



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive - MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

June 11, 2018

Re: Animal Welfare Assurance
A3217-01 [OLAW Case W]

Ms. Tamara Deuser
Associate Vice President
Arizona State University
660 South Mill Avenue, (b) (4)
Tempe, AZ 85287-6111

Dear Ms. Deuser,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 5, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Arizona State University, following up on an initial report on December 14, 2017. According to the information provided, OLAW understands that an investigator obtained skin swabs to identify a fungus from pet store amphibians. The protocol was approved only for swabbing wild caught or laboratory bred amphibians.

The corrective actions consisted of stopping the unapproved activity, amending the protocol, and counseling the investigator.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to prevent recurrence of this situation. OLAW concurs with the actions taken by the institution to comply with the PHS Policy.

Sincerely,

(b) (6)

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

cc: IACUC Chair

June 5, 2018

Brent C. Morse, DVM, DACLAM
Acting Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Re: Final Report on significant change to an IACUC-approved protocol without prior approval

Research Facility: Life Sciences
Species: Amphibians
Principal Investigator: James Collins
Protocol #: 16-1498R
Funding Source: N/A Unfunded

Dr. Morse,

On December 13, 2017, the IACUC became aware of a recruitment poster for pet store owners to allow their amphibians to participate in a research study on *Batrachochytrium dendrobatidis* (Bd) and *Batrachochytrium salamandrivorans* (Bsal). The recruitment poster was requesting to swab amphibians five times in order to detect the presence of Bd and Bsal. The animals would remain in the care and custody of the pet shop at all times. In the IACUC-approved protocol, the laboratory had approval to swab wild-caught animals and animals that were bred in their laboratory but not privately owned animals.

Corrective Action

The IACUC Chair conducted a meeting with the Principal Investigator (PI) and the student who was leading the recruitment. During the meeting, the Chair was informed that two animals had been swabbed in a pet store. The PI indicated that since they had approval to swab amphibians in the wild or those they have bred in the lab, he believed they also had approval to swab any amphibian. After a discussion with the Chair, both the PI and the student understood that the activity needed IACUC approval.

The investigator halted recruitment activity and submitted an amendment to the IACUC. The amendment and noncompliance was reviewed at the convened IACUC meeting on December 21, 2017. The Chair provided the IACUC with a summary of the events surrounding this noncompliance. The committee approved of the amendment and determined that no additional action was necessary for the noncompliance. The IACUC determined that this instance of noncompliance did not jeopardize the

animals' welfare. This event was the result of a misunderstanding of the rules. Education provided by the Chair has corrected the situation and the IACUC believes there will not be a reoccurrence.

Sincerely,

(b) (6)

Karen Kibler, PhD
Chair, IACUC
Assistant Research Professor

(b) (6)

Karen.Kibler@asu.edu

(b) (6)

Tamara Deuser, MBS, PMP
Institutional Official
Associate Vice President and Chief Operating Officer

(b) (6)

Tamara.Deuser@asu.edu

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Thursday, June 07, 2018 3:57 PM
To: OLAW Division of Compliance Oversight (NIH/OD)
Subject: FW: Final Report for Assurance #D16-00136

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, June 07, 2018 3:52 PM
To: (b) (6)
Subject: RE: Final Report for Assurance #D16-00136

Thank you for providing this report. We will send an official response soon.

Best regards, Brent Morse

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

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From: (b) (6)
Sent: Thursday, June 07, 2018 3:32 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Tamara Deuser <Tamara.Deuser@asu.edu>; (b) (6) <Karen.Kibler@asu.edu>; (b) (6) <Karen.Kibler@asu.edu>; (b) (6)
Subject: Final Report for Assurance #D16-00136

Dear OLAW,
On behalf of the ASU IACUC, I have attached the final report regarding the implementation of a significant change without prior IACUC approval.

Please let me know if you have any questions.

Thank you,

(b) (6)

Morse, Brent (NIH/OD) [E]

From: [REDACTED] (b) (6)
Sent: Thursday, May 10, 2018 5:28 PM
To: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report under Assurance #D16-00136

Dr. Morse,
I apologize for the oversight. We will get that to you asap.

Thank you,
[REDACTED] (b) (6)

From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Sent: Monday, May 07, 2018 8:58 AM
To: [REDACTED] (b) (6)
Subject: RE: Report under Assurance #D16-00136

Hello [REDACTED] (b) (6)

OLAW has no record of receiving a final report on this incident. If one is available, please send it or please send an interim update. Thank you.

Regards, Brent Morse

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

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From: [REDACTED] (b) (6)
Sent: Thursday, December 14, 2017 2:43 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Tamara Deuser <Tamara.Deuser@asu.edu>; Karen Kibler <Karen.Kibler@asu.edu>; [REDACTED] (b) (6)
[REDACTED] (b) (6)
Subject: Report under Assurance #D16-00136

Dear OLAW,
On behalf of the ASU IACUC, I am making a preliminary report of implementation of a significant change to an IACUC-approved protocol without prior IACUC approval. The situation will be reviewed by the convened IACUC on December 21st. We will provide a full report as soon as the review by the IACUC is complete.

Please let me know if you have any questions.

Thank you,

(b) (5)



Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, December 14, 2017 3:53 PM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: Tamara Deuser; Karen Kibler; (b) (6) (b) (6)
Subject: RE: Report under Assurance #D16-00136

Thank you (b) (6) We will open a compliance case file and await your IACUC's determination.

Regards, Brent Morse

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

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Please let me know if you have any questions.

Thank you,

(b) (6)