

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

January 26, 2024

PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

> Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 <u>Telephone</u>: (301) 496-7163 <u>Facimile</u>: (301) 480-3387

FOR EXPRESS MAIL:

Re: Animal Welfare Assurance A3208-01 [OLAW Case 1N]

Daniel Sui, Ph.D. Vice President for Research and Innovation Virginia Polytechnic Institute and State University 800 Drillfield Drive, Burruss Hall, (b) (4) Blacksburg, VA 24061

Dear Dr. Sui,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your letter dated January 22, 2024, reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Virginia Tech University. Your letter supplements the information in the preliminary telephone report on January 12, 2024. According to the information provided, OLAW understands that on or about November 6, 2023, it was determined that protocol non-compliance occurred with inconsistencies in planned timelines and monitoring parameters, and procedures planned to be performed on pigs that were not fully congruent with the approved protocol. The funding source for these animals is via the NIH. The PI has been informed that they must cooperate with their grant administrator to determine if any funding related actions must be taken.

Corrective and preventive actions included: The submission and subsequent IACUC approval of amendments to bring the protocol back into compliance. In addition, the IACUC placed further protocol prerequisites that are to be satisfied by the PI prior to approval for additional animals for the next six cohorts of animals.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident, provide corrective measures, and prevent recurrence. OLAW concurs that the incident warranted reporting. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse -S

Digitally signed by Brent C. Morse -S Date: 2024.01.26 19:09:13

-05'00'

Brent C. Morse, DVM Director Division of Compliance Oversight Office of Laboratory Animal Welfare

cc: IACUC contact Dr. Anna Bagwell, Acting Director of Animal Welfare Operations for Animal Care, USDA APHIS



Daniel Sui Senior Vice President for Research and Innovation Burruss Hall, (b) (4) 800 Drillfield Drive Blacksburg, Virginia 24061 (b) (6)

research.vt.edu

January 22, 2024

Axel Wolff, DVM Acting Director, Divisions of Compliance Oversight Office of Laboratory Animal Welfare National Institutes of Health Rockledge 1, Suite 360 6705 Rockledge Drive Bethesda, MD 20892

Final report for Virginia Tech [Assurance #A-3208-01]

Dear Dr. Wolff:

Virginia Tech, in accordance with Assurance A-3208-01 and PHS Policy IV.F.3., provides this report of animalrelated activities that were determined to be potentially non-compliant with the associated IACUC-approved protocol. This animal research study involves pigs.

This incident was first reported to Teagan Ware, Animal Welfare Program Analyst, OLAW, on January 12, 2024 via a telephone call led by (b) (6)

On or about November 6, 2023, it was observed that the PI's planned activities on the protocol were not fully consistent with the approved protocol. The IACUC was convened to review and discuss the facts, circumstances, and potential non-compliances with the approved protocol. There were no animal health or welfare concerns or impacts associated with the potential protocol noncompliance.

After discussion, the IACUC determined that a Minor Protocol Non-Compliance occurred due to inconsistencies in planned timelines and monitoring parameters, and procedures planned to be performed that were not fully congruent with the approved protocol. To address the situation, corrective actions were taken including the submission of amendments to bring the protocol back into compliance, and those amendments were approved by the IACUC.

In addition, protocol review prerequisites were established by the IACUC that are to be satisfied by the PI prior to approval for additional animals. The procedural corrective actions were determined by the IACUC as appropriate to reduce the potential for the PI to become noncompliant with the approved protocol and are to remain in place for minimally the next six scheduled cohorts of animals.

The funding source for these animals is via the NIH, through University of Maryland Baltimore (Federal Award #: 3000533, REQUEST: 0494). Per PHS requirement, the PI has been informed that they must cooperate with their grant administrator to determine if any funding related actions must be taken. Virginia Tech 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 contact (b) (6)

Thank you for your consideration of this matter.

Sincerely,



Dr. Daniel Sui Senior Vice President for Research and Innovation Institutional Official Virginia Tech

Ware, Teagan (NIH/OD) [E]

From:	OLAW Division of Compliance Oversight (NIH/OD)
Sent:	Monday, January 22, 2024 9:12 AM
То:	'iacucpam'
Cc:	(b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Subject:	RE: Final Report

Good morning,

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

Best, Teagan

Teagan Ware, MS, PMP Animal Welfare Program Analyst Division of Compliance Oversight Office of Laboratory Animal Welfare National Institutes of Health

Phone: 301-435-2390 Email: <u>teagan.ware@nih.gov</u>

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From: iacucpam <iacucpam@vt.edu> Sent: Monday, January 22, 2024 8:43 AM To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov> Cc: (b) (6) iacucpam <iacucpam@vt.edu> Subject: [EXTERNAL] Final Report

Hello Dr. Wolff,

Please find the final report attached from our IO. Please confirm receipt.

Thank you,

(b) (6)



A 3208-IN



Initial Report of Noncompliance

By: TDW

Date: 1/12/2029 Time: (1.00 Am
Name of Person reporting: Telephone #: Fax #: Email:
Name of Institution: <u>Virginia Tech</u> Assurance number: <u>A3268-0</u> 1
Did incident involve PHS funded activity? Funding component: Was funding component contacted (if necessary):
What happened? University transferred to another provocal, which was Not allowed on either the provocal transforming from or Vecenny the animals. No animal welford issues Personnel involved: Dates and times: Animal deaths: Norre
Projected plan and schedule for correction/prevention (if known):
Amunal protocols
Projected submission to OLAW of final report from Institutional Official:
260.90 days
DFFICE USE ONLY Case #