

### 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) 480-3387

July 10, 2020

Re: Animal Welfare Assurance A3217-01 [OLAW Case 1E]

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

Dear Ms. Deuser,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 2, 2020 letter providing an update to a previously reported instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Arizona State University. According to the information provided, OLAW understands that the Principal Investigator (PI) using marmosets has hired an experienced technician whose primary responsibility will be to train the animals to willingly enter the transfer box. This should reduce stress on the animals and allow the weighing and handling to be conducted more efficiently. The Institutional Animal Care and Use Committee will monitor the training progress.

OLAW concurs with this new initiative and commends the PI and the institution for taking this action which not only improves animal welfare but should also positively impact the scientific goals. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

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

cc: IACUC Chair Floh Thiels, NSF re: (FAIN)1539376 Robert Gibbens, D.V.M., USDA-APHIS-AC



Office of Research Integrity and Assurance

July 2, 2020

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Drive, Suite 2500
MSC 6910
Bethesda, MD 20892-6910

Re: Animal Welfare Assurance A3217-01 [OLAW Case 1E]; ASU Report of Noncompliance under Animal Welfare Assurance #DIG-00136 dated June 4, 2020

Dear Dr. Wolff,

ASU received your letter of June 12, 2020 regarding Animal Welfare Assurance A3217-01 [OLAW Case 1E]. Thank you for your recommendation regarding the training of the marmosets. In discussions with the Principal Investigator (PI) we learned that the lab has already hired a technician who will start within the next month. A majority of the technician's work hours will be dedicated to making the transfer box a non-stressful event for each of the animals. The technician has experience with marmosets and this task will be a priority.

The IACUC has requested that the PI update us regarding the progress with the training, and we will update you as the information becomes available.

Please let us know if you have any questions.

(b) (6)

Karen Kibler, PhD Chair, IACUC Assistant Research Professor

Karen.Kibler@asu.edu

Tamara Deuser, MBA, PMP
Institutional Official, Associate Vice President

Tamara.Deuser@asu.edu

(b) (6)

# Wolff, Axel (NIH/OD) [E]

From:

Walker, Keri (NIH/OD) [C]

Sent:

Wednesday, July 8, 2020 3:33 PM

To:

Wolff, Axel (NIH/OD) [E]

Subject:

FW: OLAW Case A3217-1E - ASU Reply to Dr. Wolff's Recommendation

Attachments:

ASU Letter Re OLAW Ltr A3217-01 Case 1E 07022020.pdf

Importance:

High

Follow Up Flag:

Follow up

Flag Status:

Flagged

From:

(b)(6)

Sent: Wednesday, July 8, 2020 3:18 PM

To: Walker, Keri (NIH/OD) [C] <keri.walker@nih.gov>

Cc: Tamara Deuser < Tamara. Deuser@asu.edu>;

(b) (6) iacuc@asu.edu; ethiels@nsf.gov;

Robert.m.gibbens@usda.gov

Subject: FW: OLAW Case A3217-1E - ASU Reply to Dr. Wolff's Recommendation

Importance: High

Good Afternoon Ms. Walker,

I hope you're doing well and staying safe.

Dr. Wolff's final response to OLAW Case A3217-1E included a recommendation for ASU. The attached letter lets you know our plan in this regard. Thank you for the recommendation! If you have any questions at all please don't hesitate to contact us.

Best Regards,

(b) (6)

(b) (6)

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From: Tamara Deuser

Sent: Friday, 12 June 2020 15:37:01 (UTC+00:00) Monrovia, Reykjavik

To: Walker, Keri (NIH/OD) [C]

Cc: <u>iacuc@asu.edu</u>; <u>ethiels@nsf.gov</u>; <u>Robert.m.gibbens@usda.gov</u>

Subject: RE: OLAW Case A3217-1E

Dear Ms. Walker,

Thanks very much, I hope you have a nice weekend.

Regards, Tamara

Tamara Deuser Arizona State University

From: Walker, Keri (NIH/OD) [C] < keri.walker@nih.gov >

Sent: Friday, June 12, 2020 5:34 AM

To: Tamara Deuser < Tamara. Deuser@asu.edu>

Cc: iacuc@asu.edu; ethiels@nsf.gov; Robert.m.gibbens@usda.gov

Subject: OLAW Case A3217-1E

Dear Ms. Deuser,

Attached please find Dr. Wolff's final response to OLAW Case A3217-1E.

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

Best Regards, Keri

Keri Walker
Program Analyst (Contractor)
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Dr., Suite 2500
Bethesda, MD 20892
301-435-2390
keri.walker@nih.gov



### DEPARTMENT OF HEALTH & HUMAN SERVICES

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FOR EXPRESS MAIL:
Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

June 12, 2020

Re: Animal Welfare Assurance A3217-01 [OLAW Case 1E]

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

Dear Ms. Deuser,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 4, 2020 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 March 19, 2020. According to the information provided, OLAW understands that marmosets were not being weighed at the interval described in the approved protocol. Specifically, the animals were to be weighed monthly to track baseline weights, however for some months this did not occur. The Principal Investigator stated that the animals had not been trained by positive reinforcement to be weighed and if not willing to come out of the cage on their own, they were not weighed. This study is supported by National Science Foundation grant # (FAIN)1539376.

The corrective actions consisted of amending the protocol to provide more flexibility in the weighing schedule. Laboratory and animal care staff will continue to check the animals frequently to assess well-being.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy. We recommend that a veterinarian or institutional behaviorist (if present) work with the laboratory staff to train the marmosets to enter the transfer box to prevent stress on the animals and to allow the laboratory to continue with regular weight measurements. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

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

cc: IACUC Chair Floh Thiels, NSF Robert Gibbens, D.V.M., USDA-APHIS-AC



Operations

Office of Research Integrity and Assurance

June 4, 2020

Brent Morse, DVM
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: Report of Noncompliance under Animal Welfare Assurance #DIG-00136

Research Facility: Biodesign B

Species: callithrix jacchus Principal Investigator: Yi Zhou

Funding Source: National Science Foundation

Incident: Failure to monitor the weights of all animals in the colony monthly

On March 17, 2020 the IACUC Chair, while reviewing marmoset care records, noted that a few weight points were not recorded as frequently as the IACUC protocol states. Specifically, the approved IACUC protocol states "We monitor the weights of all animals in the colony monthly and use this information to update the baseline weight of an individual annually."

The Chair met with the Principal Investigator (PI) on April 15, 2020 to discuss the non-compliance. The PI acknowledged that in some months monthly weighing was missed. The PI explained the missed weighing may be because, depending on the overall behaviors of the colony, in some months, certain individuals refused to come out. In that condition, the lab does not tend to force the animals out as colony weighing is not a positive environmental event for marmosets. The PI confirmed that the lab frequently checks the animal behaviors (vocalization, locomotion, etc.) in their assessments. The lab will share additional handling techniques with the ASU Department of Animal Care and Technologies (DACT) staff, and the PI will ask that the lab and DACT staff share behavioral observations.

### Corrective Action:

The Chair provided the committee a preliminary report of this noncompliance at the March 23, 2020 fully convened meeting. The Chair will meet with the Principal Investigator to discuss a corrective action plan which will be presented to the committee at the next IACUC meeting. A preliminary report was filed with OLAW on March 23, 2020. The committee acknowledged the information.





Office of Research Integrity and Assurance

The Chair provided an update of this noncompliance at the fully convened IACUC meeting on April 23, 2020. Given the PI's explanation that forced weighing would not be a positive experience for the animals if they refused to come out to be weighed on their own and that lab and DACT staff frequently monitor the animals, the PI submitted a Request for Changes, which was approved, to allow for more flexibility on weighing the animals given the circumstances described. Specifically, the protocol was changed to state the following:

"Weighing will be conducted by encouraging an individual animal to enter a transfer box, and the net weight will then be obtained using a tared platform scale. Approximately monthly weights will be collected for all individuals beginning at 9 months of age or earlier/more frequently if deemed necessary by the PI or veterinary staff. If an animal refuses to enter the transfer box during regular weighing procedures and continued attempts appear to cause social and emotional disturbances in the colony, additional weighing attempts will be made at a future date. If a monthly weight cannot be obtained for an individual, the maximum interval between weighing will be no longer than 60 days."

After discussion, the committee agreed that no additional action is required by the PI at this time. The committee feels the PI will make the appropriate commitment to establishing sound practices that will benefit both animal welfare and compliant scientific study. The committee will monitor laboratory records to confirm this is the case.

Please let us know if you have any questions.

(b) (б)

Karen Kibler, PhD Chair, IACUC Assistant Research Professor

Karen. Kibler@asu.edu

(b) (6)

Tamara Deuser, MBA, PMP Institutional Official, Associate Vice President (b) (6)

Tamara.Deuser@asu.edu

## Wolff, Axel (NIH/OD) [E]

Thank you for this preliminary report,

report from the IO after the IACUC has completed its investigation.

OLAW Division of Compliance Oversight (NIH/OD) From: Wednesday, June 10, 2020 7:56 AM Sent: (b)(6)To: OLAW Division of Compliance Oversight (NIH/OD) Cc: RE: Final Noncompliance Report under Assurance D16-00136 (Zhou) Subject: Thank you for this report. We will send a response soon Axel Wolff (b) (6) From: Sent: Monday, June 8, 2020 1:14 PM To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov> (b) (6) Cc: Tamara Deuser <Tamara.Deuser@asu.edu>; Karen Kibler <Karen.Kibler@asu.edu>; (b)(6)Subject: Final Noncompliance Report under Assurance D16-00136 (Zhou) Importance: High Good Morning, On behalf of the ASU IACUC, I am submitting the final Noncompliance Report for the event reported to you on March 20, 2020 below. Note the March 20, 2020 email was incorrectly entitled as "Adverse Event Report" which was not the case here. If you have any questions or need further information please don't hesitate to contact me. Best Regards, (b) (6) (b)(6)This message may contain information that is privileged, confidential and exempt from disclosure under applicable law. Please do not copy or forward this message without permission. If you are not the intended recipient, please delete all copies and notify me immediately by reply e-mail or by telephone (480) 965-6792 so we may correct our records From: OLAW Division of Compliance Oversight (NIH/OD) 
 olawdco@od.nih.gov Sent: Friday, March 20, 2020 3:55 AM (b) (6) To: Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov> Subject: RE: Adverse Event Report under Assurance D16-00136

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(b) (6) We will open a new case file and look forward to receiving a final

Axel Wolff, M.S., D.V.M. Deputy Director, OLAW

From:

(b) (6)

Sent: Thursday, March 19, 2020 1:30 PM

To: OLAW Division of Compliance Oversight (NIH/OD) < olawdco@od.nih.gov >

Cc: IACUC@asu.edu <IACUCasu.edu@mainex1.asu.edu>; Karen Kibler <Karen.Kibler@asu.edu>; Tamara Deuser

<Tamara.Deuser@asu.edu>;

(b) (6

Subject: Adverse Event Report under Assurance D16-00136

(b) (6)

Importance: High

Good Morning,

On behalf of the ASU IACUC, I am submitting a preliminary report of a failure to adhere to an IACUC-approved protocol for marmoset weighing. The IACUC is investigating this matter. A follow up message with a final report will be provided when the inquiry is complete.

If you have any questions please contact me.

Thank you,

(b) (6)

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