



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

February 13, 2019

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

Dr. Edmund Synakowski
Vice President for Research
and Economic Development
University of Wyoming
1000 E. University Avenue – (b) (4)
Laramie, WY 82071-3355

Dear Dr. Synakowski,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 8, 2019 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 report on October 8, 2018. According to the information provided, OLAW understands that a significant change was made to a protocol without prior approval from the Institutional Animal Care and Use Committee (IACUC). Specifically, mice were given intraperitoneal (IP) injections of vinyl chloride rather than receiving the compound by aerosolization as described in the protocol. After the experimental compound was no longer available from the manufacturer, the Principal Investigator (PI) mixed polyvinyl chloride with diluents and injected four mice by the IP route, after which one animal died. The PI discovered that the mixture did not produce vinyl chloride. Also, the PI failed to submit an annual protocol continuing review.

The corrective actions consisted of retraining the PIs involved and submitting a new protocol. No animal activities will be conducted until the protocol is approved by the IACUC.

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 having been informed about this matter and find no cause for further action by this Office.

Sincerely,

(b) (6)

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

cc: IACUC Chair

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

February 8, 2019

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 (D16-00135) and PHS Policy IV.F.3., provides this report of noncompliance regarding an incident funded on INBRE GMS 2P20GM103432, Sub-award 1003088Z (Award date December 14, 2016-April 30, 2018). This incident was reported to you via email on October 8, 2018 by Dr. Carolyn Broccardo, Director of Research Integrity and Compliance at UW. Below is a summary of the situation.

Two faculty collaborators were working on an INBRE funded sub-award. The PI works at Western Wyoming Community College (WWCC; listed under the UW Assurance listed above), and the collaborator is at University of Wyoming. The sub-award was to study the effects of aerosolized vinyl chloride in *Mus musculus*. However, the device to aerosolize the vinyl chloride was not functional, so the collaborators decided to switch to using IP injections, but neglected to contact the IACUC to submit an amendment for this change in procedure. The PI at UW proceeded to inject mice with vinyl chloride. Subsequently, the Sigma product # for vinyl chloride was discontinued, so the PI at WWCC could not purchase the same product that their collaborator was using at UW. Confusion ensued, and the PI at WWCC ended up purchasing polyvinyl chloride. They thought that this would be converted into vinyl chloride upon forming a suspension with DMSO and PBS. They then proceeded to perform IP injections on 4 mice in late 2017 or early 2018 with the polyvinyl chloride suspension. One mouse was found dead in a cage after receiving this injection. After later consultation with a chemist, the WWCC PI realized that he had purchased polyvinyl chloride, which is not converted into vinyl chloride upon forming a suspension. The PIs realized that there was confusion in the products delivered to the mice starting in late summer 2018. It appears that the PI at UW injected vinyl chloride, and the PI at WWCC injected polyvinyl chloride. The collaborators then contacted the Chair of the IACUC to discuss what happened in mid-September. During this time frame the PI also forgot to submit an annual continuing review for their protocol.

- o Species: *Mus musculus*
- o Category of personnel involved: Faculty, graduate student
- o Dates: Fall 2017-Spring 2018
- o Animal deaths: 1

The IACUC and the Research Office discussed the incident and agreed upon a corrective action plan. The PI's 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) Both PI's re-took the appropriate CITI training modules
- 2) They have submitted a new IACUC protocol for this research project
- 3) They will not conduct any research until they have received IACUC approval

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: Gopee, Neera (NIH/OD) [E]
Sent: Tuesday, February 12, 2019 4:28 PM
To: 'Carolyn Broccardo'
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Closeout Report

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

Best Regards,
Neera

Neera V. Gopee, DVM, PhD, DABT, DAACLAM
Acting Director, Division of Policy and Education
Office of Laboratory Animal Welfare, NIH
6700B Rockledge Drive
Bethesda, MD 20892-6910
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gopeenv@od.nih.gov

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From: Carolyn Broccardo <Carolyn.Broccardo@uwyo.edu>
Sent: Tuesday, February 12, 2019 3:00 PM
To: Gopee, Neera (NIH/OD) [E] <neera.gopee@nih.gov>
Subject: Closeout Report

Dear Dr. Gopee,

I am attaching a signed closeout report for your review. Please let me know if you need any further information.

Have a good day,

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

10/8/2018

OLAW Preliminary Report for Noncompliance

- Name and contact information of person reporting: Carolyn Broccardo, (b) (6)
- (b) (6)
- Name of institution: University of Wyoming (UW)
- Assurance number: D16-00135 (A3216-01)
- Funding component:
 - INBRE GMS 2P20GM103432
 - Sub-award 1003088Z
 - Award date: December 14, 2016 - April 30, 2018
 - PI of INBRE grant will contact the program officer

Brief description of incident (e.g., species, category of personnel involved, dates, times, animal deaths):

Two faculty collaborators were working on an INBRE funded sub-award. The PI works at Western Wyoming Community College (WWCC; listed under the UW Assurance listed above), and the collaborator is at University of Wyoming. The sub-award was to study the effects of aerosolized vinyl chloride in *Mus musculus*. However, the device to aerosolize the vinyl chloride was not functional, so the collaborators decided to switch to using IP injections, but neglected to contact the IACUC to submit an amendment for this change in procedure. The PI at UW proceeded to inject mice with vinyl chloride. Subsequently, the Sigma product # for vinyl chloride was discontinued, so the PI at WWCC could not purchase the same product that their collaborator was using at UW. Confusion ensued, and the PI at WWCC ended up purchasing polyvinyl chloride. They thought that this would be converted into vinyl chloride upon forming a suspension with DMSO and PBS. They then proceeded to perform IP injections on 4 mice in late 2017 or early 2018 with the polyvinyl chloride suspension. One mouse was found dead in a cage after receiving this injection. After later consultation with a chemist, the WWCC PI realized that he had purchased polyvinyl chloride, which is not converted into vinyl chloride upon forming a suspension. The PIs realized that there was confusion in the products delivered to the mice starting in late summer 2018. It appears that the PI at UW injected vinyl chloride, and the PI at WWCC injected polyvinyl chloride. The collaborators then contacted the Chair of the IACUC to discuss what happened in mid-September. During this time frame the PI also forgot to submit an annual continuing review for their protocol.

- Species: *Mus musculus*
 - Category of personnel involved: Faculty, graduate student
 - Dates: Fall 2017-Spring 2018
 - Animal deaths: 1
- Plan and schedule for correction and prevention

- The IACUC Chair was informed of this situation on September 15, 2018
 - The full IACUC will discuss the situation in October, 2018
- The collaborators will submit a new protocol incorporating their current method of delivery for vinyl chloride
- The collaborators will retake the relevant CITI training
- Timeframe for final report from the Institutional Official
 - No later than January 2019

Gopee, Neera (NIH/OD) [E]

From: Gopee, Neera (NIH/OD) [E]
Sent: Tuesday, October 09, 2018 2:23 PM
To: 'Carolyn Broccardo'
Cc: (b) (6)
Subject: RE: Preliminary Report for Protocol Noncompliance

Thank you for this preliminary report, Dr. Broccardo. We will start a new case file and look forward to receiving the final report from the IO after the IACUC has completed its investigation.

Best Regards,
Neera

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Veterinary Medical Officer
Office of Laboratory Animal Welfare
National Institutes of Health

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From: Carolyn Broccardo [mailto:Carolyn.Broccardo@uwyo.edu]
Sent: Monday, October 08, 2018 2:02 PM
To: Gopee, Neera (NIH/OD) [E] <neera.gopee@nih.gov>
Cc: (b) (6)
Subject: Preliminary Report for Protocol Noncompliance

Hi Dr. Gopee,

I hope you are well!

Attached is a preliminary report for a noncompliance situation. Please let me know if you need anything else.

Have a great Monday,

Carolyn Broccardo, Ph.D., PMP
Office of Research & Economic Development
Director of Research Integrity & Compliance
University of Wyoming, Old Main 303

(b) (6)
Carolyn.Broccardo@uwyo.edu