DEPARTMENT OF HEALTH & HUMAN SERVICES

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Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500 – MSC 6910
Bethesda, Maryland 20892-7982
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

DATE: December 9, 2022

TO: Nina F. Schor, M.D., Ph.D.
Deputy Director for Intramural Research, NIH

FROM: Deputy Director, Office of Laboratory Animal Welfare

SUBJECT: Animal Welfare Investigation (VRC 43-22) - Animal Welfare Assurance A4149-01 [Case 17U]

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 1, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the NIH, National Institute of Allergy and Infectious Diseases- Vaccine Research Center. According to the information provided, OLAW understands that blood sampling of mice was conducted at the request of a research technician, although this activity had not yet been approved by the Animal Care and Use Committee (ACUC). A co-investigator had informed the research technician that the study was approved, the technician failed to confirm this, and also failed to provide documentation on the cage card that the project had been started. The approved rodent ordering database indicated that the study had been approved prior to actual approval by the ACUC which resulted in the mice being ordered.

The corrective actions consisted of transferring the mice to a holding protocol and stopping all animal activities. Senior research staff were counseled on the requirement for ACUC approval of all animal activities prior to implementation. The ACUC database was updated to clearly reflect whether a project has received full ACUC approval, and all animal users were notified that full approval notices will be issued by the ACUC Coordinator, after which time research activities may proceed. Full approval notices will be used to update the rodent ordering database. Investigators were also reminded to document research manipulations on the cage card and staff has been trained on all of these updated procedures.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of these problems. OLAW concurs with the actions taken by the ACUC to comply with the PHS Policy.

Sincerely,

(b) (6)

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

cc: Dr. Richard Wyatt
Dr. Stephen Denny
Dr. Mario Roederer

A4149-17U

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
www.nih.gov

December 1, 2022

TO: Brent C. Morse, D.V.M.
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare

FROM: Deputy Director for Intramural Research, NIH

SUBJECT: Animal Welfare Investigations - Assurance D16-00602 (VRC 43-22)

This correspondence conveys the results of an animal incident investigation by the NIH National Institute of Allergy and Infectious Diseases - Vaccine Research Center (VRC) ACUC in accordance with Assurance D16-00602 and PHS Policy IV.F.3. The incident involved the initiation of a mouse study prior to its approval by the VRC ACUC. No mice were injured by the unapproved study manipulations.

The event was first reported to the NIH Office of Animal Care and Use by the VRC Animal Program Director on September 21, 2022.

Please contact me or Dr. Stephen Denny, Director, Office of Animal Care and Use, if additional information or clarifications are required.

Nina F. Schor -S
Digitally signed by Nina F. Schor -S
Date: 2022.12.01 11:19:07 -05'00'

Nina F. Schor, M.D., Ph.D.

Attachment

cc: Dr. Wyatt
Dr. Denny
Dr. Roederer

National Institute of Allergy and Infectious Diseases
Vaccine Research Center

Vaccines for Life™

Date: November 17, 2022

From: Chair, VRC/NIAID ACUC

To: Nina F. Schor, M.D., Ph.D., Deputy Director for Intramural Research

Subject: Reportable Incident: Conduct of Animal-related Activities Prior to Full IACUC Approval.

The following is a summary of a reportable incident involving conduct of animal-related activities without appropriate IACUC approval and a description of the corrective actions taken.

Summary of Incident:

A Research Technician initiated a research activity requiring blood sample collection in mice. The technician submitted a Request for Technical Assistance (RTA) to have the blood sample collections performed by Vivarium Technical staff. The Vivarium Lead Technician performed Post Approval Monitoring (PAM) on the RTA and on September 21, 2022, determined that the cited Animal Study Proposal (ASP) had not fully secured ACUC approval to conduct that procedure. Final ASP approval was executed on October 3, 2022, and the above referenced research activity was completed.

Summary of the Investigative Steps Taken:

The same day this error was found, September 21, 2022, all animals were transferred to the VRC Rodent Holding ASP and all research manipulations stopped; the Investigators, the Animal Resources Program Coordinator, the VRC ACUC coordinator, the VRC Animal Program Director, the Chair of the VRC ACUC, and the NIH Office of Animal Care and Use were notified; and the Animal Resources Program Coordinator and Animal Program Director conducted the investigation.

The study Co-PI, the Research Technician, the VRC Rodent Ordering Administrator and the ACUC Coordinator were interviewed to determine how this event occurred and to identify steps to implement to prevent a reoccurrence. The following is what was discovered during these discussions:

1. The co-investigator scheduled the study with the Lab Research Technician prior to receiving a notification email from the VRC ACUC Coordinator stating that the ASP and blood collection procedure was fully approved, and that research may commence.
2. The Research Technician did not directly confirm that the ASP was fully executed prior to performing research manipulations and before submitting the RTA. Instead, he relied on the verbal communications from the Co-investigator.
3. The Research Technician did not document on the rodent cage card that the animals had been started on a research project.
4. The "Approved ASP Rodent Ordering Database" was updated to indicate ASP approval prior to the ASP actually gaining full approval.
5. The Rodent Ordering Administrator ordered the mice based on the entries in the Approved ASP Rodent Ordering Database.

National Institute of Allergy and Infectious Diseases
Vaccine Research Center

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Summary of Corrective Actions Taken:

On Wednesday November 16, 2022, an incident report was presented to the VRC ACUC during a regularly convened meeting. The investigation results and corrective actions were discussed:

1. Senior Research staff were reminded via email and during a VRC Senior Staff meeting that conduct of animal-related activities may only be performed after securing ACUC review and approval of the ASP.
2. The ACUC Dashboard column which created confusion has been edited to better clarify that the column reflects where in the process the ASP/amendment is and not an indicator of full approval/execution of the ASP/amendment.
3. The ACUC Coordinator emailed all VRC PI's, Co-investigators and Building 40 vivarium users reminding them that an ASP/amendment is not approved until they will receive an approval notification email from the VRC ACUC Coordinator. Research may only commence after this approval notification is received.
4. Investigators were reminded by email of the need to document all research manipulations on animal cage cards.
5. The Animal Resources Program Coordinator has been added to the above cited approval communication, and once received he will update the "Approved ASP Rodent Ordering Database".
6. Retraining of pertinent staff was conducted to explain that fully approved/executed ASP/amendments are located on the "Approved ASPs" tab within the VRC ACUC Dashboard. It was clarified approved ASP/amendments are never found on the "In-Process ASP" tab.
7. The VRC PAM program successfully identified the situation allowing prompt cessation of the study and was given accolades.

Resolution of the matter:

At this point, the VRC ACUC has concluded that appropriate actions were taken to ensure that similar events do not occur in the future.

(b) (6)

Mario Roederer, PhD

Senior Investigator, VRC / NIAID / NIH

Chair, VRC ACUC

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, December 2, 2022 8:26 AM
To: Denny, Stephen (NIH/OD) [E]
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: D16-00602 NIH Animal Incident Report (VRC 43-22)

Good morning Dr. Denny,

Thank you for sending us this report and we will send an official response soon.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

From: Denny, Stephen (NIH/OD) [E] <stephen.denny@nih.gov>
Sent: Thursday, December 1, 2022 4:55 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: D16-00602 NIH Animal Incident Report (VRC 43-22)

Dear OLAW/DCO,

The attached documents from the NIH Institutional Official and the NIH National Institute of Allergy and Infectious Diseases Vaccine Research Center (VRC) ACUC address an animal incident involving the initiation of a mouse study prior to its approval by the VRC ACUC.

The incident was first reported to the NIH Office of Animal Care and Use by the VRC Animal Program Director on September 21.

If you have any questions please contact me via email or at the phone number listed below. Thank you, Steve

STEPHEN DENNY, DVM, MS, DACLAM, DACVPM | Director, Office of Animal Care and Use | NIH Bethesda Campus, Building 31/Room B1C37 | Phone: (301) 435-2188 | ***NIH . . . Turning Discovery Into Health*** |