



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 1, 2021

Re: Animal Welfare Assurance
#A3437-01 (OLAW Case 1H)

Dr. Chris King
Vice President for Research
University of Georgia
(b) (4) Tucker Hall
310 East Campus Road
Athens, GA 30602

Dear Dr. King,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 21, 2021 letter from the University of Georgia in response to the May 14, 2021 letter sent from this Office.

This letter contains the final report regarding ferrets that did not recover from anesthesia during a procedure. In summary, a research lab anesthetizing ferrets with isoflurane to perform approved procedures resulted in a ferret not recovering from anesthesia. The same research lab had a similar incident one month later with another ferret not recovering from anesthesia. Also, a different research lab anesthetizing ferrets under similar conditions had 2 ferrets fail to recover from anesthesia. This update provides a description of the completed corrective action plan developed by the IACUC to address the matter. The plan is described as the following:

- The laboratory animal veterinarian reviewed the incidents and retrained the researchers involved with the events (completed November 4, 2020).
- The laboratory animal veterinarian assessed for competency all researchers in these 2 laboratories who perform inhalant anesthesia with ferrets (completed December 10, 2020).
- The laboratory veterinarians developed written guidance regarding inhalational anesthesia of ferrets, in consultation with veterinary anesthetists. The guidance was reviewed, and endorsed by, the IACUC at its June 16th meeting. The guidelines will be distributed and posted on the IACUC website (completed, June 16, 2021).

The report states the IACUC reviewed the matter at the meeting on June 16th and determined the responses to the remedial action plan as adequate, and consider the matter resolved.

It is noted that this project is supported by HHS and NIH funds. Based on its assessment of this explanation, OLAW understands that the University of Georgia 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. King
July 1, 2021
OLAW Case A3437-1H

Sincerely,
Jacquelyn T.
Tubbs -S

Digitally signed by Jacquelyn T.
Tubbs -S
Date: 2021.07.01 13:57:51
-04'00'

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

cc: IACUC Contact
Robert M. Gibbens, DVM, Director, Animal Welfare Operations



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Office of Research

Research Integrity and Safety

June 21, 2021

Brent Morse, D.V.M.
Acting Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892-6910

RE: University of Georgia, PHS Assurance Number: D16-00276/A3437-01

Dear Dr. Morse,

I am writing to provide a final report of a serious deviation from the PHS Policy that was reported to OLAW in a preliminary report on November 23, 2020, with a follow up report on May 4, 2021. The deviation was related to ferrets that did not recover from anesthesia during a procedure.

This work is covered by an IACUC approved protocol and funded by 2 HHS contracts: HHS Contract # 75N93019C00052 and NIAID CEIRS Contract # HHSN272201400004C.

The IACUC had developed a remedial action plan to address the issue, and all 3 items have been completed. We have had no further incidents of this type.

- Action 1 (completed Nov.4, 2020): The laboratory animal veterinarian reviewed the incidents and retrained the researchers involved with the events.
- Action 2 (completed Dec. 10, 2020): The laboratory animal veterinarian assessed for competency all researchers in these 2 laboratories who perform inhalant anesthesia with ferrets.
- Action 3 (completed, June 16): The laboratory veterinarians developed written guidance regarding inhalational anesthesia of ferrets, in consultation with veterinary anesthetists. The guidance was reviewed, and endorsed by, the IACUC at its June 16 meeting. The guidelines will be distributed and posted on the IACUC website.

At its scheduled meeting on June 16, the IACUC discussed the matter, determined that the responses to the remedial action plan were adequate, and consider this event resolved.

The University of Georgia is committed to a high-quality animal care and use program and the welfare of animals used in instruction and research. We take very seriously our institutional responsibility for the evaluation, monitoring, reporting, and correction of our animal care and use program that is the foundation of the PHS Policy. Please contact me if further information or additional corrective actions are needed.

Sincerely,

(b) (6)

Christopher S. King, DVM, DACLAM
Associate Vice President for Research Integrity and Safety
Interim Institutional Official

Cc: Dr. Leanne Alworth, Attending Veterinarian

Dr. Gaylen Edwards, IACUC Chair

(b) (6)

Dr. Ted Ross, Director, Center for Vaccines and Immunology

(b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, June 23, 2021 7:03 AM
To: Leanne Alworth
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Final Report from UGA

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

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

From: Leanne Alworth <alworth@uga.edu>
Sent: Monday, June 21, 2021 2:36 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Christopher King <cking@uga.edu>; Gaylen L Edwards <gedwards@uga.edu>; (b) (6) Ted Ross <tedross@uga.edu>; (b) (6)
Subject: Final Report from UGA

Hello,

Thank you for your patience as we completed the actions related to a previous incident. Please see the attached final report, and let me know if there are any questions.

Thank you,
Leanne

Leanne Alworth, DVM, MS, DACLAM
Attending Veterinarian | Animal Care and Use
Office of Research | University of Georgia
(b) (4) Tucker Hall, 310 East Campus Road, Athens, GA 30602
Office: (b) (6) | Fax: (b) (6)
alworth@uga.edu | <http://research.uga.edu>



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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

May 14, 2021

Re: Animal Welfare Assurance
#A3437-01 (OLAW Case 1H)

Dr. David C. Lee
Vice President for Research
University of Georgia
(b) (4) Paul D. Coverdell Center for
Biomedical and Health Sciences
Athens, GA 30602

Dear Dr. Lee,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 4, 2021 interim report of an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Georgia following up on an initial November 23, 2020 notification by email.

According to the information provided, this Office understands that the University of Georgia Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: ferrets that did not recover from anesthesia during a procedure. The initial report stated a research lab anesthetizing ferrets with isoflurane to perform procedures resulted in a ferret not recovering from anesthesia. The same research lab had a similar incident occur again one month later with another ferret not recovering from anesthesia. The report also stated that a different research lab anesthetizing ferrets under similar conditions had 2 ferrets fail to recover from anesthesia. It is noted that this research is supported by HHS and NIH funding sources.

Per the interim report the IACUC developed the following corrective action plan:

- The laboratory animal veterinarian reviewed the incidents and retrained the researchers involved with the events. This action was completed on November 4, 2020.
- The laboratory animal veterinarian assessed for competency all researchers in these 2 laboratories who perform inhalant anesthesia with ferrets. This action was completed on December 10, 2020.
- The laboratory veterinarians will develop written guidance regarding inhalational anesthesia of ferrets, in consultation with veterinary anesthetists. The guidance will be reviewed, and endorsed by, the IACUC. The IACUC will then require all research laboratories to follow the guidelines. We anticipate these guidelines will be available for the IACUC to review and endorse at the regularly scheduled June 16 meeting.

Thank you for the interim report, as a reminder all final reports must be signed or acknowledged by the Institutional Official. This Office looks forward to receiving the final report related to these incidents.

Page 2 -- Dr. Lee
May 14, 2021
OLAW Case A3437-1H

Sincerely,
Jacquelyn T.
Tubbs -S
Jacquelyn T. Tubbs, DVM, DACLAM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

Digitally signed by Jacquelyn T.
Tubbs -S
Date: 2021.05.14 10:26:27 -04'00'

cc: IACUC Contact
Robert M. Gibbens, DVM, Director, Animal Welfare Operations



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Office of Research
Animal Care and Use

May 4, 2021

Brent Morse, D.V.M.
Acting Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892-6910

RE: University of Georgia, PHS Assurance Number: D16-00276/A3437-01

Dear Dr Morse,

I am writing to provide an update of a serious deviation from the PHS Policy that was reported to OLAW in a preliminary report on November 23, 2020. The deviation was related to ferrets that did not recover from anesthesia during a procedure.

This work is covered by an IACUC approved protocol and funded by 2 HHS contracts: HHS Contract # 75N93019C00052 and NIAID CEIRS Contract # HHSN272201400004C.

The IACUC had developed a remedial action plan to address the issue, and items 1 and 2 of the 3 items have been completed. We have had no further incidents of this type.

- Action 1 (completed Nov.4, 2020): The laboratory animal veterinarian reviewed the incidents and retrained the researchers involved with the events.
- Action 2 (completed Dec. 10, 2020): The laboratory animal veterinarian assessed for competency all researchers in these 2 laboratories who perform inhalant anesthesia with ferrets.
- Action 3 (pending, ETA June 16): The laboratory veterinarians will develop written guidance regarding inhalational anesthesia of ferrets, in consultation with veterinary anesthetists. The guidance will be reviewed, and endorsed by, the IACUC. The IACUC will then require all

research laboratories to follow the guidelines. We anticipate these guidelines will be available for the IACUC to review and endorse at the regularly scheduled June 16 meeting.

The University of Georgia is committed to a high-quality animal care and use program and the welfare of animals used in instruction and research. We take very seriously our institutional responsibility for the evaluation, monitoring, reporting, and correction of our animal care and use program that is the foundation of the PHS Policy. Please contact me if further information or additional corrective actions are needed.

Sincerely,

(b) (6)

Leanne Alworth, DVM, MS, DACLAM
Attending Veterinarian
Professor, Department of Population Health, College of Veterinary Medicine

Cc: Dr. David C. Lee, Vice President for Research, Institutional Official

(b) (6)

Dr. Ted Ross, Director, Center for Vaccines and Immunology

(b) (6)

Dr. Gaylen Edwards, IACUC Chair

(b) (6)

Tubbs, Jai (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, May 4, 2021 11:28 AM
To: Leanne Alworth; OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b) (6) Gaylen L Edwards; (b) (6) Ted Ross; (b) (6) David C Lee; (b) (6) Mary Ann Mccrackin
Subject: RE: report of unexpected ferret deaths

Good morning!

Thank you for the interim report. I will send an official response to the interim report soon, and will be on the lookout for the final report around sometime in June.

Kind Regards,

J Tubbs

From: Leanne Alworth <alworth@uga.edu>
Sent: Tuesday, May 4, 2021 9:09 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) Gaylen L Edwards <gedwards@uga.edu>; (b) (6) Ted Ross <tedross@uga.edu>; (b) (6) David C Lee <dclee@uga.edu>; (b) (6) Mary Ann Mccrackin <MA.McCrackin@uga.edu>
Subject: RE: report of unexpected ferret deaths

Good morning, Dr Tubbs,

As requested, attached is an interim report regarding the deviation that we reported to OLAW in November. We anticipate that the final report will be provided to you in June.

Please let me know if you have any questions in the meantime.

Thanks
Leanne

Leanne Alworth, DVM, MS, DACLAM
Attending Veterinarian | Animal Care and Use
Office of Research | University of Georgia
(b) (4) Tucker Hall, 310 East Campus Road, Athens, GA 30602
Office: (b) (6) | Fax: (b) (6)
alworth@uga.edu | <http://research.uga.edu>

From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Sent: Monday, May 3, 2021 9:24 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Leanne Alworth <alworth@uga.edu>
Subject: RE: report of unexpected ferret deaths

[EXTERNAL SENDER - PROCEED CAUTIOUSLY]

Good morning Dr. Alworth,

Can you provide an interim or final report on the matter described below? Please let me know when you can.

Kind Regards,

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

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: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Sent: Friday, November 27, 2020 7:41 AM
To: Leanne Alworth <alworth@uga.edu>
Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: RE: report of unexpected ferret deaths

Thank you for this preliminary report, Dr. Alworth. I will start a new case file and look forward to receiving the final report from the IO after the IACUC has completed its investigation. You may wish to call your USDA VMO and alert them of this issue.

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

From: Leanne Alworth <alworth@uga.edu>
Sent: Wednesday, November 25, 2020 2:29 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: David C Lee <dclee@uga.edu>; (b) (6) Ted Ross <tedross@uga.edu>; (b) (6) Gaylen L Edwards <gedwards@uga.edu>; (b) (6) Eric N Smith <smitty8@uga.edu>
Subject: report of unexpected ferret deaths

Hello

Please find attached a preliminary report from UGA regarding some unexpected deaths of ferrets under anesthesia. The report explains how our program is actively working to minimize the chances of this occurring in the future.

Please let me know if you have any questions.

Thanks
Leanne

Leanne Alworth, DVM, MS, DACLAM

Attending Veterinarian | Animal Care and Use

Office of Research | University of Georgia

(b) (4) Tucker Hall, 310 East Campus Road, Athens, GA 30602

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Office of Research
Animal Care and Use

November 23, 2020

Brent Morse, D.V.M.
Acting Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892-6910

RE: University of Georgia, PHS Assurance Number: D16-00276/A3437-01

Dear Dr Morse,

I am writing to provide a preliminary report of recent events in which ferrets died under anesthesia. One research lab anesthetizing ferrets with isoflurane to perform procedures had a ferret not recover from anesthesia. A month later, the lab had another ferret fail to recover from isoflurane anesthesia. In addition, another research lab anesthetizing ferrets under similar conditions had 2 ferrets fail to recover from anesthesia.

This work is covered by 2 HHS contracts:

- HHS contract # 75N93019C00052
- NIAID CEIRS contract # HHSN272201400004C

On September 9, a laboratory animal veterinarian was contacted because an anesthetized ferret had died under anesthesia. The Attending Veterinarian was notified on the same day. The laboratory animal veterinarian reviewed the events with the researchers, and provided guidance for enhancing anesthesia safety. However, on October 20, the research lab lost a second ferret under anesthesia. The laboratory animal veterinarian was notified immediately, and the AV was notified the next day. On October 4, another research lab anesthetizing ferrets for procedures had 2 ferrets die after showing signs of recovery and being placed into their home cages to complete recovery. The laboratory animal veterinarian was notified immediately, and the AV was notified the next day.

*The University of Georgia Animal Care and Use Program is accredited by AAALAC International.
The University of Georgia is an Equal Opportunity, Affirmative Action, Veteran, Disability Institution.*



The IACUC was notified about the first event at the regularly scheduled October meeting (10/21), and updated about the later events at the November meeting (11/18).

A remedial action plan has been established to address the issues as follows:

- Action 1 (completed): The laboratory animal veterinarian will review the incidents/retrain the researchers involved with the events. This has occurred (the same day for both events, as well as a week after the second event for the first lab, and on Nov. 4 for the second lab).
- Action 2 (pending): The laboratory animal veterinarian will assess, by observation, all researchers in these 2 labs perform anesthesia with ferrets. The veterinarian will determine if the researcher is competent, or needs additional training. The veterinarian will retrain all researchers who require it.
- Action 3 (pending): The laboratory animal veterinarians will develop written guidance regarding inhalational anesthesia of ferrets, in consultation with veterinary anesthetists. The guidance will be reviewed, and endorsed, by the IACUC. The IACUC will then require all research laboratories to follow the guidance.

The IACUC will be notified about any updates on the remedial plan, at its next scheduled meeting on Dec. 16. Once the remedial action plan is complete, and following this IACUC meeting, a full report with an update on corrective action progress will be forwarded to you.

In the interim, please contact me if you have any questions or if you require additional information.

The University of Georgia is committed to a high-quality animal care and use program and the welfare of animals used in instruction and research. We take very seriously our institutional responsibility for the evaluation, monitoring, reporting, and correction of our animal care and use program that is the foundation of the PHS Policy. Please contact me if further information or additional corrective actions are needed.

Sincerely,

(b) (6)

Leanne Alworth, DVM, MS, DACLAM
Attending Veterinarian
Professor, Department of Population Health, College of Veterinary Medicine

Cc: Dr. David C. Lee, Vice President for Research, Institutional Official

(b) (6)

Dr. Ted Ross, Director, Center for Vaccines and Immunology

(b) (6)

Dr. Gaylen Edwards, IACUC Chair

(b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, November 27, 2020 7:41 AM
To: Leanne Alworth
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: report of unexpected ferret deaths

Thank you for this preliminary report, Dr. Alworth. I will start a new case file and look forward to receiving the final report from the IO after the IACUC has completed its investigation. You may wish to call your USDA VMO and alert them of this issue.

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

From: Leanne Alworth <alworth@uga.edu>
Sent: Wednesday, November 25, 2020 2:29 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: David C Lee <dclee@uga.edu>; (b) (6) Ted Ross <tedross@uga.edu>; (b) (6)
(b) (6) Gaylen L Edwards <gedwards@uga.edu>; (b) (6) Eric N Smith
<smitty8@uga.edu>
Subject: report of unexpected ferret deaths

Hello

Please find attached a preliminary report from UGA regarding some unexpected deaths of ferrets under anesthesia. The report explains how our program is actively working to minimize the chances of this occurring in the future.

Please let me know if you have any questions.

Thanks
Leanne

Leanne Alworth, DVM, MS, DACLAM
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Office of Research | University of Georgia
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