



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

November 6, 2020

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

Ms. Tamara Deuser  
Associate Vice President  
Arizona State University  
660 South Mill Avenue, (b) (6)  
Tempe, AZ 85287-6111

Dear Ms. Deuser,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 2, 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 October 8, 2020. According to the information provided, OLAW understands that two rhesus monkeys on fluid restriction had not been weighed at the appropriate intervals as per the protocol and institutional policy.

The corrective action consisted of reinstituting twice weekly weighing with a fall back plan of one weighing per week, which is consistent with the protocol requirement. The laboratory staff was counseled on the weighing requirements described in the protocol and that these procedures must be carried out as approved. The weight logs will be checked weekly and the Principal Investigator will be informed if an animal is not weighed. The Institutional Animal Care and Use Committee (IACUC) will monitor the laboratory records.

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 IACUC 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  
Robert Gibbens, D.V.M., USDA-APHIS-AC

November 2, 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 #D16-00136

Research Facility: Biodesign B  
Species: Macaca Mulatta  
Principal Investigator: Christopher Buneo  
Funding Source: DARPA  
Incident: Failure to Weigh Animals as required by Approved IACUC Protocol

During (resumed) ASU IACUC Semi-Annual inspections on September 17, 2020, an IACUC inspector found, while reviewing weight logs, that during the summer of 2020 two of the three animals had not been weighed within the correct time frames on several occasions. According to the approved protocol, the Standard Institutional Guidelines (SIG) for NHP Fluid Regulation is to be followed, which states that animals on active fluid restriction will be weighed at least every seven days. During the period of the missing weigh-ins the animals were on fluid restriction. A preliminary report of this noncompliance was filed with OLAW on October 8, 2020.

The Principal Investigator (PI) provided the following written response to the IACUC inspection finding:

"While the SIG states that all fluid restricted animals must be weighed once every 7 days, we have always done so twice per week. This practice makes it impossible for recorded weights to fall more than 7 days apart.

When Covid-19 arrived in March, staffing in the lab was decreased significantly – both in number of people and hours spent on campus. To accommodate this change, and to ease staff workload, twice weekly weight requirements were not strictly enforced. This was done with the understanding that weights would continue to be recorded every 7 days at minimum.

Since the IACUC inspection on 09.17.2020, we have reinstituted a strict twice weekly weight requirement. All staff have been notified that animals on fluid restriction must be weighed twice a week

without exception. If the staff in charge of a particular animal is unable to do this for ANY reason, they are required to notify the lab manager so other arrangements can be made. In addition, logs will be checked every Friday to ensure that weights have been recorded as required. If any fluid restricted animal does not have 2 recorded weights, they must be weighed on Friday."

Corrective Action:

The Chair met with the Principal Investigator on October 16, 2020 to discuss the non-compliance. In addition to the PI's written response to the inspection report, the PI told the Chair that in lab discussions everyone was reminded that these gaps cannot happen for any reason. The PI also planned to report to the lab members that a report would be filed with OLAW as a result of the errors.

The IACUC Chair reviewed this inspection finding and the PI's response with the committee at the October 23, 2020 fully convened meeting. After discussion, the committee requested that in the future the PI also be notified (in addition to the lab manager) when a staff member is unable to complete a weighing for any reason and that a column be added to the weight log to document that logs were checked each Friday to ensure weights were completed for the week as required. With the addition of these two actions, the committee feels the PI's corrective action plan is sufficient and he will make the appropriate commitment to ensure the animals are weighed as required by the approved protocol. The committee will, as always, monitor laboratory records during future inspections to confirm this is the case.

The PI has committed to incorporating the committee's two requests.

Please let us know if you have any questions.

Sincerely,

(b) (6)

Karen Kibler, PhD  
Chair, IACUC  
Assistant Research Professor  
(b) (6)  
[Karen.Kibler@asu.edu](mailto:Karen.Kibler@asu.edu)

(b) (6)

Tamara Deuser, MBA, PMP  
Institutional Official  
Associate Vice President  
(b) (6)  
[Tamara.Deuser@asu.edu](mailto:Tamara.Deuser@asu.edu)

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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, November 4, 2020 10:45 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Final Noncompliance Report under Assurance D16-00136

Thank you for this report. We will send a response soon.  
Axel Wolff

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**From:** (b) (6)  
**Sent:** Wednesday, November 4, 2020 10:18 AM  
**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>; iacuc@asu.edu; (b) (6)  
**Subject:** Final Noncompliance Report under Assurance D16-00136  
**Importance:** High

Good Morning,

On behalf of the ASU IACUC, I am submitting the final Noncompliance Report for the event reported to you on October 9, 2020 below.

If you have any questions or need further information please don't hesitate to contact me.

Best Regards,  
(b) (6)

(b) (6)

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**From:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Sent:** Friday, October 9, 2020 5:26 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** RE: Preliminary Noncompliance Report under Assurance D16-00136

Thank you for this preliminary report, (b) (6) We will open a new case file and look forward to receiving the final report from the IO after the IACUC has completed its investigation.

Axel Wolff, M.S., D.V.M.

Deputy Director, OLAW

**From:** (b) (6)  
**Sent:** Thursday, October 8, 2020 1:13 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>; (b) (6)  
(b) (6) iacuc@asu.edu  
**Subject:** Preliminary Noncompliance Report under Assurance D16-00136  
**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 animal weighing. The IACUC is reviewing this matter. A follow up message with a final report will be provided when the review is complete.

If you have any questions please contact me.

Best Regards,

(b) (6)

(b) (6)

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