



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) 480-3387

April 10, 2020

Re: Animal Welfare Assurance
#A3187-01 [OLAW Case 8W]

Mr. George A. Huber
Vice Chancellor for Research Conduct and Compliance
University of Pittsburgh
(b) (4) Hieber Building
3500 Fifth Avenue
Pittsburgh, PA 15213

Dear Mr. Huber,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 3, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Pittsburgh. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the University of Pittsburgh Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: the conduct of animal-related activities without appropriate IACUC review and approval and animals with no access to water. The final report states that the incident was reviewed at the February 17, 2020 IACUC meeting. The incident involved 6 cages of mice found to be without access to water. Investigative results revealed the mice were being water restricted overnight, which was not included on the protocol. The IACUC reviewed and accepted the investigator's corrective actions as the following:

- The investigator submitted an IACUC modification that outlines the experimental rationale and duration of water restriction.
- The investigator will review the IACUC protocol with all members of the lab before any further animal work is carried out, and with any students or new members of the lab as part of their orientation.
- The investigator will require all personnel to double check IACUC protocols before ordering any animals for future experiments.

The IACUC levied the following sanctions:

- The investigator was reminded that data collected from studies involving off-protocol work represents work not approved by the IACUC and cannot be used in public presentations or publications without disclosing the lack of IACUC approval. The investigator was also informed that NIH funds cannot be used to pay for animal-related charges associated with off-protocol work.

It is noted that the research is supported by PHS funds. Based on its assessment of this explanation, OLAW understands that the University of Pittsburgh has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy. We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

(b) (6)

Jacquelyn T. Tubbs, DVM
Veterinary Medical Officer
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



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Telephone: (301) 496-7163
Facsimile: (301) 480-3387

April 10, 2020

Re: Animal Welfare Assurance
#A3187-01 [OLAW Case 8Y]

Mr. George A. Huber
Vice Chancellor for Research Conduct and Compliance
University of Pittsburgh
(b) (4) Hieber Building
3500 Fifth Avenue
Pittsburgh, PA 15213

Dear Mr. Huber,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 3, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Pittsburgh. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the University of Pittsburgh Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: an incident that jeopardized the health and well-being of animals resulting in harm and death to animals. The final report states on December 15, 2019 a mouse cage (referred to as a "box") from an auto water rack was found mistakenly placed on a rack labeled as a manual water bottle rack by a member of the investigator's lab following room change on December 12th. A water bottle was not provided, and the cage contained one surviving and one dead adult mouse.

The IACUC reviewed the incident at the February 17, 2020 meeting. The committee reviewed and accepted the investigator's corrective action plan and the animal facility director's summary of preventative actions, they include the following:

- The animal care technician was retrained on daily husbandry checks.
- The investigator and lab members will pay closer attention to animal rack designations in the housing room.
- Every newly created cage that is to be placed in the manual supply rack will be double checked for the presence of a water bottle.
- Members of the lab will be briefed on this incident and will be urged to implement additional measures to ensure the well-being of the research animals.

The IACUC also levied the following sanctions:

A letter of reprimand was sent to the investigator, the Director of the animal care program, and their supervisors regarding this event.

It is noted that these animals were involved in PHS supported animal activities. Based on its assessment of this explanation, OLAW understands that the University of Pittsburgh has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy. We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

(b) (6)

Jacquelyn T. Tubbs, DVM
Veterinary Medical Officer
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



DEPARTMENT OF HEALTH & HUMAN SERVICES

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FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

August 25, 2021

Re: Animal Welfare Assurance
#A3187-01 [OLAW Case 9M]

Dr. Bill Yates
Interim Vice Chancellor for Research Protections
University of Pittsburgh
(b) (4) Hieber Building
3500 Fifth Avenue
Pittsburgh, PA 15213

Dear Dr. Yates,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 23, 2021 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at the University of Pittsburgh. According to the information provided, OLAW understands that two mice died due to lack of food. The food hopper had not been filled when the animals were weaned by a postdoctoral fellow. The animal caretaker could not see the mice during the daily health check because they were hidden behind the food hopper.

The corrective actions consisted of retraining the postdoctoral fellow responsible on weaning procedures and this individual will check each cage for the presence of food before leaving the animal facility. To prevent a recurrence, the food hopper will now be pre-filled with food and left in the hood where cages are processed for weaning. A letter of reprimand was issued to the investigator and supervisor.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to reduce the likelihood of a recurrence. OLAW concurs with the actions taken by the institution to comply with the PHS Policy.

Sincerely,

(b) (6)

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

cc: IACUC Chair



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6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

August 25, 2021

Re: Animal Welfare Assurance
#A3187-01 [OLAW Case 9N]

Dr. Bill Yates
Interim Vice Chancellor for Research Protections
University of Pittsburgh
(b) (4) Hieber Building
3500 Fifth Avenue
Pittsburgh, PA 15213

Dear Dr. Yates,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 23, 2021 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at the University of Pittsburgh. According to the information provided, OLAW understands that three of four mice died due to lack of water. The cage had been provided with a full water bottle, the mice drank the water, but the animal care staff failed to notice that it had become empty.

The immediate action taken upon discovery consisted of providing hydrogel to the surviving mouse, which subsequently recovered. The corrective actions consisted of retraining the animal caretakers on providing food/water and on conducting daily health checks appropriately. A letter of reprimand was sent to the Division of Laboratory Animal Resources Director and their supervisor.

Based on its assessment of this explanation, OLAW understands that corrective actions were taken in this situation. While OLAW concurs with the actions taken by the institution, this Office is concerned that the initial as well as the redundant health checks failed. Ongoing vigilance is imperative to prevent animals from dying due to preventable incidents of lack of food/water. Please continue to aggressively enforce the provision of food/water as well as vigilance by all staff to ensure animal welfare.

Sincerely,

(b) (6)

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

cc: IACUC Chair



DEPARTMENT OF HEALTH & HUMAN SERVICES

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FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

January 14, 2022

Re: Animal Welfare Assurance
#A3187-01 [OLAW Case 9P]

Dr. Bill Yates
Acting Vice Chancellor for Research Protections
University of Pittsburgh
3500 Fifth Avenue, (b) (4) Heiber Building
Pittsburgh, PA 15213

Dear Dr. Yates,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 20, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Pittsburgh. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the University of Pittsburgh Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: mice lacking access to food. The final report states on October 18, 2021, three boxes with 8 adult mice were discovered in the animal facility without access to food. Seven animals were found dead, a surviving mouse was provided supportive care, but ultimately was euthanized by laboratory personnel. It is understood the investigator's lab personnel did not provide food when the boxes were setup on October 15th. Also, animal facility staff did not identify the lack of food until October 18th. The following corrective action plans were provided by the animal facility and investigator and approved by the IACUC:

- All facility staff members were retrained on the proper way to conduct health, food, and water checks. Each check is to be completed separate from the others so the tech can concentrate on one item at a time.
- Since the accidental loss, the investigator has been placing "Recently Weaned" tags on each cage that is weaned.
- The investigator has created a task checklist, including food supply, for animal breeding work so that tasks aren't missed.
- The investigator will assign two workers (rather than one) to execute all animal work.

It is noted that this research is supported by PHS funding. Based on its assessment of this explanation, OLAW understands that the University of Pittsburgh has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy.

We appreciate being informed of these matters and find no cause for further action by this Office.

Page 2 – Dr. Yates
January 14, 2022
OLAW Case A3187-9P

Sincerely,

Jacquelyn
T. Tubbs -S

Digitally signed by
Jacquelyn T. Tubbs -S
Date: 2022.01.14
15:01:58 -05'00'

Jacquelyn Tubbs, DVM, DACLAM
Senior Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact



DEPARTMENT OF HEALTH & HUMAN SERVICES

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FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

February 17, 2022

Re: Animal Welfare Assurance
#A3187-01 [OLAW Case 9Q]

Dr. Bill Yates
Acting Vice Chancellor for Research Protections
University of Pittsburgh
3500 Fifth Avenue, (b) (4) Hieber Building
Pittsburgh, PA 15213

Dear Dr. Yates,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 7, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Pittsburgh. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the University of Pittsburgh Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: animal deaths likely due to lack of access to water. The final report states on December 15, 2021, five mice were found without access to water. Two animals were found dead, and the remaining 3 mice were given fluids and soft food. The following morning, two of the remaining animals were found dead and it was determined death was likely due to lack of water and stressors related to the experimental procedures.

Per the report, the mice underwent a procedure involving the bladder on December 13th. Afterwards, the cage was placed on a rack not equipped with automatic water and a water bottle was not provided. Per the approved protocol, the animals were to be monitored daily by the investigator's lab personnel. In response to the incident, the investigator discussed with each lab member the need to ensure that animal cages are returned to the correct rack.

The IACUC approved the investigator's corrective action plan and levied the following sanctions:

- A letter of reprimand was sent to the investigator and his supervisors regarding this event.
- The investigator and laboratory staff will undergo training on animal monitoring.

It is understood the experimental procedure was performed on December 13th and the animals were discovered two days later without access to water. It is not clear if this rack was in an investigator-managed area or in a general animal housing room. If the rack was in a general animal housing room, OLAW recommends that it is also emphasized to husbandry staff the importance of daily observations of animals to prevent future recurrence.

It is noted that this research is supported by PHS funding. Based on its assessment of this explanation, OLAW understands that the University of Pittsburgh has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy.

We appreciate being informed of these matters and find no cause for further action by this Office.

Page 2 – Dr. Yates
February 17, 2022
OLAW Case A3187-9Q

Sincerely,

Jacquelyn T. Tubbs -S
Digitally signed by
Jacquelyn T. Tubbs -S
Date: 2022.02.17
12:39:42 -05'00'

Jacquelyn Tubbs, DVM, DACLAM
Senior Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact



DEPARTMENT OF HEALTH & HUMAN SERVICES

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FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

March 14, 2022

Re: Animal Welfare Assurance
#A3187-01 [OLAW Case 9S]

Dr. Bill Yates
Acting Vice Chancellor for Research Protections
University of Pittsburgh
3500 Fifth Avenue, ^{(b)(4)}Hieber Building
Pittsburgh, PA 15213

Dear Dr. Yates,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 4, 2022 letter reporting three similar instances of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Pittsburgh. According to the information provided, OLAW understands that:

For incident 1: On Saturday, December 18, 2021, one box of five mice was found on an auto-water rack without a lixit. Three of the mice were found deceased. The surviving two mice were given supportive care. It is estimated they went two days without water. The PI has several boxes at any given time in the room for which they disconnect the lixits and supply "special water" in bottles, but it was not determined why this specific box was without a lixit.

For incident 2: On Sunday, January 23, 2022, one box of two mice was found on an auto-water rack without a lixit. Both mice were found deceased. The investigator's technician may have accidentally placed the box in a slot used by a different investigator who uses "special water" bottles instead of the lixit, which is typically removed. It was not determined why this specific box was in a slot without a lixit. Animal facility technicians did not notice the missing lixit during two daily room checks.

For Incident 3: On Tuesday, January 11, 2022, five boxes of five total mice were found housed on an auto-water rack with the wrong type of grommet in the boxes and without access to water. Three of the mice, each in a different box, were found deceased. The PI staff did not notice the difference and housed mice in the wrong boxes. It was not caught during the daily room checks.

The IACUC approved the corrective action plan submitted by the animal facility director, which included the following items:

1. Animal facility technicians were retrained to ensure a lixit is in place in every slot and is properly installed during daily checks (incident 1, 2, and 3).
2. A designated row on one rack was labeled for use for water bottles only (incidents 1 and 2).
3. The cagewash and husbandry technicians were retrained to notice the differences in the two types of boxes and remove them if found in the wrong corridor (incident 3).

Page 2 – Dr. Yates
March 14, 2022
OLAW Case A3187-9S

The IACUC levied the following sanction:

- A letter was sent to the animal facility director regarding these events.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate these incidents and prevent recurrences. OLAW concurs that the incidents warranted reporting. We appreciate being informed of these matters and find no cause for further action by this office.

Sincerely,

Brent C. Morse -S

Digitally signed by Brent C.

Morse -S

Date: 2022.03.15 07:45:59 -04'00'

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact



DEPARTMENT OF HEALTH & HUMAN SERVICES

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6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

May 19, 2022

Re: Animal Welfare Assurance
#A3187-01 [OLAW Case 9W]

Dr. Bill Yates
Acting Vice Chancellor for Research Protections
University of Pittsburgh
3500 Fifth Avenue, (b) (4) Hieber Building
Pittsburgh, PA 15213

Dear Dr. Yates,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 2, 2022 letter reporting two similar instances of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Pittsburgh. IT was not stated if the associated activities were PHS supported. According to the information provided, OLAW understands that:

For incident 1: On March 28th, 2022, one box containing one mouse was discovered without food during daily rounds in the animal facility. The mouse was given wet food and supportive care but was found deceased the next morning. The animal facility technician performing daily checks missed this box for at least 48 hours.

For incident 2: On February 15, 2022, one box containing three deceased mice was discovered without access to water in the animal facility. The box was housed on an automatic water rack, but the wrong type of box was employed, preventing mice from obtaining water.

OLAW understands that the IACUC approved the corrective action plan submitted by the animal facility director for the incidents, which included the following items:

1. Animal facility technicians were reminded to ensure all cages have food, a lixit or bottle present, as part of the daily health check.
2. The specific flat grommet boxes not to be used on most automatic water racks have been marked to distinguish them from the normal boxes.

The IACUC levied the following sanction:

- Letters for these incidents were sent to the animal facility director regarding these events.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate these incidents and prevent recurrences, but OLAW also notes the similarities of these incidents to those reported by you in your March 4, 2022 letter. OLAW views instances of lack of basic living requirements such as food, water, and a proper cage environment with great concern. OLAW concurs that the incidents warranted reporting. We appreciate being informed of these matters and find no cause for further action by this office, at this time.

Page 2 – Dr. Yates
May 19, 2022
OLAW Case A3187-9W

Sincerely,

Brent C. Morse -

Digitally signed by Brent C.
Morse -S

S

Date: 2022.05.19 15:15:14 -04'00'

Brent C. Morse, DVM

Director

Division of Compliance Oversight

Office of Laboratory Animal Welfare

cc: IACUC contact



DEPARTMENT OF HEALTH & HUMAN SERVICES

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FOR EXPRESS MAIL:

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6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
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January 6, 2020

Re: Animal Welfare Assurance
#A3187-01 [OLAW Case 8T]

Mr. George A. Huber
Vice Chancellor for Research Conduct
and Compliance
University of Pittsburgh
(b) (4) Hieber Building
3500 Fifth Avenue
Pittsburgh, PA 15213

Dear Dr. Huber,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 19, 2019 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at the University of Pittsburgh. According to the information provided, OLAW understands that one mouse died due to lack of food in the cage.

The corrective actions consisted of providing diet gel and food, placing the technician responsible on administrative leave, counseling the laboratory staff, retraining the laboratory staff on ensuring adequate food and water is in the cage following cage setup and weaning, having a laboratory member conduct weekly cage checks, having a senior technician assist with cage setup and weaning, and retraining all current and one new technician. A letter of reprimand was issued to the Principal Investigator and Executive Director of the animal care program.

Based on its assessment of this explanation, OLAW understands that measures have been implemented in this specific incident to address the problem. However, this Office remains concerned about the ongoing issue of animal deaths due to lack of food/water and we await the response to case A3187-8Q regarding program wide steps to be taken to prevent such problems. Thank you for informing OLAW about this matter.

Sincerely,

(b) (6)

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

cc: IACUC Chair



DEPARTMENT OF HEALTH & HUMAN SERVICES

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FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
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February 13, 2020

Re: Animal Welfare Assurance
#A3187-01 [OLAW Case 8Q]

Mr. George A. Huber
Vice Chancellor for Research Conduct
and Compliance
University of Pittsburgh
(b) (4) Hieber Building
3500 Fifth Avenue
Pittsburgh, PA 15213

Dear Dr. Huber,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 29, 2020 response to my December 9, 2019 request for information on measures being taken to prevent rodent deaths due to lack of food/water at the University of Pittsburgh. According to the information provided, OLAW understands the following:

- The Institutional Animal Care and Use Committee (IACUC) conducted a detailed review of husbandry practices.
- The animal care and use program is committed to preventing animal deaths due to human error.
- A training program is in place for new animal caretakers who are closely supervised until considered proficient.
- Husbandry errors result in retraining.
- Newly weaned rodents are monitored by Division of Laboratory Animal Resources (DLAR) staff to ensure good health and provision of food/water.
- An enhanced DLAR training program has been implemented and a new Training Manager has been hired. The training will include animal care and research staff.
- Two additional training staff have also been hired.

Responses to OLAW's specific questions are as follows:

- 1) A root cause of why the problems occurred was conducted and concluded that incidents of rodent deaths occurred in different facilities and involved different staff and supervisors. There were no repeat failures by the same staff.
- 2) In addition to retraining, an incentive program has been established which rewards staff that identify mock cages missing food/water.

- 3) Staff performance problems are documented in employee records and repeat violations are addressed by increasing discipline.
- 4) The institution is aware that any animal death due to human error is unacceptable and is committed to achieving 100% compliance.
- 5) The IACUC is involved in the proposed corrective actions and is requiring all animal care staff to enroll in the new training program. The IACUC will monitor improvement in animal husbandry. The IACUC, DLAR, and investigators are invested in continuing improvement. The number of staff should be proportionate to the number of animals.

OLAW received the January 14, 2020 report which stated that one sentinel mouse died and one required treatment due to not having water. The corrective action consisted of retraining the caretaker on the conduct of daily health checks and all animal facility staff was counseled. A letter of reprimand was issued to the Executive Director of the animal care program and their supervisor.

Based on its assessment of the actions being proposed or already in place, OLAW finds them to be an acceptable approach to achieve the goal of significantly reducing or eliminating rodent deaths caused by human error. We are confident that measures such as the mock cages are a positive approach which should yield the expected results because they have been successfully applied at other institutions facing the same problem. As with similar cases, OLAW is obligated to monitor the success of the proposed program and is hereby placing the University of Pittsburgh on an enhanced reporting schedule. Under this schedule OLAW is requesting an update every two months on the first day of the month to report success as measured by a reduction in deaths. Near misses that have been successfully caught and corrected should also be reported. Any other metrics such as the status of the mock cage program, the percentage of people trained, and any additional hires should be included. Reportable events, including deaths due to lack of food/water are to be independently promptly reported. We look forward to receiving the first report on **April 1, 2020**. 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

- 5) Two mice died of dehydration due to a missing water bottle. A laboratory member had moved the cage to the wrong rack and the problem was not identified during daily health checks.

Corrective actions: The animal caretakers were retrained and new laboratory staff will be counseled on ensuring food/water for all animals.

- 6) A mouse died because it had crawled into the feeder during cage change and could not access the water.

Corrective actions: The animal caretaker was retrained on cage changing, health checks, and was monitored. All staff was counseled on this incident.

- 7) One dead and one live mouse were found in a cage without food. The mice had been weaned but not given food and the problem was not identified during daily health checks.

Corrective actions: The surviving mouse was given food mush, the animal caretaker for the room was retrained, all facility caretakers were counseled, the laboratory member responsible was retrained on weaning, and the facility manger was counseled.

- In each situation, a letter of reprimand was issued to the Attending Veterinarian, the Principal Investigator, and their supervisors.

Based on its assessment of these explanations, OLAW understands that measures have been implemented in each case to address and correct the problem. While OLAW concurs with overall actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals, the ongoing nature of these husbandry failures is of concern to this Office. Before potentially placing the University of Pittsburgh on an enhanced reporting schedule, please address the following:

- 1) Has a root cause analysis been conducted to determine the cause of these repeat deficiencies (i.e., insufficient training, insufficient supervision, insufficient staffing)?
- 2) While retraining may be an appropriate response to address something such as use of different caging, it is not adequate when negligence results in animals dying due to lack of food/water. All staff should be aware that animals require food/water in order to survive and additional steps must be taken to ensure adequate husbandry.
- 3) Repeat instances of failing to provide food/water or failing to adequately monitor animals must be addressed with escalating sanctions for staff and supervisors.
- 4) OLAW realizes that seven noncompliant fatal food/water issues over several months may not appear to be of great magnitude in a large program, however such failures constitute a serious animal welfare concern and steps must be taken to prevent them throughout the program.
- 5) Provide information on how the Institutional Animal Care and Use Committee plans to address the matter program wide to include animal care staff, technicians, laboratory staff, veterinarians, investigators, supervisors, and facility managers.

Please provide any and all information on the steps being taken to prevent animal deaths due to lack of food/water by **January 6, 2020**. Upon evaluation of the proposed plan and schedule, this Office will determine which additional steps need to be taken to ensure compliance. 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



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) 480-3387

July 9, 2021

Re: Animal Welfare Assurance
#A3187-01 [OLAW Case 8Q]

Dr. Bill Yates
Interim Vice Chancellor for Research Protections
University of Pittsburgh
(b) (4) Hieber Building
3500 Fifth Avenue
Pittsburgh, PA 15213

Dear Dr. Yates,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 10 and June 14, 2021 letters providing a final update under an enhanced reporting schedule for the University of Pittsburgh as well as an update on a previously reported incident. According to the information provided, OLAW understands the following:

- 1) In an April 28, 2021 report it was stated that no water bottle was provided to a mouse cage upon weaning and that the animal care staff failed to notice the missing bottle. The Institutional Animal Care and Use Committee (IACUC) received additional information which stated that the dead mouse had been a runt and it was not possible to determine how long the cage had been without water and who was responsible for the incident.
- 2) Due to ongoing reports of mice dying due to mostly preventable lack of food/water, the University of Pittsburgh had been placed on enhanced reporting by OLAW in February 2020 to allow measures to be implemented to significantly reduce or eliminate this problem. The actions taken in response consisted of using mock mouse cages without food/water to serve as a training tool for husbandry staff. Also, a second food/water check of all rodent cages was implemented with two separate individuals checking all cages. This led to a significant decrease in food/water deaths with only four cages incurring losses out of 33,000 over a five month period.

Based on its assessment of this and all of the preceding reports, OLAW finds the current policies and procedures in place to be effective in significantly reducing or eliminating rodent deaths due to lack of food/water. As such, the enhanced reporting schedule is hereby lifted and no further updates need to be submitted to OLAW, although any future such incidents should still be promptly reported. OLAW thanks you, the IACUC, the veterinary staff, technical staff, and husbandry staff for successfully implementing actions which enhance the welfare of research animals at the University of Pittsburgh.

Sincerely,

(b) (6)

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

cc: IACUC Chair



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
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FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
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Telephone: (301) 496-7163
Facsimile: (301) 480-3387

May 3, 2021

Re: Animal Welfare Assurance
#A3187-01 [OLAW Case 8Q]

Dr. Bill Yates
Acting Vice Chancellor for Research Protections
University of Pittsburgh
(b) (4) Hieber Building
3500 Fifth Avenue
Pittsburgh, PA 15213

Dear Dr. Yates,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 6 and 28, 2021 letters providing an update under an enhanced reporting schedule for the University of Pittsburgh as well as a report on mouse deaths due to lack of food/water. According to the information provided, OLAW understands the following about the incidents and the corresponding corrective actions:

- 1) Two adult mice and three pups did not have access to water and one pup died. A technician had weaned the cage but did not provide a water bottle and the problem was not noted by animal care staff during the daily health check.
- 2) Three adult mice were found without food and one mouse died. The problem was not noted either by animal care staff during the daily health check or by research staff working with the mice.

Corrective actions: Husbandry staff was retrained on the appropriate conduct of daily health checks; the investigator was counseled to ensure water bottles are placed on mouse cages; the laboratory staff was counseled to ensure that food and water is present for all mice. Letters of reprimand were issued to the director of Division of Laboratory Animal Resources, the investigators, and their supervisors.

Other than these two incidents, there were no further rodent deaths due to lack of food/water during February and March. The twice daily food/water checks, which are conducted by a different technician, has resulted in a significant reduction of deaths due to lack of food/water. A total of four animal caretakers were hired during these two months and five left. Additional training was provided to a faculty member and staff and to animal care staff.

Based on the success of the twice daily health checks and decreasing trends in rodent deaths due to lack of food/water, we request that the update on **June 15, 2021** constitute a brief summary of the original problem, the steps taken to address it, and an outline of the decreasing numbers (or complete elimination) of deaths. Barring any unforeseen complications, OLAW feels that the enhanced reporting requirements will be able to be lifted upon receipt of the report. Any instances of death due to lack of food/water should still be reported independently. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

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

cc: IACUC Chair



DEPARTMENT OF HEALTH & HUMAN SERVICES

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FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

February 12, 2021

Re: Animal Welfare Assurance
#A3187-01 [OLAW Case 8Q]

Dr. Bill Yates
Interim Vice Chancellor for Research Protections
University of Pittsburgh
(b) (4) Hieber Building
3500 Fifth Avenue
Pittsburgh, PA 15213

Dear Dr. Yates,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 9, 2021 letter providing an update under an enhanced reporting schedule for the University of Pittsburgh to allow this Office to monitor the steps being taken to eliminate rodent deaths due to lack of food/water. According to the information provided, OLAW understands that a major change in the daily conduct of health checks has been implemented whereby all cages are now checked twice daily by a different technician. These two independent daily food/water checks have already resulted in a significant reduction in mortality. Specifically, only one animal died over the past two months due to a husbandry deviation and this case will be reported separately to this Office. Also, six animal caretakers were hired in December and January but three left. Two caretakers received additional training on the proper conduct of health checks.

OLAW applauds the programmatic change which appears to have resulted in immediate positive outcomes. We will continue to monitor the impact of the new initiative as well as other steps taken to address the primary problem. As such, please provide the next update by **April 15, 2021**. Thank you for keeping OLAW apprised on these matters.

Sincerely,

(b) (6)

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

cc: IACUC Chair



DEPARTMENT OF HEALTH & HUMAN SERVICES

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FOR EXPRESS MAIL:

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6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
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December 9, 2020

Re: Animal Welfare Assurance
#A3187-01 [OLAW Case 8Q]

Dr. Bill Yates
Interim Vice Chancellor for Research Protections
University of Pittsburgh
(b) (4) Hieber Building
3500 Fifth Avenue
Pittsburgh, PA 15213

Dear Dr. Yates,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 8, 2020 letter providing an update under an enhanced reporting schedule for the University of Pittsburgh to allow this Office to monitor the steps being taken to eliminate rodent deaths due to lack of food/water. We also acknowledge receipt of one report from October 30, 2020 and two reports from December 4, 2020 reporting rodent deaths due to lack of food or water and the corrective actions as follows:

- 1) One mouse died from lack of food as none was provided following a cage change; the problem was not identified during the daily health check.
Corrective action: The animal caretaker was retrained and a letter of reprimand was used to the Division of Laboratory Animal Resources (DLAR) Director and supervisor.
- 2) Four mice died due to lack of food. Food was not provided during cage set up and the problem was not identified during the daily health check.
Corrective action: The animal care staff in the facility was retrained on the conduct of daily health checks; a letter of reprimand was issued to the DLAR Director and supervisor.
- 3) One mouse died of dehydration because the water valve had not been attached. The problem was not identified during the daily health check.
Corrective action: The animal care staff in the facility was retrained on cage changing procedures and on attaching water valves; a letter of reprimand was issued to the DLAR Director and supervisor.

According to the information provided, OLAW understands the following:

- 1) During October and November, 20 mice died due to lack of food and water.
- 2) During that time period, ten full time animal caretakers were hired and six left.
- 3) During that time period, no new full time cage wash technicians were hired and one left.
- 4) During that time, five caretakers received retraining on the proper conduct of health checks.

While OLAW understands that the percentage of rodents dying due to lack of food/water is a small portion of the total animals in-house, the goal of the current efforts must be to eliminate these preventable incidents. Other institutions on similar monitoring by OLAW often show a slight increase of cases as a result of the enhanced scrutiny but as internal enforcement efforts increase, the death rate soon drops to zero or very close to zero. It is imperative that the current training efforts, enhanced supervision, escalating sanctions, and program wide awareness continue, or increase, in order to prevent additional deaths. Please provide the next status update by **February 15, 2021**.

Sincerely,

(b) (6)

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

cc: IACUC Chair



DEPARTMENT OF HEALTH & HUMAN SERVICES

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FOR EXPRESS MAIL:

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6700B Rockledge Drive, Suite 2500
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Facsimile: (301) 480-3387

October 16, 2020

Re: Animal Welfare Assurance
#A3187-01 [OLAW Case 8Q]

Dr. Bill Yates
Interim Vice Chancellor for Research Protections
University of Pittsburgh
(b) (4) Hieber Building
3500 Fifth Avenue
Pittsburgh, PA 15213

Dear Dr. Yates,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 9, 2020 letter providing an update under an enhanced reporting schedule for the University of Pittsburgh to allow this Office to monitor the steps being taken to eliminate rodent deaths due to lack of food/water. OLAW also acknowledges receipt of the October 6, 2020 preliminary report from the Institutional Animal Care and Use Committee chair stating that 29 mice died from dehydration due to an improperly connected water line. The surviving mice were given mush and recovered. This information was incorporated in the current report.

According to the information provided, OLAW understands the following:

- 1) During August and September, 40 mice died due to lack of food/water. The spike in August was due to the disconnected water line described above.
- 2) During this time, 56 mock cages were set up (in August only as this activity was temporarily discontinued for September); 46 were identified within 48 hours and 10 were identified thereafter.
- 3) Three additional full time animal caretakers were hired in each month and one additional cage wash technician was hired.
- 4) During this time four husbandry care technicians received additional training on the proper conduct of health checks; facility personnel were retrained on connecting water lines to rodent racks.
- 5) Rodent cages have food/water added when noted to be below an established level. Low levels can be due to health issues, behavioral issues, or low levels at set up of the cage.

Based on its assessment of this update, OLAW understands that efforts are ongoing regarding ensuring adequate staffing levels and training. OLAW concurs with the actions being taken by the institution to attempt to eliminate animal deaths due to lack of food/water and will continue to monitor the situation. Please provide the next status update by **December 15, 2020** and continue to promptly report deaths as they occur. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

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

cc: IACUC Chair



DEPARTMENT OF HEALTH & HUMAN SERVICES

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6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

August 12, 2020

Re: Animal Welfare Assurance
#A3187-01 [OLAW Case 8Q]

Mr. George A. Huber
Vice Chancellor for Research Conduct
and Compliance
University of Pittsburgh
(b) (4) Hieber Building
3500 Fifth Avenue
Pittsburgh, PA 15213

Dear Mr. Huber,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 10, 2020 letter providing an update under an enhanced reporting schedule for the University of Pittsburgh to allow this Office to monitor the steps being taken to eliminate rodent deaths due to lack of food/water. OLAW also acknowledges receipt of the July 20, 2020 letter reporting the deaths of four mice due to dehydration. The wrong cage had been used on the automatic watering rack and could not be seated properly to allow access to water. The corrective action consisted of retraining animal care staff on the different types of cages and racks used in the facility.

According to the information provided, OLAW understands the following:

- 1) During June and July, 13 mouse deaths occurred due to lack of food/water.
- 2) During this time, 123 mock cages were set up; 106 were identified within 48 hours while 17 were identified later.
- 3) There are currently 79 animal caretakers and 23 cage wash technicians on board.
- 4) During June and July, 3 fulltime animal caretakers and 1 cage wash technician were hired.
- 5) During this time 21 caretakers were trained on the proper conduct of daily health checks.
- 6) Rodent cages have food/water added when noted to be below an established level. Low levels can be due to health issues, behavioral issues, or low levels at set up of the cage.

Based on its assessment of this update, OLAW understands that efforts are ongoing regarding ensuring adequate staffing levels, mock cage setups, and training. OLAW concurs with the actions being taken by the institution to attempt to eliminate animal deaths due to lack of food/water and will continue to monitor the situation. Please provide the next status update by **October 15, 2020** and continue to promptly report deaths as they occur. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

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

cc: IACUC Chair



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
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FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

June 19, 2020

Re: Animal Welfare Assurance
#A3187-01 [OLAW Case 8Q]

Mr. George A. Huber
Vice Chancellor for Research Conduct
and Compliance
University of Pittsburgh
(b) (4) Hieber Building
3500 Fifth Avenue
Pittsburgh, PA 15213

Dear Mr. Huber,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 15, 2020 letter providing the second report under an enhanced reporting schedule for the University of Pittsburgh to allow this Office to monitor the steps being taken to eliminate rodent deaths due to lack of food/water. OLAW also acknowledges receipt of letters from April 16, May 4, and May 8, 2020 which constitute independent noncompliance reports relevant to the matter. According to the information provided, OLAW understands the following about the incidents and the corresponding corrective actions:

- April 16, 2020 answers to OLAW questions from April 10, 2020.
 1. Rodent cages have food and water added when noted to be low due to regular consumption or excessive consumption due to behavior or health condition (i.e. diabetes).
 2. Specific patterns have not been identified as to why cages may be missing food/water.
 3. There have been no instances of repeat noncompliance for the same staff member.
 4. All staff is aware of the heightened attention being given to the current initiative.
- May 4, 2020 letter. Three out of four mice died due to lack of food. The empty hopper was not noted during the daily health check. The corrective action consisted of retraining husbandry staff on the appropriate conduct of health checks and food/water levels. A letter of reprimand was sent to the animal facility director and supervisor.
- May 8, 2020 letter. One mouse died due to lack of food. The empty hopper was not noted during the daily health check. Laboratory staff had manipulated the cage. The corrective action consisted of retraining the husbandry staff on the appropriate conduct of health checks and food/water levels. The laboratory technician involved will be supervised by the investigator, a checklist will be used when weaning or handling mice, and the technician will double check all cages for food/water.
- June 15, 2020 letter. Due to the COVID-19 pandemic, cage changing had been temporarily switched to once every 14 days, which required additional topping off of food/water. The schedule has subsequently been restored to rodent cage changes every 7-10 days.

1. Rodent deaths due to lack of food/water consisted of 4 in March, 4 in April, and 14 in May.
2. Sixty plus mock boxes were placed with approximately 80 plus percent identified by staff within 48 hours.
3. There were 74 animal care technicians on board in March and April, and 78 in May. New hires consisted of 2 in March, 1 in April, and 5 in May. The staffing levels of cage wash technicians was also listed.
4. Additional training on the conduct of health checks was provided to 22 husbandry technicians in March, 20 in April, and 13 in May.

Based on the information provided, OLAW understands that between 0.01% and 0.02% of rodent cages were identified as having animal deaths due to lack of food/water. To further reduce the number of deaths, the mock cage program is being continued to increase staff vigilance, additional animal care staff has been hired, and additional training was provided to the animal care staff. OLAW concurs with the actions being taken by the institution to attempt to eliminate animal deaths due to lack of food/water and will continue to monitor the situation. As such, please provide the next status update by **August 15, 2020**. Continue to promptly report deaths promptly as they occur. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

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

cc: IACUC Chair



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
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FOR EXPRESS MAIL:
Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
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April 10, 2020

Re: Animal Welfare Assurance
#A3187-01 [OLAW Case 8Q]

Mr. George A. Huber
Vice Chancellor for Research Conduct
and Compliance
University of Pittsburgh
(b) (4) Hieber Building
3500 Fifth Avenue
Pittsburgh, PA 15213

Dear Mr. Huber,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of Dr. Chapman's April 7, 2020 letter providing a status update under an enhanced reporting period for the University of Pittsburgh to allow this Office to monitor the steps being taken to eliminate rodent deaths due to lack of food/water. According to the information provided, OLAW understands the following:

- 1) Out of a total of 34,437 rodent cages, four cages had deaths due to lack of food/water. A total of 13,695 cages needed to have food/water provided, which was done and resulted in no deaths.
- 2) A mock cage system has been put into place to help animal care staff become more vigilant in finding cages that may need food/water. In the first month of this program, 68 mock cages were placed and 56 were identified within two days. The remainder were found after two days.
- 3) There are currently 74 animal caretakers and 23 cage wash technicians on board. New staff is being hired and may serve as a reserve work-force to be called upon in case of staff illness during the pandemic. These include two full time animal care husbandry technicians, two full time cage wash technicians, and three temporary cage wash technicians.
- 4) Additional training on the proper conduct of daily health checks has been provided to 22 husbandry technicians.

Based on its assessment of this information, OLAW understands that 0.01% rodents died due to lack of food/water, a mock cage program is in place to increase staff vigilance and appears to be successful, additional staff has been hired, and additional training was provided to the animal care staff. OLAW concurs with the actions being taken by the institution to attempt to eliminate animal deaths due to lack of food/water. Dr. Chapman's summary data is clear, concise, and will allow easy comparison to subsequent summaries to assess trends. In the next report, due **June 15, 2020**, please provide the same data sets and answer these additional questions:

- 1) For the 13,695 cages that needed food/water, were they actually without food/water; had they been missed; did they just need "topping off"; and why was the number so high?

- 2) Have any patterns emerged for behaviors that result in animals not having food/water and dying (i.e. weaning, food restriction studies)?
- 3) Have any personnel actions been necessary for repeat noncompliance, if this has occurred?
- 4) Are all staff members, including research personnel, animal care personnel, technicians, and veterinary staff aware of the heightened attention under this current initiative?
- 5) Provide any additional updates on any other steps being taken to address the issue.

Thank you for keeping OLAW apprised on this matter.

Sincerely,

 (b) (6)

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

cc: IACUC Chair



DEPARTMENT OF HEALTH & HUMAN SERVICES

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FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
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February 13, 2020

Re: Animal Welfare Assurance
#A3187-01 [OLAW Case 8Q]

Mr. George A. Huber
Vice Chancellor for Research Conduct
and Compliance
University of Pittsburgh
(b) (4) Hieber Building
3500 Fifth Avenue
Pittsburgh, PA 15213

Dear Dr. Huber,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 29, 2020 response to my December 9, 2019 request for information on measures being taken to prevent rodent deaths due to lack of food/water at the University of Pittsburgh. According to the information provided, OLAW understands the following:

- The Institutional Animal Care and Use Committee (IACUC) conducted a detailed review of husbandry practices.
- The animal care and use program is committed to preventing animal deaths due to human error.
- A training program is in place for new animal caretakers who are closely supervised until considered proficient.
- Husbandry errors result in retraining.
- Newly weaned rodents are monitored by Division of Laboratory Animal Resources (DLAR) staff to ensure good health and provision of food/water.
- An enhanced DLAR training program has been implemented and a new Training Manager has been hired. The training will include animal care and research staff.
- Two additional training staff have also been hired.

Responses to OLAW's specific questions are as follows:

- 1) A root cause of why the problems occurred was conducted and concluded that incidents of rodent deaths occurred in different facilities and involved different staff and supervisors. There were no repeat failures by the same staff.
- 2) In addition to retraining, an incentive program has been established which rewards staff that identify mock cages missing food/water.

- 3) Staff performance problems are documented in employee records and repeat violations are addressed by increasing discipline.
- 4) The institution is aware that any animal death due to human error is unacceptable and is committed to achieving 100% compliance.
- 5) The IACUC is involved in the proposed corrective actions and is requiring all animal care staff to enroll in the new training program. The IACUC will monitor improvement in animal husbandry. The IACUC, DLAR, and investigators are invested in continuing improvement. The number of staff should be proportionate to the number of animals.

OLAW received the January 14, 2020 report which stated that one sentinel mouse died and one required treatment due to not having water. The corrective action consisted of retraining the caretaker on the conduct of daily health checks and all animal facility staff was counseled. A letter of reprimand was issued to the Executive Director of the animal care program and their supervisor.

Based on its assessment of the actions being proposed or already in place, OLAW finds them to be an acceptable approach to achieve the goal of significantly reducing or eliminating rodent deaths caused by human error. We are confident that measures such as the mock cages are a positive approach which should yield the expected results because they have been successfully applied at other institutions facing the same problem. As with similar cases, OLAW is obligated to monitor the success of the proposed program and is hereby placing the University of Pittsburgh on an enhanced reporting schedule. Under this schedule OLAW is requesting an update every two months on the first day of the month to report success as measured by a reduction in deaths. Near misses that have been successfully caught and corrected should also be reported. Any other metrics such as the status of the mock cage program, the percentage of people trained, and any additional hires should be included. Reportable events, including deaths due to lack of food/water are to be independently promptly reported. We look forward to receiving the first report on **April 1, 2020**. 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



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
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December 9, 2019

Re: Animal Welfare Assurance
#A3187-01 [OLAW Case 8Q]

Mr. George A. Huber
Vice Chancellor for Research Conduct
and Compliance
University of Pittsburgh
(b) (4) Hieber Building
3500 Fifth Avenue
Pittsburgh, PA 15213

Dear Dr. Huber,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 27, 2019 letter reporting seven serious deviations from the provisions of the *Guide for the Care and Use of Laboratory Animals* at the University of Pittsburgh. According to the information provided, OLAW understands the following about the incidents and the corresponding corrective actions:

- 1) Two mice died due to lack of water caused by using the wrong cages on an automatic watering rack which prevented the mice from reaching the lixits. Nine pups and one adult survived. The cages had been incorrectly marked, thus leading to the dehydration deaths.

Corrective actions: The surviving mice were given water, diet gel, and were monitored. The animal caretaker was retrained on which mouse cages to use on which racks and the cage wash technician was trained on the various types of mouse cages, how to mark them, and how they are placed on racks.

- 2) Eight mice died due to lack of food. The animals had been weaned and placed into new cages without food and the animal care staff failed to identify the problem during daily health checks.

Corrective actions: The husbandry staff was retrained and monitored. The laboratory's standard operating procedure for weaning was revised to require notification of a supervisor following weaning to verify provision of food/water.

- 3) Two mice died due to lack of food. Food had not been added following a cage change and the problem was not identified by husbandry staff during daily health checks.

Corrective actions: The caretaker responsible was retrained on cage changing and health checks.

- 4) Three of five mice died due to lack of food and the problem was not identified during daily health checks.

Corrective actions: The surviving mice were given food and were monitored. The husbandry staff was retrained and observed performing health checks. The investigator modified that food hoppers to accommodate the experimental powdered food.

- 5) Two mice died of dehydration due to a missing water bottle. A laboratory member had moved the cage to the wrong rack and the problem was not identified during daily health checks.

Corrective actions: The animal caretakers were retrained and new laboratory staff will be counseled on ensuring food/water for all animals.

- 6) A mouse died because it had crawled into the feeder during cage change and could not access the water.

Corrective actions: The animal caretaker was retrained on cage changing, health checks, and was monitored. All staff was counseled on this incident.

- 7) One dead and one live mouse were found in a cage without food. The mice had been weaned but not given food and the problem was not identified during daily health checks.

Corrective actions: The surviving mouse was given food mush, the animal caretaker for the room was retrained, all facility caretakers were counseled, the laboratory member responsible was retrained on weaning, and the facility manger was counseled.

- In each situation, a letter of reprimand was issued to the Attending Veterinarian, the Principal Investigator, and their supervisors.

Based on its assessment of these explanations, OLAW understands that measures have been implemented in each case to address and correct the problem. While OLAW concurs with overall actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals, the ongoing nature of these husbandry failures is of concern to this Office. Before potentially placing the University of Pittsburgh on an enhanced reporting schedule, please address the following:

- 1) Has a root cause analysis been conducted to determine the cause of these repeat deficiencies (i.e., insufficient training, insufficient supervision, insufficient staffing)?
- 2) While retraining may be an appropriate response to address something such as use of different caging, it is not adequate when negligence results in animals dying due to lack of food/water. All staff should be aware that animals require food/water in order to survive and additional steps must be taken to ensure adequate husbandry.
- 3) Repeat instances of failing to provide food/water or failing to adequately monitor animals must be addressed with escalating sanctions for staff and supervisors.
- 4) OLAW realizes that seven noncompliant fatal food/water issues over several months may not appear to be of great magnitude in a large program, however such failures constitute a serious animal welfare concern and steps must be taken to prevent them throughout the program.
- 5) Provide information on how the Institutional Animal Care and Use Committee plans to address the matter program wide to include animal care staff, technicians, laboratory staff, veterinarians, investigators, supervisors, and facility managers.

Please provide any and all information on the steps being taken to prevent animal deaths due to lack of food/water by **January 6, 2020**. Upon evaluation of the proposed plan and schedule, this Office will determine which additional steps need to be taken to ensure compliance. Feel free to contact me should you have any questions.

*Page 2 – Dr. Huber
December 9, 2019
OLAW Case A3187-SQ*

Sincerely,

(b) (6)

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

cc: IACUC Chair



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) 480-3387

January 14, 2022

Re: Animal Welfare Assurance
#A3187-01 [OLAW Case 9P]

Dr. Bill Yates
Acting Vice Chancellor for Research Protections
University of Pittsburgh
3500 Fifth Avenue, (b) (4) Heiber Building
Pittsburgh, PA 15213

Dear Dr. Yates,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 20, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Pittsburgh. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the University of Pittsburgh Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: mice lacking access to food. The final report states on October 18, 2021, three boxes with 8 adult mice were discovered in the animal facility without access to food. Seven animals were found dead, a surviving mouse was provided supportive care, but ultimately was euthanized by laboratory personnel. It is understood the investigator's lab personnel did not provide food when the boxes were setup on October 15th. Also, animal facility staff did not identify the lack of food until October 18th. The following corrective action plans were provided by the animal facility and investigator and approved by the IACUC:

- All facility staff members were retrained on the proper way to conduct health, food, and water checks. Each check is to be completed separate from the others so the tech can concentrate on one item at a time.
- Since the accidental loss, the investigator has been placing "Recently Weaned" tags on each cage that is weaned.
- The investigator has created a task checklist, including food supply, for animal breeding work so that tasks aren't missed.
- The investigator will assign two workers (rather than one) to execute all animal work.

It is noted that this research is supported by PHS funding. Based on its assessment of this explanation, OLAW understands that the University of Pittsburgh has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy.

We appreciate being informed of these matters and find no cause for further action by this Office.

Page 2 – Dr. Yates
January 14, 2022
OLAW Case A3187-9P

Sincerely,

**Jacquelyn
T. Tubbs -S**

Digitally signed by
Jacquelyn T. Tubbs -S
Date: 2022.01.14
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Jacquelyn Tubbs, DVM, DACLAM
Senior Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact