



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

July 26, 2021

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

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 July 9, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals within the animal care and use program at SRI International. Your letter supplemented the information contained in an initial telephone report to this office on July 7, 2021. According to the information provided, OLAW understands that technicians collected retroorbital blood samples from two mice using the same eye on May 28, 2021 and on June 2, 2021. The second sample should have been collected from the opposite eye according to the IACUC protocol. SRI International IACUC guidelines require a two-week resting period between ipsilateral retroorbital sampling, unless the second sample is taken as part of a terminal procedure. The mice were not euthanized following the second collection, but no adverse clinical signs were observed following the second retroorbital bleed. The error was discovered by the research staff after the animals were euthanized and the Attending Veterinarian was notified immediately. The mice involved in this incident were supported by NIH funding.

Corrective and preventive measures included retraining of the Contract Services department technicians by the Principal Investigator, Study Director, and Toxicology Services Director. Retraining included the need to adhere to the IACUC-approved protocol and IACUC guidelines. SRI International will notify the funding agency of this event.

OLAW appreciates the consideration of this matter by SRI International which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident and prevent recurrence. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Robyn M. Engel -S

Digitally signed by Robyn M.
Engel -S
Date: 2021.07.26 14:29:29 -04'00'

Robyn M. Engel, DVM
Animal Welfare Program Specialist
Office of Laboratory Animal Welfare

cc: IACUC contact

SRI International

July 9, 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 July 7, 2021.

The incident involves 2 mice on a pharmacokinetic study being conducted for the National Institute of Allergies and Infectious Diseases (NIAID), contract# 75N93020D00011 (TO B-1, 75N93020F00002). Two female mice were bled retro-orbitally on study day 10 (5/28/21) and inadvertently from the same eye on study day 15 (6/2/21) instead of from the alternate eye as outlined in the IACUC protocol. As per IACUC guidelines, retro-orbital collection from the same eye requires a 2-week resting period between blood sampling, unless the second collection is a terminal collection. These mice were not euthanized following the second collection. No adverse clinical signs were observed for these animals following the last (second) collection. The blood collection error was discovered by the research staff after the animals were euthanized, and SRI's Attending Veterinarian was then immediately notified.

To prevent such noncompliance from recurring, the PI, the Study Director, and the Toxicology Services Director, were involved in retraining the technicians in the Contract Services department on the need to adhere to the IACUC-approved protocol and IACUC guidelines. Retraining of staff and review of the IACUC protocol was conducted from 6/29/2021 through 7/2/2021.

The funding agency will be notified separately.

SRI fully understands all the implications of deviations from IACUC protocols and guidelines 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)
Fax:
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, July 9, 2021 12:43 PM
To: Michael Vigil
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: 7.9.21 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: Friday, July 9, 2021 11:54 AM
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: 7.9.21 Self-report to OLAW

Dear Sir/Madam:

Enclosed is the written report of an incident initially reported to Dr. Morse on 7/7/2021.

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
Office: (b) (6)
Fax: (b) (6)



Initial Report of Noncompliance

By: BCM

Date: 7/7/2021

Time: 3:00

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? ?

Funding component:

Was funding component contacted (if necessary):

What happened? Two mice were bled retro-orbitally 5 days apart instead of 14 days apart per institutional policy.

Species involved: Mouse

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 #