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 20892-7982
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: May 5, 2022

TO: Michael M. Gottesman, M.D.
Deputy Director for Intramural Research, NIH

FROM: Director
Division of Compliance Oversight, OLAW

SUBJECT: Animal Welfare Investigation (NIAID-VCR #09-22) - Animal Welfare Assurance A4149-01 [Case 16M]

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 27, 2022 memo regarding an incident of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the National Institute of Allergy and Infectious Diseases – Vaccine Research Center (NIAID-VRC). According to the information provided, OLAW understands that on February 25, 2022, 15 mice died after being irradiated in irradiator holding cages. Four of the deceased animals were submitted for diagnostic necropsy, and a clear cause of death could not be determined by gross or histopathological examination. It was promptly confirmed that the irradiator was operating correctly.

The following corrective actions were proposed:

1. Irradiator holding cages will be limited to two (2) cages of mice, with each holding cage distributed between three (3) sections of the irradiator holding cage. There will be no more than 2 animals per section, and animals must be able to demonstrate normal postural movements while in the irradiator holding cage.

2. The appropriate SOP was revised to reflect the changes above.

3. Creation of irradiator signage which outlines review steps prior to placing animals into the irradiator.

4. The Project Manager will review updated SOPs with technical staff as well as any other staff member who will be responsible for placing or removing animals from irradiator holding cages.

The actions taken to resolve the issue and prevent recurrence were appropriate and accepted by OLAW, given the undetermined cause of the fatalities. 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: 2022.05.05 15:49:47 -04'00'

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

cc: Dr. Stephen Denny
Dr. Richard Wyatt
Dr. Roederer, NIAID-VRC ACUC Chair

A4149 - 16 M

National Institute of Allergy and Infectious Diseases
Vaccine Research Center

Vaccines for Life™

Date: April 14, 2022

From: Chair, VRC/NIAID ACUC

To: Michael M. Gottesman, M.D., Deputy Director for Intramural Research

Subject: Reportable incident regarding lapse in animal husbandry

The following is a summary of a reportable incident involving animal death post cesium irradiation, the investigative steps taken, and a description of the corrective actions taken.

Summary of Incident:

On the morning of Friday February 25th, 2022, 80 mice were scheduled for irradiation as part of a VRC ACUC approved ASP. Two irradiation holding cages were prepared and transported to the irradiation room. The first cage was irradiated, removed from the device, and then was promptly returned to the vivarium. While this was being done, the second holding cage was irradiated, removed, and was also promptly returned to the vivarium. While uncrating the first holding cage, one mouse was found dead, at which time the irradiator operator was notified, and all irradiation ceased. The second holding cage was immediately examined, and fourteen (14) mice were found to have died.

Four of the deceased animals were submitted for diagnostic necropsy, and a clear cause of death could not be determined by gross or histopathological examination.

Summary of the Investigative Steps Taken:

The investigators, the Animal Program Manager, the ACUC Coordinator, and the VRC Animal Program Director were notified on the day of the incident. The Chair of the VRC ACUC and the NIH Office of Animal Care and Use were notified the next business day and updated once gross necropsy results were obtained. The Facility Manager and the Animal Program Director conducted the investigation.

To rule out an irradiator malfunction, the NIH Irradiator Security Manager was contacted on the day of the incident to rule out potential human radiation exposure and ensure proper operation of the Gamma Cell Irradiator. She coordinated a prompt inspection of the irradiator by a NIH Health Physicist. It was confirmed that the irradiator was operating correctly, and no human radiation exposure occurred.

Diagnostic necropsy did not determine a clear cause of death in the animals; therefore, an extensive evaluation of the existing SOPs, signage, and personnel training was conducted.

Summary of Corrective Actions Taken:

On Wednesday April 13th, an incident report was presented to the VRC ACUC during a regularly convened meeting. The investigation results were discussed, and the following corrective actions were proposed:

1. Irradiator holding cages will be limited to two (2) cages of mice, with each holding cage distributed between three (3) sections of the irradiator holding cage. There will be no more than 2 animals

per section, and animals must be able to demonstrate normal postural movements while in the irradiator holding cage.

2. Revision of TRP SOP 6850 – Irradiation of mice in the Gamma Cell Irradiator to include cage holding limits, enhanced animal observations pre and post irradiation, adjustments to disinfection procedures and an outline of standard post irradiation.
3. Creation of irradiator signage which outlines review steps prior to placing animals into the irradiator.
4. The Project Manager will review updated SOPs with technical staff as well as any other staff member who will be responsible for placing or removing animals from irradiator holding cages.

Resolution of the matter:

A report of the incident and presentation of update TRP SOP 6850 was presented and discussed by the VRC ACUC on April 13, 2022.

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

(b) (6)

Mario Roederer, PhD

Chair, VRC IACUC

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov

April 27, 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 (NIAID-VRC 09-22)

This correspondence conveys the results of an animal incident investigation by the NIH National Institute of Allergy and Infectious Diseases-Vaccine Research Center (NIAID-VRC) ACUC in accordance with Assurance D16-00602 and PHS Policy IV.F.3. The incident involved the preparation of mice for radiation exposure in an ACUC-approved animal study. Failure of research technicians to follow approved animal staging procedures contributed to the death of fourteen mice.

The event was first reported to the NIH Office of Animal Care and Use by the Attending Veterinarian on February 28, 2022.

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

Michael M. Gottesman -S

Digitally signed by Michael M. Gottesman -S
Date: 2022.04.28 09:10:47 -04'00'

Michael M. Gottesman, M.D.

Attachment

cc: Dr. Wyatt
Dr.Roederer
Dr. Denny

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, April 29, 2022 7:34 AM
To: Denny, Stephen (NIH/OD) [E]
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: D16-00602 NIH Animal Incident Report (NIAID VRC 09-22))

Thank you for this report, Dr. Denny. We will send a response soon.

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

From: Denny, Stephen (NIH/OD) [E] <stephen.denny@nih.gov>
Sent: Thursday, April 28, 2022 11:00 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: D16-00602 NIH Animal Incident Report (NIAID VRC 09-22))

Dear OLAW/DCO,

The attached documents from the NIH Institutional Official and the NIH National Institute of Allergy and Infectious Diseases – Vaccine Research Center (NIAID-VRC) ACUC address an animal incident involving the failure of a research team to properly restrain mice for an experimental procedure according to ACUC policy and the ACUC-approved animal study proposal. The event was first reported to the NIH Office of Animal Care and Use by the NIAID-VRC Attending Veterinarian on February 29, 2022.

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*** |