



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

April 25, 2022

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

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 April 7, 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 March 28, 2022. According to the information provided, OLAW understands that a PI and research group discovered that 103 transgenic mice were bred from 11/2/2020 through 3/24/2022 without being included in the protocol. An amendment to add the mouse strain and additional animals was approved by the IACUC on 3/25/2022. Although the use of this strain is approved under the PI's experimental protocol, this strain was omitted from the 2019 renewal of the breeding protocol. The related activity is PHS-funded. The funding agency will be notified separately.

SRI International's reporting of the matter was consistent with the philosophy of self-regulation. Similarly, the action taken to respond to the issue 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

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Date: 2022.04.26 10:29:24
-04'00'

Brent C. Morse, DVM

Director

Division of Compliance Oversight

Office of Laboratory Animal Welfare

cc: IACUC contact

SRI International

AC025-1C

April 7, 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 March 28, 2022.

The protocol noncompliance incident involved 103 transgenic mice (i.e., two breeding pairs, 99 pups) on a breeding protocol (i.e., protocol 01026-b) for studies being conducted for the National Institute of Neurological Disorders (NINDS), grant# R01 NS103529.

While preparing the usage accounting table for protocol 01026-b's three year renewal, the PI and research group discovered that mice of mouse strain Th-Cre were bred from 11/2/2020 through 3/24/2022 without being included in the protocol. An amendment to add the Th-Cre mouse strain and additional animals was approved by the IACUC on 3/25/2022. Although the use of this strain is approved under the PI's experimental protocol, this strain was omitted from the 2019 renewal of the 01026-b breeding protocol despite the fact that it was approved on the 2016 renewal of this protocol. The PI thought the incident may have occurred from attempting to eliminate strains in preparation of the 2019 renewal that were no longer being used at that time.

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, April 8, 2022 7:20 AM
To: Michael Vigil
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: 4.7.22 Self-report to OLAW

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

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

From: Michael Vigil <michael.vigil@sri.com>
Sent: Thursday, April 7, 2022 6:25 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] 4.7.22 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 3/28/2022.

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)



A3025-1C

Initial Report of Noncompliance

By: BCM

Date: 3/28/2022

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: NINDS

Was funding component contacted (if necessary):

What happened? 28 Tg mice bred on breeding protocol which did not list specific strain. 18 month period.

Species involved: Mus

Personnel involved: PI

Dates and times:

Animal deaths: no

Projected plan and schedule for correction/prevention (if known):

IACUC approved amendment adding strain.

Projected submission to OLAW of final report from Institutional Official:

I instructed to not charge grant for \$\$ associated with 28 mice up until date of amendment approval.

OFFICE USE ONLY

Case #