



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

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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>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

January 20, 2023

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

Mr. John McIntire
Chief Legal Officer
SRI International
333 Ravenswood Avenue
Menlo Park, CA 94025

Dear Mr. McIntire,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 13, 2023 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 29, 2022. According to the information provided, OLAW understands that nine male mice on an irradiation study were not properly removed from study after meeting the IACUC protocol's euthanasia criteria. The activity was PHS funded.

Corrective and preventive measures: the research staff received refresher training that included review of the protocol's early removal criteria for irradiation studies. The funding agency was 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 -S

Brent C. Morse, DVM
Director

Division of Compliance Oversight
Office of Laboratory Animal Welfare

Digitally signed by Brent C.
Morse -S
Date: 2023.01.20 16:15:12 -05'00'

cc: IACUC contact

A3025-1F

SRI International

January 13, 2023

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 29, 2022.

The protocol noncompliance incident involved 9 mice on an irradiation study being conducted for the National Institute of Allergy and Infectious Diseases (NIAID), contract# 75N93020D00011 (TO B-2, 75N93021F00002).

Nine irradiated male animals were not properly removed from study after meeting the IACUC protocol's euthanasia criteria on either Days 5 or 6 post irradiation. Although they had met removal criteria, none of these animals were found dead. Missed removals were discovered during data review following the end of the in-life phase of the study.

Four of the animals met removal criteria on Days 5 or 6, but instead were removed one day late on either Days 6 or 7, respectively. Removal criteria that qualified their euthanasia were moderate body weight (20-29% weight loss) and either moderate hunched posture or ruffled fur, and minimally one additional slight clinical finding (ruffled fur, dehydration, and/or hunched posture). The remaining five animals also met removal criteria (1/Day 5 and 4/Day 6), but were mistakenly not removed from the study. These animals remained on study and survived to the end of the study on Day 29.

To prevent such noncompliance from recurring, the research staff received refresher training that included review of the protocol's early removal criteria for irradiation studies.

The funding agency was 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

(b) (6)

Email: john.mcintire@sri.com

SRI International

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

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, January 17, 2023 8:06 AM
To: Michael Vigil
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: 1.13.23 Self-report to OLAW

Good morning Mike,

Thank you for sending us this report and we will send an official response soon.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Phone: 301-435-2390
Email: devora.mccoy@nih.gov

From: Michael Vigil <michael.vigil@sri.com>
Sent: Friday, January 13, 2023 6:12 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: IACUC Correspondence <anim-use@sri.com>; (b) (6)
Subject: [EXTERNAL] 1.13.23 Self-report to OLAW

Dear Sir/Madam:

Enclosed is the written report of an incident initially reported to Dr. Morse on 12/29/2022.

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)

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A3025-1F

Initial Report of Noncompliance

By: BCM

Date: 12/29/2022

Time: 1:00

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: ?

Was funding component contacted (if necessary):

What happened? Researcher failed to remove mice from irradiation study when required by protocol.

Species involved: Mouse

Personnel involved: Researcher

Dates and times: ?

Animal deaths:

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

Projected submission to OLAW of final report from Institutional Official:

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Case #