



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 18, 2021

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

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 October 15, 2021 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at SRI International, following up on an initial telephone report on October 13, 2021. According to the information provided, OLAW understands that 53 mice were without water for 19 hours due to a misunderstanding of staff resulting in a failure to provide water bottles. There was no negative impact noted with the mice but the action constituted a deviation from the approved protocol.

The immediate action taken upon discovery consisted of providing the water bottles to the cages, evaluating the animals, and contacting the veterinarian. The preventive actions consisted of counseling staff not to remove water bottles from cages when conducting clinical observations and evaluating the installation of automatic watering systems in all animal rooms.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals.

Sincerely,

(b) (6)

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

cc: IACUC Chair

SRI International

October 15, 2021

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 October 13, 2021. The protocol noncompliance incident involved 53 mice on an irradiation study being conducted for the National Institute of Allergies and Infectious Diseases (NIAID), contract# 75N93020D00011 (TO B-1, 75N93020F00002). The mice were irradiated in the morning on study day 1 (10/13/21). Following the irradiation procedure, clinical observations were conducted 2-4 hours post irradiation, starting at approximately 12:00 pm. Water bottles were removed from cages during clinical observations. Research staff routinely remove water bottles while performing clinical evaluations to reduce cage weight, and to help avoid repetitive strain injuries previously experienced by staff.

The study mice were housed in two ventilated cage racks, situated in two housing rooms, one rack per room. Mice were provided water in one room with an automatic water system, and with water bottles in the other room. When the research staff returned the mice to the two housing rooms, a senior technician instructed the staff that both rooms had automatic watering systems, and that they did not need to return the water bottles to the cages. The 53 male mice housed in the room without an automatic watering system were without water from 12:00 pm on 9/13/21 to 7:15 am on 9/14/21 (approximately 19 hours). The IACUC protocol for this study stated that water would be provided *ad libitum*. Once animals were discovered without water, water bottles were provided immediately, and animals were evaluated by staff. Animals did not appear to be dehydrated and did not immediately drink from water bottles once water was provided. SRI's Attending Veterinarian was then immediately notified on 9/14/21.

To prevent such noncompliance from recurring, the research management team has advised the staff to not remove water bottles from the housing cage during clinical observations going forward, and will work with the animal care management team to explore the possibility of providing automatic watering systems to rooms currently not fitted with these systems. 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: Monday, October 18, 2021 7:24 AM
To: Michael Vigil
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: 10.15.21 Self-report to OLAW

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

From: Michael Vigil <michael.vigil@sri.com>
Sent: Friday, October 15, 2021 6:55 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: 10.15.21 Self-report to OLAW

Dear Sir/Madam:

Enclosed is the written report of an incident initially reported to Dr. Wolff on 10/13/2021.

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)



Initial Report of Noncompliance

By: (b) (6)

Date: 10/13/21

Time: 11:00

Name of Person reporting: Michael Vigil
 Telephone #: (b) (6)
 Fax #:
 Email:

Name of Institution: SRI
 Assurance number: A3025

Did incident involve PHS funded activity? Yes

Funding component:
 Was funding component contacted (if necessary):

What happened?

Radioactive protection study, mice didn't get water
 for 19 hrs. No water restriction on protocol, were on water bottle.

Species involved: Mice

Personnel involved:

Dates and times:

Animal deaths: No

Projected plan and schedule for correction/prevention (if known):
 More drip lines put in

Projected submission to OLAW of final report from Institutional Official:

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Case #