

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

August 20, 2019

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

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

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 letter dated August 8, 2019 reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Wyoming. Your letter supplements the information provided in an email report to this office on June 14, 2019. According to the information provided, OLAW understands that on March 31, 2019 an undergraduate Research Fellow was injecting mice infected with *toxoplasma gondii*. The mouse moved and the student was stuck with the needle. The student was treated at the local hospital and it was later determined that the student was not listed on the approved IACUC protocol for the project. There were no animal welfare concerns associated with this incident. The student is no longer employed by the lab. The project is PHS supported.

Corrective and preventive actions include safety and compliance retraining for the PI and all associated students to include a mock "accident" to practice what to do in the event of an accidental exposure. Personnel assignments to protocols have been updated. A wallet card was developed for the lab to present to hospital personnel in the event of accidental exposure to *T. gondii.* "Grab sheets" are in the lab that include approved procedures in place to deal with accidental exposures. All animal users in the lab have been retrained on needle safety and there are designated individuals who can easily perform restraint and injection for those lab members who are not able. Further training will be provided in the Fall, 2019.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken by the University of Wyoming to investigate this incident, provide corrective measures, and prevent recurrence. OLAW concurs that the incident warranted reporting. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,	
	(b) (6)
Brent C. Morse, DVM	
Director	
Division of Compliance Oversight	
Office of Laboratory Animal Welf	are

University of Wyoming

Office of Research Economic Development

Research Integrity and Compliance

Animal Care & Use Conflict of Interest Drones Export Control Human Subjects Research Misconduct Old Main 305/308 Dept. 3355 1000 E. University Ave. Laramie, WY 82071 Phone: (307) 766-5353 Fax: (307) 766-2608

> Biological Safety 101 Wyoming Hall Dept. 4305 1000 E. University Ave. Laramie, WY 82071 Phone: (307) 766-2723 Email: mjd@uwyo.edu

Radiation Safety 102 Wyoming Hall Dept. 4305 1000 E. University Ave. Laramie, WY 82071 Phone: (307) 766-2638 Email: herrold@uwyo.edu

uwyo.edu/research/ compliance August 8, 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 (reported to program officer on June 18, 2019). This incident was reported to Dr. Morse via email on June 14, 2019 by Dr. Carolyn Broccardo, Director of Research Integrity and Compliance at UW. Below is a summary of the situation.

An undergraduate, INBRE funded Research Fellow was working in the lab at 7 pm on 3/31/2019. They were injecting mice infected with *toxoplasma gondii* with deferiprone (an iron chelating agent). The mouse moved and they were stuck with the needle, and the student bled. They emailed the PI and texted a graduate student. They then went to the local hospital and were prescribed prophylactic medications. A workers compensation claim was filed on 5/17/2019 and our office learned of this incident on 5/21/19. Upon learning of this situation, it was discovered that the student was not listed on the IACUC protocol for this project. Prior to the incident, the student had been extensively trained by their PI in animal handling techniques and how to perform injections. The student is no longer employed in the laboratory, so does not need to be added to the relevant protocols.

Briefly:

•

- Species: Mus Musculus
- Category of Personnel: Undergraduate Research Fellow
- Date and Time: March 31st, 2019; 7 pm
- No animal injury or deaths

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 preventative and corrective actions would be taken. The IACUC determined that this was an isolated incident and not a programmatic failure.

Per the PI, the following corrective action plan has been completed:

1. We have completed safety and compliance retraining for all students and myself via the CITI training courses. Those certificates have been forwarded to IACUC.

2. All personnel working on approved IACUC protocols were updated to appropriate protocols, as needed.

3. On July 19th 2019 we conducted a mock "accident" so all lab members could practice what to do in the event of accidental exposure. This helped immensely to get people more comfortable with how to proceed if they should come into accidental contact via needle stick or some other method to biohazardous materials in the lab.

4. We developed a wallet card for all animal users in my lab that they can carry with them to present to emergency room personnel at the hospital so the hospital can follow proper procedures and accurately deal with accidental exposure to both *T. gondii*.

University of Wyoming

Office of Research Economic Development

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uwyo.edu/research/ compliance 5. We now have quick grab sheets in the lab that anyone can take with them, which describe the Institutional Biosafety Committee procedures in place and approved to deal with accidental exposures.

6. We are currently still working on developing alternative procedures for injections when scruffing the mice is not achievable. We instead have designated individuals who can easily perform this procedure to complete injections for those who are unable.

7. We have retrained all animal users in the lab for how to be safe with needles.

8. We will coordinate with the Research Office to deliver a compliance and safety training to our department in Fall, 2019.

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 Dr. Carolyn Broccardo, 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, August 19, 2019 9:31 AM	
To:	Carolyn Broccardo	
Subject:	RE: Report of Noncompliance	

Thank you for providing this final report. 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

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: Monday, August 12, 2019 5:19 PM To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov> Subject: RE: Report of Noncompliance

Hi Dr. Morse,

Attached is a signed closeout letter for the situation that was reported below.

Please let me know if you have any questions.

Thank you,

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)

Carolyn.Broccardo@uwyo.edu

From: Morse, Brent (NIH/OD) [E] <<u>morseb@mail.nih.gov</u>> Sent: Wednesday, June 19, 2019 1:44 PM To: Carolyn Broccardo <<u>Carolyn.Broccardo@uwyo.edu</u>> Subject: RE: Report of Noncompliance

This message was sent from a non-UWYO address. Please exercise caution when clicking links or opening attachments from external sources. Thank you for submitting this report Dr. Broccardo. 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: Carolyn Broccardo [mailto:Carolyn.Broccardo@uwyo.edu] Sent: Friday, June 14, 2019 3:05 PM To: Morse, Brent (NIH/OD) [E] <<u>morseb@mail.nih.gov</u>> Subject: Report of Noncompliance

Hi Dr. Morse,

Attached is a report of noncompliance.

Thank you,

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

Report of Noncompliance

Name and contact information of person reporting: Carolyn Broccardo,

(b) (6)

A (3216-K

Name of institution: University of Wyoming (UW)

Assurance number: D16-00135 (A3216-01)

Funding component and if contacted: INBRE P20GM103432 (will be contacted by PI of grant)

Brief description of incident

Mus Musculus Undergraduate Research Fellow March 31st, 2019; 7 pm No animal injury or deaths

An undergraduate, INBRE funded Research Fellow was working in the lab at 7 pm on 3/31/2019. They were injecting mice infected with *toxoplasma gondii* with deferiprone (an iron chelating agent). The mouse moved and they were stuck with the needle, and the student bled. They emailed the PI and texted a graduate student. They then went to the local hospital and were prescribed prophylactic medications. A workers compensation claim was filed on 5/17/2019 and I learned of this incident on 5/21/19. Upon learning of this situation, I discovered that the student was not listed on the IACUC protocol for this project. The student was extensively trained by their PI in animal handling techniques and how to perform injections. The student is no longer employed in the laboratory, so does not need to be added to the relevant protocols.

Plan and schedule for correction and prevention

- o This situation will be reported to the Wyoming INBRE Program Manager
- Conduct safety and compliance refresher training with laboratory members
- Conduct a mock "safety accident" with laboratory members, including appropriate immediate response and follow-up actions with UW
- Work with safety coordinator to develop a "wallet card" for laboratory members to keep in their wallet and present at the ER in case of a laboratory accident or exposure
- Develop a "quick grab sheet" to take to ER for each agent (place in envelope sleeve on wall)
- Develop new laboratory guidelines outlining best safety practices, including not working on potentially hazardous protocols alone
- Develop alternate options for holding mice for injections (scruffing, tube restraint)
- Conduct retraining regarding needle safety
- o Ensure all personnel working on projects are listed on appropriate protocols
- Laboratory personnel must retake appropriate online CITI certifications
- Collaborate with compliance office to deliver compliance and safety training to home department

• Timeframe for final report from the Institutional Official: August 2019

x

Morse, Brent (NIH/OD) [E]

From:	Morse, Brent (NIH/OD) [E]	
Sent:	Wednesday, June 19, 2019 3:44 PM	
То:	Carolyn Broccardo	
Subject:	RE: Report of Noncompliance	
Subject.	Re. Report of Noncompliance	

Thank you for submitting this report Dr. Broccardo. 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: Carolyn Broccardo [mailto:Carolyn.Broccardo@uwyo.edu]
Sent: Friday, June 14, 2019 3:05 PM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Subject: Report of Noncompliance

Hi Dr. Morse,

Attached is a report of noncompliance.

Thank you,

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

Carolyn.Broccardo@uwyo.edu