



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

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

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



Office of Research Protections

Suite 401, Hieber Building
3500 Fifth Avenue
Pittsburgh, PA 15213
412-624-2202
ghuber@pitt.edu
orp.pitt.edu

George A. Huber, JD, MSIE, MSSM
Vice Chancellor for Research Protections
Professor of Health Policy and Management

December 19, 2019

Brent Morse, DVM, DACLAM
NIH Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive – MSC 7982
Bethesda, MD 20892-7982

Dear Dr. Morse:

As the Institutional Official responsible for the University of Pittsburgh’s Animal Care and Use Program (Assurance number D16-00118), I am writing to report an incident of non-compliance¹ that was reviewed by the University’s Institutional Animal Care and Use Committee (IACUC) at its November 18, 2019 meeting.

On September 30, 2019, it was determined that one box of mice covered by the investigator’s IACUC protocol was not provided with food. Immediately upon discovery, the mice were provided with diet gel and food. One mouse did not survive.

The University of Pittsburgh IACUC reviewed and accepted the investigator’s corrective action plan (CAP), which consisted of the following items:

1. Consistent with University practice, the technician responsible for the cage was placed on administrative leave until an investigation has been completed.
2. The Principal Investigator discussed the noncompliance at a lab meeting on October 21, 2019.
3. Lab personnel were retrained on ensuring adequate food and water is provided to mice at the time of cage setup and weaning.
4. A lab member will perform weekly checks of all cages for adequate food and water.
5. A senior technician will assist with new cage setup and weaning.
6. A new technician will be trained with the assistance of a veterinary technician for animal care and handling issues.
7. Animal care technicians were retrained.

¹ PHS Policy IV.C.1.d

Brent Morse, DVM, DACLAM
Page 2
December 19, 2019

The investigator's research is supported by the following NIH grants:

- THE ROLE OF ACOD1 IN IMMUNOMODULATION IN INTRAPULMONARY KLEBSIELLA PNEUMONIAE INFECTION
- HOST CONTROL MECHANISMS AGAINST K. PNEUMONIAE INFECTION IN THE LUNGS
- MECHANISMS OF HOST PROTECTION AGAINST PATHOGEN-SECRETED PROTEASES IN ACUTE LUNG INJURY

The IACUC has levied the following sanctions:

1. A letter of reprimand was sent to the Principal Investigator, the Executive Director of the animal care program, and their supervisors regarding this incident of non-compliance. The letter has been placed in our files as evidence of the same.

Please do not hesitate to contact me if you have any questions or concerns.

Sincerely,

(b) (6)

George A. Huber

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, December 19, 2019 3:50 PM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Reportable Event Notice

Thank you for providing these final reports (b) (6) We will send official responses soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: (b) (6)
Sent: Thursday, December 19, 2019 2:59 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Reportable Event Notice

Please review the attached correspondence forwarded on behalf of George A. Huber, Vice Chancellor for Research Protections. Thank you.

(b) (6)





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

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

A3187-8W



*George A. Huber, JD, MSIE, MSSM
Vice Chancellor for Research Protections
Professor of Health Policy and Management*

Office of Research Protections

Suite 401, Hieber Building
3500 Fifth Avenue
Pittsburgh, PA 15213
412-624-2202
ghuber@pitt.edu
orp.pitt.edu

April 3, 2020

Brent Morse, DVM, DAACLAM
NIH Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive – MSC 7982
Bethesda, MD 20892-7982

Dear Dr. Morse:

As the Institutional Official responsible for the University of Pittsburgh's Animal Care and Use Program (Assurance number D16-00118), I am writing to advise your office of a reportable incident¹ that was reviewed by the University's Institutional Animal Care and Use Committee (IACUC) at its February 17, 2020 meeting.

Six cages of mice assigned to the investigator's protocol were found to be without access to water. Upon further investigation, the mice were being water restricted overnight, which was not included on the protocol.

The University of Pittsburgh IACUC reviewed and accepted the investigator's corrective action plan (CAP), which consisted of the following item:

1. The investigator submitted an IACUC modification that outlines the experimental rationale and duration of water restriction.
2. 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.
3. The investigator will require all personnel to double check IACUC protocols before ordering any animals for future experiments.

The investigator's research is supported by the following NIH grant:

**POPULATION GENOMIC ANALYSIS OF GUT MICROBIAL COLONIZATION IN
PREMATURE INFANTS (1R01AI092531-01)**

¹ PHS Policies IV.B.7 and IV.C.1.d

Brent Morse, DVM, DACLAM

Page 2

April 3, 2020

The IACUC has levied the following sanctions:

1. 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. Additionally, the investigator was informed that NIH funds cannot be used to pay for animal-related charges associated with off-protocol work.

Please do not hesitate to contact me if you have any questions or concerns.

Sincerely,

(b) (6)

George A. Huber

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, April 6, 2020 7:40 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Reportable Event Notice

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

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

From: (b) (6)
Sent: Friday, April 3, 2020 11:21 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Reportable Event Notice

Please review the attached correspondence forwarded on behalf of George A. Huber, Vice Chancellor for Research Protections. Thank you.

(b) (6)





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

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



Office of Research Protections
Suite 401, Hieber Building
3500 Fifth Avenue
Pittsburgh, PA 15213
412-624-2202
ghuber@pitt.edu
orp.pitt.edu

*George A. Huber, JD, MSIE, MSSM
Vice Chancellor for Research Protections
Professor of Health Policy and Management*

April 3, 2020

Brent Morse, DVM, DACLAM
NIH Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive – MSC 7982
Bethesda, MD 20892-7982

Dear Dr. Morse:

As the Institutional Official responsible for the University of Pittsburgh’s Animal Care and Use Program (Assurance number D16-00118), I am writing to advise your office of a reportable incident¹ that was reviewed by the University’s Institutional Animal Care and Use Committee (IACUC) at its February 17, 2020 meeting.

On December 15, 2019, a box from an auto water rack was found to have been mistakenly placed on a rack labeled as a manual water bottle rack by a member of the investigator’s lab following a room change on December 12. A water bottle was not provided. Upon discovery, the box contained one surviving and one deceased adult mouse.

The University of Pittsburgh IACUC reviewed and accepted the investigator’s corrective action plan (CAP) and the animal facility Director’s summary of preventative actions, which consisted of the following items:

1. The animal care technician was retrained on daily husbandry checks.
2. The investigator and lab members will pay closer attention to animal rack designations in the housing room.
3. 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.
4. Members of the laboratory will be briefed on this incident and will be urged to implement additional measures to ensure the well-being of the research animals.

The investigator’s research is supported by the following NIH grant:

**PULMONARY ARTERIOLE OCCLUSION BY PLATELET-NEUTROPHIL MICRO-
EMBOLISM ACUTE CHEST SYNDROME (R01HL128297-05)**

¹ PHS Policy IV.C.1.d

Brent Morse, DVM, DACLAM
Page 2
April 3, 2020

The IACUC has levied the following sanctions:

1. A letter of reprimand was sent to the investigator, the Director of the animal care program, and their supervisors regarding this event. The letter has been placed in our files.

Please do not hesitate to contact me if you have any questions or concerns.

Sincerely,

 (b) (6)

George A. Huber

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, April 6, 2020 7:40 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Reportable Event Notice

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

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

From: (b) (6)
Sent: Friday, April 3, 2020 11:21 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Reportable Event Notice

Please review the attached correspondence forwarded on behalf of George A. Huber, Vice Chancellor for Research Protections. Thank you.

(b) (6)





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

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



University of
Pittsburgh

Office of
Research Protections

A 3187-9M

Bill J. Yates, PhD
Vice Chancellor for Research Protections
Professor of Otolaryngology & Neuroscience &
Clinical and Translational Science

(b) (4) Hieber Building
3500 Fifth Avenue
Pittsburgh, PA 15213
Phone: (b) (6)
Fax: (b) (6)
Email: vcorp@pitt.edu

August 23, 2021

Brent Morse, DVM, DACLAM
NIH Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive – MSC 7982
Bethesda, MD 20892-7982

Dear Dr. Morse:

As the Institutional Official responsible for the University of Pittsburgh's Animal Care and Use Program (Assurance number D16-00118), I am writing to advise your office of a reportable incident¹.

On June 21, 2021, during a daily room check, a box containing two deceased mice was discovered without food. The food hopper was upside down inside the cage and had not been filled when the animals were weaned by a postdoctoral fellow during the afternoon of June 18. The mice were discovered behind the food hopper. Because of this obstructed view the cage appeared to be empty to animal care technicians checking the box.

The corrective actions taken in this case consisted of the following items:

1. The postdoc's workflow has been evaluated and reconfigured, and he has been retrained in weaning procedures.
2. Going forward, food hoppers will always be pre-filled with food and left in the hood until being replaced in the cage prior to placing the cage back in the rack. This will provide a clear indication if a cage is missing food as the hopper would be visible in the hood instead of in the cage.
3. Additionally, the postdoc will visually check each cage being weaned from or weaned to, verifying that each has food, before leaving the animal facility.

The investigator's research is supported by the following NIH grants:

5R01AI043603-21

Murine Memory B Cell Development and Function

¹ PHS Policy IV.C.1.d

Brent Morse, DVM, DACLAM
August 23, 2021
Page 2

4R37AI118841-06	Investigating How TLR7 Activates and TLR9 Regulates Systemic Autoimmunity
5R01AI105018-07	Signaling and Selection in Germinal Center B Cells
1R21AI154267-01A1	Exploring the Role of Long Noncoding RNAs in Germinal Center B cells

The IACUC levied the following sanctions:

1. A letter of reprimand was sent to the investigator and his supervisors regarding this event. This letter has been placed in our files.

Please do not hesitate to contact me if you have any questions or concerns.

Sincerely,

 (b) (6)

Bill J. Yates, PhD

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, August 23, 2021 8:04 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: University of Pittsburgh

Thank you for these reports, (b) (6) We will send a response soon.

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

From: (b) (6)
Sent: Monday, August 23, 2021 7:50 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: University of Pittsburgh

Please review the attached correspondence forwarded on behalf of Bill J. Yates, PhD, Vice Chancellor for Research Protections. Thank you.

(b) (6)





DEPARTMENT OF HEALTH & HUMAN SERVICES

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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



University of
Pittsburgh

Office of
Research Protections

A3187-9N

*Bill J. Yates, PhD
Vice Chancellor for Research Protections
Professor of Otolaryngology & Neuroscience &
Clinical and Translational Science*

(b) (4) Hieber Building
3500 Fifth Avenue
Pittsburgh, PA 15213
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August 23, 2021

Brent Morse, DVM, DACLAM
NIH Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive – MSC 7982
Bethesda, MD 20892-7982

Dear Dr. Morse:

As the Institutional Official responsible for the University of Pittsburgh's Animal Care and Use Program (Assurance number D16-00118), I am writing to advise your office of a reportable incident¹.

On June 28, 2021, one box containing four adult mice was found in the animal facility without access to water. Three of these mice were deceased upon discovery. The surviving mouse was provided with hydrogel and monitored for twenty-four hours, during which no further issues were evident. The box was changed on June 23 and, given that one mouse survived, a filled water bottle was likely provided at that time and the water was subsequently consumed by the mice over the next few days. As there was no evidence that the water bottle leaked after being provided, there was a period during which the emptied water bottle was not noticed by animal care staff during daily health checks.

The corrective actions taken in these cases consisted of the following item:

- Animal care staff were retrained on how to properly perform food, water and health checks.

The IACUC levied the following sanctions:

- A letter of reprimand was sent to the DLAR Director and his supervisors regarding this event. This letter has been placed in our files.

¹ PHS Policy IV.C.1.d

Brent Morse, DVM, DACLAM
August 20, 2021
Page 2

Please do not hesitate to contact me if you have any questions or concerns.

Sincerely,

 (b) (6)

Bill J. Yates, PhD

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, August 23, 2021 8:04 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: University of Pittsburgh


Thank you for these reports, (b) (6) We will send a response soon.

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

From: (b) (6)
Sent: Monday, August 23, 2021 7:50 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: University of Pittsburgh

Please review the attached correspondence forwarded on behalf of Bill J. Yates, PhD, Vice Chancellor for Research Protections. Thank you.

(b) (6)





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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



University of
Pittsburgh

Office of
Research Protections

A3187-9P

*Bill J. Yates, PhD
Vice Chancellor for Research Protections
Professor of Otolaryngology & Neuroscience &
Clinical and Translational Science*

(b) (4) Hieber Building
3500 Fifth Avenue
Pittsburgh, PA 15213
Phone: (b) (6)
Fax:
Email: vcorp@pitt.edu

December 20, 2021

Brent Morse, DVM, DACLAM
NIH Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive – MSC 7982
Bethesda, MD 20892-7982

Dear Dr. Morse:

As the Institutional Official responsible for the University of Pittsburgh's Animal Care and Use Program (Assurance number D16-00118), I am writing to advise your office of a reportable incident¹.

On October 18, 2021, three boxes containing eight adult mice were found in the animal facility without access to food. Seven of the mice were deceased upon discovery. The surviving mouse was provided with supportive care and was later humanely euthanized by the investigator's laboratory personnel. The investigator's lab personnel did not provide food when the boxes were set up on October 15 and animal facility staff did not detect the lack of food until October 18.

The IACUC approved the animal facility and the investigator's corrective action plans, which included the following items:

1. 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.
2. Since the accidental loss, the investigator has been placing "Recently Weaned" tags on each cage that is weaned.
3. The investigator has created a task checklist, including food supply, for animal breeding work so that tasks aren't missed.
4. The investigator will assign two workers (rather than one) to execute all animal work.

¹ PHS Policy IV.C.1.d

The investigator's research is supported by the following NIH grants:

R01-HL142997-03	Epigenetic Modulation in Septic Immunosuppression
R01-HL149719-02	Role of TACC2 in smoking-induced COPD

The IACUC levied the following sanction:

- A letter of reprimand was sent to the investigator and his supervisors regarding this event. This letter has been placed in our files.

Please do not hesitate to contact me if you have any questions or concerns.

Sincerely,

(b) (6)

Bill J. Yates, PhD

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, December 20, 2021 8:15 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: University of Pittsburgh

Thank you for these reports, (b) (6) We will send responses soon.
Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: (b) (6)
Sent: Monday, December 20, 2021 8:01 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: [EXTERNAL] University of Pittsburgh

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Please review the attached correspondence forwarded on behalf of Bill J. Yates, PhD, Vice Chancellor for Research Protections. Thank you.

(b) (6)



DEPARTMENT OF HEALTH & HUMAN SERVICES

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NATIONAL INSTITUTES OF HEALTH

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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

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



University of
Pittsburgh

Office of
Research Protections

A3187-9Q

Bill J. Yates, PhD
Vice Chancellor for Research Protections
Professor of Otolaryngology & Neuroscience &
Clinical and Translational Science

(b) (4) Hieber Building
3500 Fifth Avenue
Pittsburgh, PA 15213
Phone: (b) (6)
Fax:
Email: vcorp@pitt.edu

February 7, 2022

Brent Morse, DVM, DACLAM
NIH Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive – MSC 7982
Bethesda, MD 20892-7982

Dear Dr. Morse:

As the Institutional Official responsible for the University of Pittsburgh's Animal Care and Use Program (Assurance number D16-00118), I am writing to advise your office of a reportable incident¹.

On Wednesday, December 15, 2021, one box containing five mice was found without access to water. Two of the mice were recently deceased. The other three mice in the box were alive and given fluids and soft food. The next morning two of these mice were found deceased; the cause of death seems to have been the lack of water and stressors related to the experimental procedures.

These mice had undergone an experimental procedure on their bladders on December 13. After the procedure was completed, the box was accidentally placed in a rack not equipped with automatic water and a water bottle was not provided. According to the investigator's protocol, the manipulated mice were to be monitored daily by the investigator's lab personnel.

The IACUC approved the investigator's corrective action plan, which included the following item:

The investigator discussed with each lab member the need to ensure that the animal cages are returned to the correct rack.

The investigator's research is supported by the following NIH grant:

5R01DK119183-03

Role of PIEZO Channels in Bladder Function and
Dysfunction

¹ PHS Policy IV.C.1.d

Brent Morse, DVM, DACLAM
February 7, 2022
Page 2

The IACUC levied the following sanctions:

1. A letter of reprimand was sent to the investigator and his supervisors regarding this event. This letter has been placed in our files.
2. The investigator and laboratory staff will undergo training on animal monitoring.

Please do not hesitate to contact me if you have any questions or concerns.

Sincerely,

 (b) (6)

Bill J. Yates, PhD

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, February 9, 2022 7:19 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Reportable Event Notice

Thank you for this report. We will send a response soon.

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

From: (b) (6)
Sent: Monday, February 7, 2022 9:47 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: [EXTERNAL] Reportable Event Notice

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Please review the attached correspondence forwarded on behalf of Bill J. Yates, PhD, Vice Chancellor for Research Protections. Thank you.

(b) (6)





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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



University of
Pittsburgh

Office of
Research Protections

A3187-98

Bill J. Yates, PhD
Vice Chancellor for Research Protections
Professor of Otolaryngology & Neuroscience &
Clinical and Translational Science

(b) (4) Hieber Building
3500 Fifth Avenue
Pittsburgh, PA 15213
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Fax: (b) (6)
Email: vcorp@pitt.edu

March 4, 2022

Brent Morse, DVM, DACLAM
NIH Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive – MSC 7982
Bethesda, MD 20892-7982

Dear Dr. Morse:

As the Institutional Official responsible for the University of Pittsburgh's Animal Care and Use Program (Assurance number D16-00118), I am writing to advise your office of three similar reportable incidents¹.

Incident 1: On Saturday, December 18, 2021, one box of five mice was found on an autowater rack without a lixit. Three of the mice were found deceased. The surviving two mice were given supportive care. The room underwent a box change on December 13th. The PI has several boxes at any given time in the room for which they disconnect the lixits and supply "special water" in bottles. Animal facility personnel could not determine who moved the box or why the lixit was missing, however, and the technician who changed the room on the previous Monday was certain all lixits were in place. Given the condition of the mice when found, it is estimated they went two days without water.

Incident 2: On Sunday, January 23, 2022, one box of two mice was found on an autowater rack without a lixit. Both mice were found deceased. The room underwent a box change on January 18th and the lixit was present. 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. Animal facility personnel could not determine if or when this happened, however, or when the box was placed in the wrong space. Animal facility technicians missed the missing lixit during two daily room checks.

Incident 3: On Tuesday, January 11, 2022, five boxes of five total mice were found housed in an automatic water rack with the wrong type of box and without access to water. Three of the mice, each in a different box, were found deceased. The animal facility in question has two types of housing boxes that look very similar. One type is a flat grommet and the other is a deep grommet box. They are kept in separate corridors. Five of the deep grommet boxes were mistakenly sent to a flat grommet corridor. The PI staff did not notice the difference and housed mice in the wrong boxes. It was not caught during the daily room checks.

¹ PHS Policy IV.C.1.d

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).

The IACUC levied the following sanction:

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

Please do not hesitate to contact me if you have any questions or concerns.

Sincerely,

 (b) (6)

Bill J. Yates, PhD

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, March 7, 2022 7:15 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Reportable Event Notices

Thank you for these reports. We will send responses soon.

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

From: (b) (6)
Sent: Sunday, March 6, 2022 8:41 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: [EXTERNAL] Reportable Event Notices

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Please review the attached correspondence forwarded on behalf of Bill J. Yates, PhD, Vice Chancellor for Research Protections. Thank you.

(b) (6)





DEPARTMENT OF HEALTH & HUMAN SERVICES

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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

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



University of
Pittsburgh

Office of
Research Protections

A3187-9W

Bill J. Yates, PhD
Vice Chancellor for Research Protections
Professor of Otolaryngology & Neuroscience &
Clinical and Translational Science

(b) (4) Hieber Building
3500 Fifth Avenue
Pittsburgh, PA 15213
Phone: (b) (6)
Fax: (b) (6)
Email: vcorp@pitt.edu

May 2, 2022

Brent Morse, DVM, DACLAM
NIH Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive – MSC 7982
Bethesda, MD 20892-7982

Dear Dr. Morse:

As the Institutional Official responsible for the University of Pittsburgh's Animal Care and Use Program (Assurance number D16-00118), I am writing to advise your office of two similar reportable incidents¹.

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.

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.

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.

¹ PHS Policy IV.C.1.d

Brent Morse, DVM, DACLAM

May 2, 2022

Page 2

Please do not hesitate to contact me if you have any questions or concerns.

Sincerely,

 (b) (6)

Bill J. Yates, PhD

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, May 6, 2022 7:47 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Reportable Event Notice

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

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

From: (b) (6)
Sent: Wednesday, May 4, 2022 1:38 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: [EXTERNAL] Reportable Event Notice

Please review the attached correspondence forwarded on behalf of Bill J. Yates, PhD, Vice Chancellor for Research Protections. Thank you.

(b) (6)

A large rectangular area of the document is completely redacted with a solid grey fill. The redaction covers the majority of the lower half of the page.

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