



DEPARTMENT OF HEALTH & HUMAN SERVICES

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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

April 26, 2019

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

Dr. Edmund Synakowski
Vice President for Research
and Economic Development
University of Wyoming
1000 E. University Avenue – Dept. 3355
Laramie, WY 82071-3355

Dear Dr. Synakowski,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 15, 2019 letter responding to my April 8, 2019 request for additional information regarding a suspension of animal activities at the University of Wyoming. According to the information provided, OLAW understands the following:

- 1) The Attending Veterinarian (AV) noted several problems in a laboratory conducting rat surgery including inadequate surgical recordkeeping, protocol deviations involving anesthetics/analgesics, failure to use aseptic technique and sterilize equipment, and inadequate conditions for rats recovering from surgery. All of the investigator's protocols were suspended by the Institutional Animal Care and Use Committee (IACUC), including one NIH-supported one.
- 2) NIH had not been notified about the suspension because the problems found in the laboratory were not associated with the NIH supported protocol.*
- 3) Monthly post-approval monitoring by the AV subsequently found that all deficiencies had been corrected and that no new problems had occurred.
- 4) All laboratory staff has been retrained on aseptic technique and surgery. No new surgeries have been conducted since the suspension, but once they resume the AV will observe the staff for proficiency. Records will also be audited monthly by the AV.

Based on its assessment of these explanations, OLAW has a better understanding of the original deficiencies which prompted the suspension as well as the measures taken to correct and prevent recurrence. OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. *Please note that the NIH funding component must be notified of the suspension even if the supported protocol did not have any animal welfare problems. Suspension constitutes a serious institutional/IACUC action and requires reporting to OLAW, USDA (if covered species are involved), and any federal agency funding the activity. Thank you for keeping OLAW apprised on this matter.

Page 2 – Dr. Synakowski
April 26, 2019
OLAW Case A3216-J

Sincerely,

(b) (6)

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

cc: IACUC Chair

UNIVERSITY OF WYOMING

Office of
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April 15, 2019

Axel Wolff, MS, DVM
Deputy Director
Office of Laboratory Animal Welfare
National Institutes of Health
BG 6700B Rm 2528
6700B Rockledge Drive
Bethesda, MD 20817

Dear Dr. Wolff:

The University of Wyoming has received your April 8, 2019 letter regarding Animal Welfare Assurance A3216-01 [OLAW Case J] and the request for additional information. We are happy to clarify on the points highlighted herein.

1. Describe the initial noncompliance noted by the AV which led to the protocol suspension.

The researcher contacted the AV for a refill of medications on one of their protocols. The AV decided to stop by to drop off the medication and pay a site visit at the lab. Upon arriving, the AV noted immediate and serious concerns, including: poor documentation of surgical procedures and related animal welfare record keeping; protocol deviations related to techniques as well as analgesic and anesthetic usage; improper or insufficient aseptic techniques and equipment sterilization; and insufficient recovery conditions for rats recovering from surgery. These collective errors and oversights were brought to the attention of the IACUC who determined that the best course of action was to suspend all rat protocols by the investigator until sufficient appropriate steps could be taken to remedy all of these issues. While several protocols were suspended, only one was NIH-funded, but there were no direct animal welfare concerns found on that protocol.

2. Indicate whether the suspension was reported to the NIH funding component.

Because none of the aforementioned violations were directly associated with the NIH-funded protocol, neither NIH nor INBRE were formally notified following the discovery, ruling, and follow-through made by the IACUC, aside from our OLAW reporting.

3. Provide an update on the findings of the PAM visit.

The AV has made random monthly inspections of the laboratory and surgical areas to ensure that all noted deficiencies have been corrected and continue to meet IACUC's expectations. So far, all requested improvements have been made and the AV has not found any signs of recidivism.

4. Provide an assessment of the current proficiency of the research staff and the quality of the record keeping.

All lab personnel have attended a supplemental training session on aseptic technique and the surgeries utilized in their lab. This session was taught by a highly-qualified MD/PhD from another lab group, and the training was observed by the AV. To date, no surgical procedures have occurred since the suspension, so no observation of surgeries by the AV have taken place to evaluate the additional training that the researcher and their lab personnel have taken to improve surgical technique and/or monitoring. When the researcher begins performing surgeries again, the AV will observe until the IACUC is satisfied that procedures are conducted following AVMA guidelines and as trained during the remediation. Monthly inspections of the breeding and lab notebooks have been carried out by the AV to ensure accurate and regular recordkeeping of animal care activities, as well as adequate PI oversight of records. The research staff has greatly improved their recordkeeping, and the AV will continue to frequently monitor this until the IACUC is satisfied

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that these improvements have become routine and expected, after which the AV will return to their regular monthly inspection.

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 of Research Integrity & Compliance.

Thank you for your consideration of this manner.

Sincerely,

(b) (6)

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

Wolff, Axel (NIH/OD) [E]

From: Ward, Joan (NIH/OD) [E]
Sent: Thursday, April 25, 2019 6:30 AM
To: Wolff, Axel (NIH/OD) [E]
Subject: FW: OLAW Case A3216-J
Attachments: Signed IACUC letter- Wolf.pdf

FYI

From: Carolyn Broccardo <Carolyn.Broccardo@uwyo.edu>
Sent: Wednesday, April 24, 2019 5:14 PM
To: Ward, Joan (NIH/OD) [E] <wardjoa@od.nih.gov>
Cc: Institutional Animal Care and Use Committee <iacuc@uwyo.edu>; (b) (6)
Subject: RE: OLAW Case A3216-J

Hi Joan,

Attached is the signed response letter as requested below. Please let us know if you need anything further.

Carolyn Broccardo, Ph.D., PMP
Office of Research & Economic Development
Director of Research Integrity & Compliance
Research Integrity Officer
University of Wyoming, Bureau of Mines, (b) (4)

(b) (6)

Carolyn.Broccardo@uwyo.edu

From: Ward, Joan (NIH/OD) [E] <wardjoa@od.nih.gov>
Sent: Thursday, April 11, 2019 7:25 AM
To: Edmund J. Synakowski <esynakow@uwyo.edu>
Cc: Institutional Animal Care and Use Committee <iacuc@uwyo.edu>
Subject: OLAW Case A3216-J

◆ This message was sent from a non-UWYO address. Please exercise caution when clicking links or opening attachments from external sources.

Dear (b) (6)

Attached please find Dr. Axel Wolff's initial response to OLAW Case A3381-2J.

If you have any questions, feel free to contact us by phone or by e-mail.

Regards,
Joan

*Joan Ward
Program Specialist
Office of Laboratory Animal Welfare
National Institutes of Health*

6705 Rockledge Dr., Suite 360
Bethesda, MD 20892
301-496-7163
wardjoa@od.nih.gov



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April 8, 2019

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

Dr. Edmund Synakowski
Vice President for Research
and Economic Development
University of Wyoming
1000 E. University Avenue – Dept. 3355
Laramie, WY 82071-3355

Dear Dr. Synakowski,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 12, 2019 letter reporting the suspension of specific animal activities at the University of Wyoming, following up on an initial telephone report on November 1, 2018. According to the information provided, OLAW understands that the Institutional Animal Care and Use Committee (IACUC) took this action following a report of concerns by the veterinarian regarding some rat studies.

In addition to the suspension, the IACUC required hands-on and online retraining of the laboratory staff. The laboratory was placed on enhanced post-approval monitoring (PAM), the IACUC reviewed animal care records and will audit these monthly, the Attending Veterinarian (AV) will observe surgeries and euthanasia, and the AV will assess surgical proficiency when new procedures are planned.

In order for OLAW to have a complete understanding of the facts in this case, please provide the following additional information:

- 1) Describe the initial noncompliance noted by the AV which led to the protocol suspension.
- 2) Indicate whether the suspension was reported to the NIH funding component.
- 3) Provide an update on the findings of the PAM visit.
- 4) Provide an assessment of the current proficiency of the research staff and the quality of the record keeping.

Please provide the requested information by **April 29, 2019**.

Sincerely,

(b) (6)

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

cc: IACUC Chair

UNIVERSITY OF WYOMING

Office of Research Economic Development

Research Integrity and Compliance

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March 12, 2019

Brent Morse, DVM, DACLAM
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. Morse:

The University of Wyoming, in accordance with Assurance D16-00135 (A3216-01) and PHS Policy IV.F.3., provides this report of noncompliance regarding an incident funded on NIH NIGMS Wyoming INBRE 2P20GM103432-17 (Project date September 10, 2018 to April 30, 2019). This incident was reported to you via phone on November 1, 2018 by Dr. Carolyn Broccardo, Director of Research Integrity and Compliance at UW. Below is a summary of the situation.

A researcher contacted the UW attending veterinarian (AV) for a refill of medications on a different protocol. The AV decided to stop by the laboratory and noted several concerns. Based on these concerns, the IACUC decided to suspend all protocols by the PI involving rats. One of the suspended protocols was NIH-funded, but there were no direct animal welfare concerns found on this protocol.

- Species: *Rattus norvegicus*
- Category of personnel involved: Faculty, graduate student
- Dates: Fall 2018
- Animal deaths: 0

The IACUC and the UW 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 and 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 has been completed:

1. All lab personnel associated with animal work on the affected protocol took a hands-on workshop in general rodent research techniques and surgery, which was accompanied by the AV.
2. All personnel re-took the relevant CITI courses, including: Working with the IACUC, Aseptic Surgery, Post Approval Monitoring, Working with Mice in Research, Working with Rats in Research, and Working with Sheep and Goats in Research Settings.

The following corrective action plan will continue to be upheld:

1. Monthly and random lab inspections of laboratory and surgical area by representatives of the IACUC.
2. Initial review by representatives of the IACUC of all laboratory and animal care records to ensure appropriate record keeping for all animal records including procedures, observations, and animal care.
3. Monthly audit of all animal records including breeding and lab notebooks to ensure accurate and regular recording of animal care activities and procedures, and adequate PI oversight of recordkeeping.
4. The UW AV will attend and initially observe all surgical procedures to ensure that American Veterinary Medical Association-approved procedures are practiced. The AV will attend

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any animal surgeries, procedures, or euthanasia until the AV and/or the IACUC determine that regular observation is no longer required for each technique.

5. Before implementing any surgical procedure for the PI or personnel, proper evidence of training for the procedure and demonstrated competence must be given to the AV and/or IACUC.

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 of Research Integrity & Compliance

Thank you for your consideration of this manner.

Sincerely,

(b) (6)

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

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Monday, March 25, 2019 12:32 PM
To: (b) (6)
Cc: Carolyn Broccardo
Subject: RE: University of Wyoming Noncompliance Situation Closeout

Thank you for providing this final report (b) (6). We will send an official response soon.

Best regards, Brent Morse

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

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From: (b) (6)
Sent: Thursday, March 21, 2019 5:02 PM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Cc: Carolyn Broccardo <Carolyn.Broccardo@uwyo.edu>
Subject: University of Wyoming Noncompliance Situation Closeout

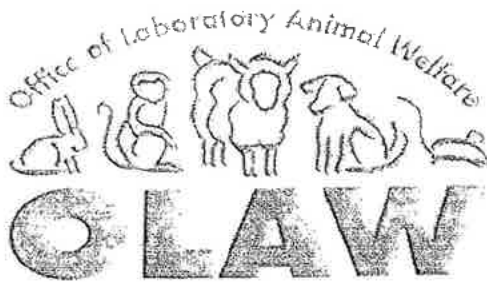
Dr. Morse-

I hope this email finds you well. I'm the new (b) (6) at the University of Wyoming. We have recently completed the corrective measures for a self-reported noncompliance concern, and the attached document is our closeout of the situation. Should you have any questions, please do not hesitate to contact Dr. Carolyn Broccardo, Director of Research Integrity and Compliance.

Have a wonderful day.

(b) (6)

(b) (6)



Initial Report of Noncompliance

By: BMDate: 11/1/18Time: 11:45Name of Person reporting: Caroline BroccardoTelephone #: (b) (6)

Fax #:

Email:

Name of Institution: U. of WyomingAssurance number: A3216Did incident involve PHS funded activity? Yes NIGMS INBRE grant
P20GM103432-17

Funding component: _____

Was funding component contacted (if necessary): Will be

What happened? IACUC suspended all rat protocols for PI even though no non-compliance was associated with this one NIH-funded protocol.

Species involved: Rat Vet concerns related to

Personnel involved: PI other protocols.

Dates and times: Late October 2018

Animal deaths: No

Projected plan and schedule for correction/prevention (if known): _____

Funding component will be notified of suspension.

Projected submission to OLAW of final report from Institutional Official:

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Case # _____