

#### 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

Pl 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 Pl'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

A3025-1C

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.

John McIntire
Chief Legal Officer
Institutional Official

Email: john.mcintire@sri.com

Tel.:

## 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:

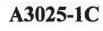
Enclosed is the written report of an incident initially reported to Dr. Morse on 3/28/2022.

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

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# **Initial Report of Noncompliance**

By: BCM

Date: 3/28/2022		Time: 4:00
Name of Person report Telephone #: Fax #: Email:	rting: Mike Vigil, Chair (b) (6)	
Name of Institution: Assurance number:	SRI, IntlA3025	
Funding component	PHS funded activity?yes :NINDS nent contacted (if necessary):	÷
What happened? 28 month period.	Tg mice bred on breeding protoco	l which did not list specific strain. 18
Species involved: A Personnel involved 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 #		