation of the young pups including proper flow rate, procedures of checking for cessation of breathing/heartbeat, decapitation with scissors, secondary method of euthanasia, and disposal of carcasses. Following the procedural demonstration, the PI's breeding and research holding colonies of mice were examined.

Both Post-Approval Monitoring visits went very well. The proper use of CO₂ as a primary method of euthanasia was demonstrated, as was the proper secondary method (decapitation for neonates and induced pneumothorax or cervical dislocation of weanlings). All of the procedures were carried out precisely as described in the protocol, and we did not observe any off-protocol work. Additionally, the procedures were performed professionally and met all of the applicable humane care standards.



A post-letter was submitted to the PI with the summary of the PAM and recommendations and reminders were provided to continue to follow our policies of care as referred to the *Guide*.

A review of billing records showed that all costs with the procurement, care, and use of the PI's animals were not directly associated with PHS supported activities.

Within this 3 month discovery period, the IACUC continued to meet monthly (October 6th, November 1st and December 8th) and updates were provided and discussed on every agenda. The committee accepted following each discussion that the PI has continued to adequately address all corrective actions and that this was an isolated incident that required re-training. Going forward, the IACUC in conjunction with the Bioresources department will continue to provide training opportunities on euthanasia, specific to the use of CO₂ for rodents with appropriate secondary methods, to current staff and new hires to prevent any further incidents and improve the program of animal care at HFHS.

HFHS is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact, Pamela Harding, PhD, IACUC Chair at phardin1@hfhs.org or the IACUC Coordinator at iacuc@hfhs.org

Thank you for your consideration of this matter.

Sincerely,

Signature

Margot C. LaPointe, Ph.D.
Vice President for Research / Institutional Official
Henry Ford Health System



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Phone Number
Phone Number
Phone Number

Email: mlapoin1@hfhs.org

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Research Administration
One Ford Place- 2F
Detroit, MI 48202-2689
(313) 874-4464 Office

October 2, 2017

Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360
6705 Rockledge Drive
Bethesda, MD 20892

To Whom it May Concern:

The Henry Ford Health System (HFHS), in accordance with Assurance D16-00090 (A3148-01) and PHS Policy IV.F.3., provides this preliminary report of noncompliance regarding an incident of improper euthanasia in mice pertaining to grants R01A1119041-02 and R01AR069681-02. This incident was reported to the IACUC on September 22nd, 2017 by Bioresources staff.

On Thursday, 21 September 2017, a bag of improperly euthanized neonatal mice was found in the refrigerated disposal room at One Ford Place by Bioresources technical staff. Several of these mice were conscious and in a distressed state. The Bioresources technicians immediately examined all of the mice in the bag and humanely euthanized those that were conscious and noted that several had been cannibalized. Bioresources technical staff also alerted the Bioresources Supervisor, who immediately reached out to the PI to notify him of the concern and re-issued the IACUC policy manual, which includes the policy on euthanasia. Additionally, the PI and all of his staff were informed that euthanasia retraining was immediately required.

On Sept 22, the incident was reported to the IACUC and an IACUC subcommittee was formed and met on 9/27. This subcommittee determined that the incident should be reported as a noncompliant event to the Office of Laboratory Animal Welfare at the NIH, and to inform the PI that recurrence could lead to the suspension of all of the PI's approved protocols. At this time, the PI was informed by the IACUC that there was a temporary halt of euthanasia performed by all staff members in the laboratory until everyone was retrained and the investigation completed. The PI and his staff were informed that if euthanasia was needed this time, Bioresources and/or a Bioresources technician should be notified.

An urgent full board constituted IACUC meeting was convened on September 28th, 2017 and at this time the subcommittee informed the rest of the IACUC committee of the animal welfare concern and the IACUC committee voted to report the event to OLAW.

While the IACUC was aware that this situation was resolved immediately and all of the PI's staff were retrained in appropriate euthanasia by September 28th, 2017, to avoid any further incidents, the committee required the following items to be completed by PI/staff:

- 1) Repeat Citi Training ("Working with Mice in Research" module). PI and all lab personnel must complete by October 6th, 2017.
- 2) Evaluate all of the PI's approved IACUC protocols via the IACUC's Post Approval Monitoring (PAM) program for the duration of the protocols.

In 3 months, the subcommittee will reconvene to evaluate that compliance has been assured and all responsibilities under the PI's protocols are being met. At this time, a final report will be provided by Henry Ford's Institutional Official, Dr. Margot C. LaPointe. HFHS is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact me at pardin1@hfhs.org or the IACUC Coordinator at iacuc@hfhs.org

Sincerely,
Pamela Harding, Ph.D. Chair, IACUC
Cc: Margot C. LaPointe, Ph.D. Vice President for Research / Institutional Official

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, October 03, 2017 9:20 AM
To: Secondary Individual OLAW Division of Compliance Oversight (NIH/OD)
Cc: LaPointe, Margot; Harding, Pamela; Secondary Individual; Secondary Individual
Subject: RE: Preliminary Report_HFHS

Thank you for sending this preliminary report. We will open a case file and await the final report after the subcommittee has evaluated the compliance with the corrective measures in three months.

Sincerely, 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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From: Secondary Individual [mailto:Secondary Individual@hfhs.org]
Sent: Monday, October 02, 2017 4:11 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: LaPointe, Margot <MLaPoin1@hfhs.org>; Harding, Pamela <PHARDIN1@hfhs.org>; Secondary Individual
Secondary Individual@hfhs.org; Secondary Individual @hfhs.org
Subject: Preliminary Report_HFHS

Hello,

The Henry Ford Health System (HFHS), in accordance with Assurance D16-00090 (A3148-01) and PHS Policy IV.F.3. provides the attached preliminary report of noncompliance. HFHS is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact the Chair, Dr. Pamela Harding, at phardin1@hfhs.org or the IACUC Coordinator at iacuc@hfhs.org

Thank you.

Sincerely,

Secondary Individual

IACUC Compliance

T: Phone Number

Research Administration 2F
Henry Ford Health System
1 Ford Place



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