

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

October 10, 2018

FOR EXPRESS MAIL: Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817

Telephone: (301) 496-7163 Facsimile: (301) 402-7065

Re: Animal Welfare Assurance A3216-01 [OLAW Case H]

PUBLIC HEALTH SERVICE

NATIONAL INSTITUTES OF HEALTH

Edmund J. Synakowski, Ph.D. Vice President for Research and Economic Development University of Wyoming 1000 E. University Avenue, Department ^{(b) (4)} Laramie, WY 82071

Dear Dr. Synakowski,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 9, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Wyoming, following up on an initial telephone notification on July 26, 2018. According to the information provided, OLAW understands that veterinary care was not provided to a ewe in poor health due to a failure in notifying the institutional veterinarians. Medical records identified during an unannounced USDA inspection indicated that the animal vomited almost daily from June 4 to June 25, 2018, and the animal was observed to be thin with protruding spine and hip bones. The animal had worn down teeth and was being fed alfalfa pellets separate from the herd. The attending veterinarian examined the animal on this PHS-funded study immediately upon discovery.

The corrective actions consisted of the IACUC issuing a letter of reprimand to the Principal Investigator (PI); conducting in-person retraining of all staff and PIs involved on this project with a reminder to notify the attending veterinarian of any animal welfare concerns; all personnel retaking relevant CITI training inclusive of a signed acknowledgment that the attending veterinarian will be contacted for all animal welfare concerns and the PI establishing a chain of command for reporting animal welfare concerns to include contacting the attending veterinarian as part of his action plan.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct and prevent recurrence of the noncompliance. We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

(b) (6)

Neera V. Gopee, DVM, PhD, DACLAM, DABT Animal Welfare Program Specialist Division of Compliance Oversight Office of Laboratory Animal Welfare

cc: IACUC Chair Dr. Robert M. Gibbens, Director Western Sector, USDA, APHIS, AC

University of Wyoming

Vice President for Research & Economic Development

1000 E. University Avenue, Department 3355 • Room 305/308, Old Main • Laramie, WY 82071 (307) 766-5353 • (307) 766-5320 • fax (307) 766-2608 • www.uwyo.edu/research

October 9, 2018

Neera Gopee, DVM, PhD Division of Compliance Oversight Office of Laboratory Animal Welfare National Institutes of Health 6700B Rockledge Drive, Suite 2500, MSC 6910 Bethesda, MD 20892

Dear Dr. Gopee:

The University of Wyoming, in accordance with Assurance A3216-01 and PHS Policy IV.F.3., provides this report of noncompliance regarding an incident with an emaciated and vomiting sheep funded by NIH RO1HD070096-01A1 on the approved IACUC protocol entitled "Impact of maternal obesity on cardiovascular function of daughters, granddaughters, and great – granddaughters." This incident was first reported to Dr. Neera Gopee, OLAW, on July 26, 2018 via a telephone call by Carolyn Broccardo, Ph.D., Director Research Integrity & Compliance at UW.

On July 10, 2018 UW received an unannounced inspection from USDA-APHIS. It was found in the written daily observations that ewe #7070 had been vomiting almost on a daily basis between 6/4 and 6/25, 2018. A sheep facility representative informed the APHIS inspector that they had been feeding her alfalfa pellets separately from the herd, as she was very thin and her teeth were worn down. It was stated that she had not been seen by a veterinarian recently. On inspection, APHIS inspector observed that ewe #7070 was thin, and her spine and hip bones were protruding. The attending veterinarian stated that neither they nor the other veterinarian on staff had examined the sheep. Immediately, the attending veterinarian provided a veterinary consultation for the sick animal, and remains in contact with the research group regarding the health of the sheep.

The IACUC and the Research Office discussed the incident and agreed upon a corrective action plan. The PI expressed remorse for this incident and took responsibility for the noncompliance. The PI assured the IACUC that an incident of such nature would not occur again. The IACUC determined that this was an isolated incident and not a programmatic failure.

The following corrective action plan was implemented after the incident:

1. The PI submitted multiple correspondence to the IACUC and Research Office stating his commitment to proper animal welfare and husbandry and expressed remorse for this incident.

- 2. The IACUC and Research Office submitted a formal letter of reprimand to the PI outlining the severity of this situation on August 21, 2018.
- 3. In close collaboration with the IACUC, the Research Office conducted face-to-face retraining of all personnel and PIs on this project on September 11, 2018. Personnel were reminded of their responsibility to contact the attending veterinarian with any animal welfare concern. All personnel were required to retake the relevant CITI online training, and all signed an assurance that they will contact the attending veterinarian with any animal welfare concerns.
- 4. The PI described corrective measures that have been implemented to prevent recurrence of an incident of this nature. The measures include implementing a clear chain of command for reporting animal welfare concerns, including contacting the attending veterinarian.

At their meeting on July 31, 2018 the IACUC also reviewed and accepted the corrective action plan as recommended by the IACUC and Research Office.

The University of Wyoming is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact Carolyn Broccardo, PhD, Director Research Integrity & Compliance.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Edmund Synakowski, PhD Vice President for Research & Economic Development Institutional Official University of Wyoming

Gopee, Neera (NIH/OD) [E]

From: Sent: To: Cc: Subject: Gopee, Neera (NIH/OD) [E] Tuesday, October 09, 2018 2:32 PM 'Carolyn Broccardo' (b) (6) RE: Close Out Letter

Thank you for this final report Dr. Broccardo. We will send an official response soon.

Best Regards, Neera

Neera V. Gopee, DVM, PhD, DACLAM, DABT Veterinary Medical Officer 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: Carolyn Broccardo [mailto:Carolyn.Broccardo@uwyo.edu] Sent: Tuesday, October 09, 2018 2:23 PM To: Gopee, Neera (NIH/OD) [E] <neera.gopee@nih.gov> Cc: (b) (6)

Subject: Close Out Letter

Dear Dr. Gopee,

Please find the attached closeout letter for a case we discussed over the phone in July.

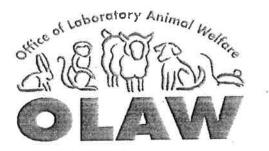
Please let me know if you need any additional information.

Have a great day,

Carolyn Broccardo, Ph.D., PMP Office of Research & Economic Development Director of Research Integrity & Compliance University of Wyoming, Old Main ^{(b) (4)}

Carolyn.Broccardo@uwyo.edu

A32.16 - H



Initial Report of Noncompliance

By: Neara Guges

Date: 7-26-18

Time: 2:57 pm

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Name of Person reporting: Carolyn broccardo (b) (6) Telephone #: Fax #: Email:

Name of Institution: University 02 Wywary Assurance number: A3216-61

Did incident involve PHS funded activity? <u>Jes</u> (NIH ROI GHD070096-01AI) Funding component: Was funding component contacted (if necessary): _____

An 11 yr old slace had been variety frequetty down the period By 11 yr old slace had been variety frequetty and to offer the B Juie 4-25th, 2018 but facility marger failed to offer the

What happened?

Species involved: shear Personnel involved: Dates and times: Animal deaths:

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Projected plan and schedule for correction/prevention (if known): ____ Intorny spect to rotey betwinenen is any issues or centers

is gestion

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY Case #