



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 28, 2022

Re: Animal Welfare Assurance
#A3025-01 [OLAW Case 1A]

Mr. John McIntire
Deputy General Counsel and
Institutional Official
SRI International
333 Ravenswood Avenue
Menlo Park, CA 94025

Dear Mr. McIntire,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 16, 2022 letter concerning a report of a noncompliance with the Public Health Service Policy on the Humane Care and Use of Laboratory Animals within the animal care and use program at SRI International. Your letter supplements the information contained in a preliminary phone report submitted on February 4, 2022. According to the information provided, OLAW understands that on Monday, January 31, 2022, one cage with three mice was found without food in the hopper. The three mice had lost weight since Friday, January 28th in the afternoon, at which time they had been placed into a new cage. Immediately upon discovery, food was provided to the animals, and the veterinary staff were notified. The health of the animals was evaluated, and the animals appeared bright and active with shiny coats, and despite having lost weight they did not appear thin or unhealthy. The mice were rechecked by veterinary staff daily for the next two days during which they gained weight and continued to appear healthy. It is unknown whether the new cage provided on the 28th was completely without food or with an insufficient amount. The protocol was approved for fasting animals up to 20 hours. This activity was PHS-funded. The funding agency will be notified separately.

To prevent such noncompliance from recurring, the research and husbandry staff received refresher training for conducting proper daily animal observation procedures, including confirmation of adequate food in every cage.

SRI International's reporting of the matter was consistent with the philosophy of self-regulation. Similarly, the action taken to respond to the issue and prevent recurrence was appropriate. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse -

Digitally signed by Brent C.
Morse -S
Date: 2022.02.28 08:57:42
-05'00'

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Brent C. Morse, DVM

Director

Division of Compliance Oversight

Office of Laboratory Animal Welfare

cc: IACUC contact

SRI International

A3025-1A

February 16, 2022

Brent Morse, DVM, DACLAM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare, NIH
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892-7982
Re: Assurance #3025-01; D16-00012 (new number)

Dear Dr. Morse:

This letter is the written report of the incident phoned in by SRI's IACUC Chair on February 4, 2022. The protocol noncompliance incident involved 3 mice on an irradiation study being conducted for the National Institute of Allergies and Infectious Diseases (NIAID), contract# 75N93020F00002 (TO B-1, 75N93020F00002).

During a prestudy evaluation of mice on Monday 1/31/22, one cage with three mice was found without food in the hopper. The three mice had lost weight since the randomization day which was Friday 1/28/22 in the afternoon, at which time they had been placed into a new cage. All other cages in the rack had full food hoppers on 1/31, and no other animals had lost weight. The cages were all attached to an automatic watering system. Immediately upon discovery, food was provided to the animals, and the veterinary staff were notified. The health of the animals was evaluated and the animals appeared bright and active with shiny coats, and despite having lost weight they did not appear thin or unhealthy. The mice were rechecked by veterinary staff daily for the next 2 days during which they gained weight and continued to appear healthy. It is unknown whether the new cage provided on 1/28/22 was completely without food or with an insufficient amount. The protocol was approved for fasting animals up to 20 hours.

To prevent such noncompliance from recurring, the research and husbandry staff received refresher training on 2/9/2022 and 2/11/2022, respectively, for conducting proper daily animal observation procedures, including confirmation of adequate food in every cage.

The funding agency will be notified separately.

SRI fully understands all the implications of deviations from IACUC protocols and will take all reasonable approaches to prevent a recurrence. Please do not hesitate to contact me should you have any questions.

Sincerely,

(b) (6)

John McIntire
Chief Legal Officer
Institutional Official

Tel.: (b) (6)

Email: john.mcintire@sri.com

SRI International

333 Ravenswood Avenue • Menlo Park, California 94025-3493 • 650.859.2000

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, February 18, 2022 8:22 AM
To: Michael Vigil
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: 2.16.22 Self-report to OLAW

Thank you for this report, Mr. Vigil. We will send a response soon.

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

From: Michael Vigil <michael.vigil@sri.com>
Sent: Wednesday, February 16, 2022 4:39 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: IACUC Correspondence <anim-use@sri.com>; John McIntire <john.mcintire@sri.com>
Subject: [EXTERNAL] 2.16.22 Self-report to OLAW

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Dear Sir/Madam:

Enclosed is the written report of an incident initially reported to Dr. Morse on 2/4/2022.

We look forward to the formal response from OLAW. In the interim, may we request confirmation (e.g. email) that the written report has been received? Thank you very much for your time.

Best regards,
Mike

Michael Vigil, BS, LATG, CPIA
IACUC Manager
IACUC Chairperson
SRI International
333 Ravenswood Ave
Menlo Park, CA 94025

(b) (6)

A3025-1A



Initial Report of Noncompliance

By: BCM

Date: 2/4/2022

Time: 4:00

Name of Person reporting: Mike Vigil, Chair

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: SRI, Intl

Assurance number: A3025

Did incident involve PHS funded activity? yes

Funding component: ?

Was funding component contacted (if necessary):

What happened? Three mice left in cage over weekend with water but no food. Exceeded food withholding approved in protocol. Fed Monday morning and looked O.K.

Species involved: Mus

Personnel involved: Researcher

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:

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Case #