

DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

FOR EXPRESS MAIL:
Office of Laboratory Animal Welfare
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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 18, 2022

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

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 January 10, 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 December 22, 2021. According to the information provided, OLAW understands that the Laboratory Animals Medicine Department (LAMD) husbandry staff removed food from two rats at 6 pm on 12/14/21 for a study-driven overnight fast. A fasting period of up to 24 hours is approved under the IACUC protocol. Upon completion of the study, the rats were inadvertently not fed due to a misunderstanding between the investigative and husbandry staff. Each staff assumed the other would feed the rats when the fasting period ended at 3:30 pm on 12/15/21. Consequently, the two rats were not fed until approximately 7:00 am on 12/16/21. The rats were without food for approximately 37 hours. The study was funded by the PHS. The funding agency will be notified separately.

Upon discovery of no food on 12/16, the rats were immediately fed by a LAMD staff member and examined by SRl's veterinary staff. Both rats were noted to have normal appearance and behavior. Body weights were also measured. Animals were examined and weighed again by the veterinary staff on 12/17 to ensure that the rats were continuing to thrive. The Attending Veterinarian (AV) and Principal Investigator (as well as all LAMD and the research team) were also informed of this event on the morning of 12/16. To prevent such noncompliance from recurring, emails were sent to both groups by the AV stressing the importance of verbal and written communication between groups, and in particular the importance that Service Requests regarding changes in feeding must include clear details regarding when and by whom animals will be fed after a protocol driven fast. On 12/21/21, the two research technicians involved in this incident received training from a senior LAMD staff member on how to feed and document feeding of animals that are fasted for study work. Refresher training for the entire LAMD staff was provided at the LAMD staff meeting on 12/21/21.

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.

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Sincerely,
Brent C. Morse

-S

Date: 2022.01.18 15:00:12
-05'00'

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

cc: IACUC contact

SRI International

January 10, 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 December 22, 2021.

The incident involved two rats on a study being conducted for the National Institute on Alcohol Abuse and Alcoholism (NIAAA), grant # U01AA013521 . The Laboratory Animals Medicine Department (LAMD) husbandry staff removed food from the rats at 6 pm on 12/14/21 for a study-driven overnight fast. A fasting period of up to 24 hours is approved under the IACUC protocol in order to measure the metabolic response to glucose administration. Upon completion of the study, the rats were inadvertently not fed due to a misunderstanding between the investigative and husbandry staff. Each staff assumed other would feed the rats when the fasting period ended at 3:30 pm on 12/15/21. Consequently, the two rats were not fed until approximately 7:00 am on 12/16/21. The rats were without food for approximately 37 hours.

Upon discovery of no food on 12/16, the rats were immediately fed by a LAMD staff member, and examined by SRI's veterinary staff. Both rats were noted to have normal appearance and behavior. Body weights were also measured. Animals were examined and weighed again by the veterinary staff on 12/17 to ensure that the rats were continuing to thrive. The Attending Veterinarian (AV) and Principal Investigator (as well as all LAMD and the research team) were also informed of this event on the morning of 12/16.

To prevent such noncompliance from recurring, emails were sent to both groups by the AV stressing the importance of verbal and written communication between groups, and in particular the importance that Service Requests regarding changes in feeding must include clear details regarding when and by whom animals will be fed after a protocol driven fast. On 12/21/21, the two research technicians involved in this incident received training from a senior LAMD staff member on how to feed and document feeding of animals that are fasted for study work. Refresher training for the entire LAMD staff was provided at the LAMD staff meeting on 12/21/21.

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.



Email: john.mcintire@srl.com

SRI International

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

Wolff, Axel (NIH/OD) [E]

From:

OLAW Division of Compliance Oversight (NIH/OD)

Sent:

Wednesday, January 12, 2022 7:04 AM

To:

Michael Vigil

Cc:

OLAW Division of Compliance Oversight (NIH/OD)

Subject:

RE: 1.10.22 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: Monday, January 10, 2022 3:07 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] 1.10.22 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 12/22/2021.

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

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Initial Report of Noncompliance

By: BCM

Date:	12/22/2021	Time: 4:00
Name	of Person reporting: Mike Vigil, Chair Telephone #: Fax #: Email:	
Name Assur	of Institution:SRI, Intlance number:A3025	у
Fund	cident involve PHS funded activity?yes ling component:NIAAA funding component contacted (if necessary):	
What happened? Rat finished 24 hour fasting experiment but due to miscommunication between lab and animal husbandry, rat was not given food until next morning. Went 37 hours w/o food. Rat was O.K.		
Per: Dat	cies involved: Rattus sonnel involved: Researcher es and times: ? mal deaths: no	
Projected plan and schedule for correction/prevention (if known):		
Projec	ted submission to OLAW of final report from Insti	tutional Official:
	CE USE ONLY #	