



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

October 26, 2021

Re: Animal Welfare Assurance
A3200-01 [OLAW Case 3L]

Dr. Susan Buskirk
Vice President – Chief Accountability Officer
University of Maryland Baltimore
620 West Lexington St. (b) (4)
Baltimore, MD 21201-1559

Dear Dr. Buskirk,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 12, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Maryland Baltimore (UMB) following up on an initial June 1, 2021 notification by telephone.

According to the information provided, this Office understands that the UMB Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: the conduct of animal activities without prior IACUC review and approval. The final report states on May 20, 2021, Veterinary Resources (VR) received a request for clinical evaluation of a cage of animals from a research lab. The evaluation identified a dead mouse (likely the dam), 3 dead pups, 2 dehydrated and ataxic pups in the cage. Investigative results revealed the lab was housing mice and initiated a breeding colony of mice in the lab without IACUC approval.

On May 24, 2021, VR Leadership informed OAWA Director that the Principal Investigator (PI) acknowledged maintaining and breeding animals in the lab to protect her immunocompromised strains from ongoing pathogen outbreaks within the facilities. In response, the IACUC Chair requested the PI to cease all unapproved animal activities and adhere to the approved protocol. Some additional requests included: returning animals to the animal facility, conducting breeding only in the animal facility and explaining why it was considered necessary to establish a breeding colony outside the animal facility. The PI responded on May 27th confirming compliance with the requests. It is understood a request to establish a new PI-managed Satellite Housing facility for breeding of innate immune-deficient strains was submitted for IACUC review and was approved on June 7th.

The IACUC discussed the matter on June 21, 2021, and concluded there was sufficient evidence provided to support the PI-manage Satellite Housing request. The committee considered the case closed and closure correspondence stated future incidents of noncompliance may result in suspension of all animal work. The following corrective actions were included in the correspondence:

- The PI and lab personnel must ensure that no animal work is conducted without prior IACUC approval and ensure adherence to all UMB ACUP policies and procedures.
- Ongoing monitoring will continue to ensure the lab's compliance with their IACUC-approved protocol.

Per the report, the satellite housing area was inspected Fall 2021 and no animal welfare or compliance issues were identified. It is noted that this research is supported by PHS funding.

Based on its assessment of this explanation, OLAW understands that the University of Maryland Baltimore 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

Digitally signed by
Jacquelyn T. Tubbs -S
Date: 2021.10.26
14:22:03 -04'00'

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

cc: IACUC Contact

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, October 13, 2021 8:04 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: UMB # D16-00125 (A3200-01): Final Report

Thank you for this report (b) (6) We'll send a response soon.
Axel Wolff

From: (b) (6)
Sent: Tuesday, October 12, 2021 1:04 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Buskirk, Susan <sbuskirk@umaryland.edu>; (b) (6)
Subject: UMB # D16-00125 (A3200-01): Final Report
Importance: High

Dear OLAW Division of Compliance Oversight,

Please find attached a PDF copy of the final report signed by our Institutional Official for incident VRCCSV0521 (*initially reported via phone on 06/01/21*).

If you have any questions or require any additional information, please do not hesitate to contact me directly.
Sincerely,

(b) (6)



UNIVERSITY of MARYLAND
BALTIMORE



October 12, 2021

Brent C. Morse, DVM, DACLAM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892

RE: Final Report of Reportable Situation (VRCCSV0521)

Dear Dr. Morse,

The University of Maryland Baltimore (UMB), in accordance with Assurance No. D16-00125 (A3200-01) and PHS Policy IV.F.3., provides this final report on a reportable situation involving the conduct of animal work without IACUC approval. This incident was first reported to OLAW Division of Compliance Oversight on June 1, 2021 by the OAWA Director.

BACKGROUND

On May 20, 2021, Veterinary Resources (VR) received a request from a research lab for a clinical evaluation of a cage of animals for which one dead mouse was identified. Upon review, the VR clinical team identified another cage with 3 dead pups and 2 dehydrated and ataxic pups. These pups likely came from the deceased dam. This cage was lacking a cage card and appeared dirty indicating it missed the weekly cage change. Upon further investigation and a site visit to the lab; it was identified that the lab was housing mice and initiated a breeding colony of mice in the lab without IACUC approval.

ACTIONS TAKEN, COMMITTEE DELIBERATIONS AND OUTCOME

The IACUC Chair was informed of the clinical case report on May 20th; at that time VR Leadership was still looking into the findings and meeting with the Principal Investigator (PI). On May 24th, VR Leadership notified the OAWA Director that the PI admitted maintaining and breeding animals in the lab to protect her immunocompromised strains from ongoing pathogen outbreaks within the facilities.

On May 24th, the IACUC Chair requested that the PI confirm all unapproved activities will stop and the approved protocol will be adhered to; that animals will be returned to the animal facility; that breeding will only occur in the animal facility (as approved), and requested the PI provide a brief explanation for why it was deemed necessary to establish a breeding colony outside of the animal facility including what strain or strains were being maintained in the lab, how many cages were being maintained, how many offspring were generated, for what duration of time was this activity occurring in the lab without

IACUC approval, and what source of funds were used to support these animals. The PI was also advised if there was scientific justification for breeding in the laboratory, a PI-managed Satellite Housing Facility form, along with SOP, husbandry logs and a physical plant assessment could be submitted for IACUC review and approval.

On May 27th, the PI responded confirming the unapproved breeding in the lab has stopped, breeders have been separated, and requested permission to maintain non-breeding animals in the lab in her IACUC approved satellite until this matter was resolved. Both the IACUC Chair and VR Leadership agreed that this was a reasonable and appropriate biosecurity solution. The PI indicated a small colony (8 cages) of TLR4-SNP and TLR4-/- mice were maintained in the lab over the last year. Approximately 100 offspring were generated. A request to establish a new PI-managed Satellite Housing facility for breeding of innate immune-deficient strains was submitted for IACUC review and approval. This request was IACUC approved on June 7th.

The IACUC met on June 21, 2021. A VR Veterinarian provided a summary of the VR clinical case and review findings from May 20th. The IACUC Chair's preliminary queries and the PI's response was reviewed. The IACUC determined the actions taken by VR and the IACUC Chair were appropriate and that while the appropriate corrective actions were taken to resolve these findings and the requested information was provided, the PI's response in general was unacceptable. The PI should have engaged the IACUC or Institutional Official regarding observed mortalities and variability in research data vs. taking matters into her own hands, thereby creating a non-compliance situation for the lab and the Institution. The IACUC determined there was sufficient evidence provided to support the PI-managed Satellite Housing request and that would likely have been the case a year ago. The committee concurred that this case could be closed, but the following must be communicated to the investigator in the closure correspondence:

- As a senior faculty member that has conducted animal research at UMB for 19 years; the actions taken to house animals and establish a breeding colony in the lab without IACUC approval and not disclose the location during IACUC semi-annual inspections over the last year demonstrated a disregard for, and circumventing of, UMB animal care and use program (ACUP) policies and procedures, federal regulations and could subsequently jeopardize the Institution's Animal Welfare Assurance on file with NIH Office of Laboratory Animal Welfare (OLAW).
- Future incidents of non-compliance may result in suspension of all animal work at UMB.
- The PI and lab personnel must ensure that no animal work is conducted without prior IACUC approval and ensure adherence to all UMB ACUP policies and procedures.

Ongoing monitoring will continue to ensure the lab's compliance with their IACUC approved protocol.

On September 8th, the PI-managed Satellite Housing facility was inspected during Fall 2021 IACUC semi-annual inspections. Room and cages were clean and well maintained; census was low and husbandry logs were complete. No animal welfare concerns, or compliance issues were identified.

This protocol is supported by PHS funds (R01AI123371; R01AI125215; R01AI143845). The NIAID Program Officials are cc'd on this final report for notification of the unapproved, satellite housing facility for colony maintenance.

The UMB 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 do not hesitate to contact my office or the (b) (6). Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Susan C. Buskirk, DM, MS, CCEP
Vice President
Chief Accountability Officer
Institutional Official for Animal Research
University of Maryland, Baltimore

SCB:ap

cc: IACUC File

Nancy Vazquez-Maldonado, Program Officer at National Institutes of Health, NIAID

Amy Krafft, Program Officer at National Institutes of Health, NIAID

Michael Minnicozzi, Program Officer at National Institutes of Health, NIAID



Initial Report of Noncompliance

By: J Tubbs

Date: ~~06-01/2020~~ 2021 ^{CE JTT 06-07-21} Time: 2:47pm

Name of Person reporting: (b) (6)

Telephone #:

Fax #:

Email: (b) (6)

Name of Institution: University of Maryland Baltimore

Assurance number: D16-00125

Did incident involve PHS funded activity? Y

Funding component: unknown currently

Was funding component contacted (if necessary): _____

What happened?

Previously approved for satellite housing, and learned she was housing longer than 7d and established a breeding colony within the lab.

Species involved: ~~rats~~ mice

Personnel involved:

Dates and times:

Animal deaths: no

Projected plan and schedule for correction/prevention (if known): _____

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____