



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

February 12, 2021

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

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 January 28, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Arizona State University. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the Arizona State University Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: the conduct of animal-related activities without prior IACUC approval. The final report states a review of IACUC protocols by the IACUC Chair noted that a Request for Change (RFC) to a protocol had not completed the Designated Review process and therefore was not approved for implementation by the principal investigator (PI). It is stated the RFC submitted on August 5, 2020 described immunization of mice during the fall semester. When the IACUC Chair contacted the PI on January 15, 2021, the investigator confirmed he had conducted the work during the fall semester course. The Chair explained that through an error in the process, the RFC had not completed the review process and requested clarifications to the RFC. The report states the personnel identified were appropriately trained for the procedure, and the chemicals were cleared by veterinary review. All clarifications were completed by January 15th at which time the Chair informed the IACUC coordinator that the RFC was approved by Designated Review.

Following discussion of the incident by the IACUC, it was determined no additional action was required, as the matter was considered an honest mistake on the part of the Designated Reviewer. The Research Integrity Office Assistant Director notified the committee that more robust follow up measures will be implemented by the compliance staff to ensure that protocols going through the Designated Review process are brought to conclusion in a timely manner.

It is noted this research is not supported by PHS funds. Based on its assessment of this explanation, OLAW understands that the Arizona State University has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy. We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

Jacquelyn T.

Tubbs -S

Jacquelyn T. Tubbs, DVM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

Digitally signed by Jacquelyn T.
Tubbs -S
Date: 2021.02.12 08:43:54
-05'00'

cc: IACUC Chair

January 28, 2021

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: MIC 421: Experimental Immunology Laboratory (ASU)
Species: Mice *Mus musculus*
Principal Investigator: Joseph Blattman/Douglas Lake
Funding Source: N/A
Incident: Conduct of animal-related activities without appropriate IACUC review and approval

On January 15, 2020 the IACUC Chair, while reviewing IACUC records, noted that Request for Change (RFC) # 2 of protocol 19-1684T had not completed the Designated Review process and thus was not approved for implementation by the PI.

RFC #2 of 19-1684T, submitted to the IACUC on August 5, 2020, amended the approved protocol to permit immunization of mice during the fall semester with 50 ug of a novel 17 amino acid peptide derived from HTLV-1 gp21 (AQNRRLDLLFWEQGGL) containing H-2 L^d and K^d T cell epitopes. The protocol, prior to submission of RFC #2, approved immunization activity during the spring semester only.

RFC #2 was approved by the IACUC for the Designated Review process. The IACUC Chair was identified as the Designated Reviewer. RFC #2 completed Veterinary pre-review on August 7, 2020. When the IACUC Chair contacted the PI on January 15, 2021, the PI confirmed he had conducted the work described in RFC #2 during the Fall semester 2020 course.

The Chair informed the PI on January 15th that through an error in the process (hers, not the PI's), the RFC had not completed the review process and asked for several clarifications to the RFC, none of which had bearing on how the work itself was proposed. The changes to the RFC included 1) insertion of a table to show the additional chemicals in use; 2) identification of who would be doing the procedures; and 3) notation of the time interval between procedure and euthanasia. The personnel identified were appropriately trained for the procedure, and the chemicals had been cleared by the veterinary review. The time interval did not have any impact on animal welfare or procedural outcomes. All three clarifications were completed by January 15th, at which time the Chair notified the IACUC coordinator that the RFC was approved by Designated Review.

Corrective Action:

The Chair informed the committee of this noncompliance at the January fully convened IACUC meeting. After discussion, the committee agreed that no additional action is required at this time.

The committee feels that while this was an honest mistake on the part of the Designated Reviewer, closer attention to review assignments is necessary.

The Research Integrity Office Assistant Director also informed the committee that more robust follow up measures will be implemented by the compliance staff to ensure that protocols going through the Designated Review process are brought to final conclusion in a timely manner.

Further, the PIs associated with protocol 19-168T have been counseled by the IACUC Chair that work is not to be performed prior to receiving final IACUC approval.

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

(b) (6)

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

(b) (6)

Tamara.Deuser@asu.edu

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, February 3, 2021 7:23 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report of Noncompliance Report under Assurance D16-00136

Thank you for this report, (b) (6) We will send a response soon.

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

From: (b) (6)
Sent: Friday, January 29, 2021 4:53 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>; iacuc@asu.edu
Subject: Report of Noncompliance Report under Assurance D16-00136
Importance: High

Good Afternoon,

On behalf of the ASU IACUC, the attached Noncompliance Report is submitted.

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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