



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

June 27, 2022

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

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 June 15, 2022, letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at SRI International. According to the information provided, OLAW understands a retroorbital blood collection procedure was performed on the eye of a rat that was used approximately 4 hours previously, contrary to the SRI IACUC blood removal guidelines which state that "blood may be collected from a previously used eye provided that a recovery period of at least 2 weeks has been allowed for the used eye, or the collection is terminal." The technician failed to check the blood collection records to verify that retroorbital bleeding was performed previously and should have used an alternate blood collection route. The associated animal activity in question was PHS-funded.

The corrective action consisted of the responsible technician rereading the approved protocol.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

Neera V. Gopee -S

Digitally signed by Neera V. Gopee
-S
Date: 2022.06.27 10:40:48 -04'00'

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Associate Director, Animal Welfare Policy
Office of Laboratory Animal Welfare
National Institutes of Health

cc: IACUC Chair

SRI International

June 15, 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 June 2, 2022.

The protocol noncompliance incident involved 1 rat on a toxicokinetic study being conducted for the National Institute of Allergy and Infectious Diseases (NIAID), contract# HHSN272201800001I

The dose regimen for the toxicokinetic study was intravenous infusion over 60 min, BID for a single day, 7.9 hr interval, with blood collection time points of 0, 5, 15, 20 and 60 min, 2, 4, 7.9 hr post first dose and 4 hr post second dose. During a series of blood collections on 5/10/2022, a rat's omniport that had been used to collect blood samples from 0 to 60 minutes post first dose was not patent for the 2 hour post first dose time point. As an alternate route, retro-orbital (RO) blood collection was used to collect the remaining time points (2 hr post 1st dose, 4 hr post 1st dose, 7.9 hr post 1st dose, and 4 hr post 2nd dose). Technicians had used the RO route to collect the earlier time points for 2 hr post 1st dose and 4 hr post 1st dose. The technician who was collecting blood from this specific rat for the 2, 4, and 7.9 hr post dose inadvertently did not check the blood collection documentation to see that RO was used previously. An alternate route, such as tail vein, should have been used to collect the 7.9 hr post 1st dose time point instead of RO, so that the RO route could have been used for 4 hr post 2nd dose collection. SRI IACUC blood removal guidelines state that "blood may be collected from a previously used eye provided that a recovery period of at least 2 weeks has been allowed for the used eye, or the collection is terminal." Therefore, blood collection procedures deviated from the IACUC guidelines and protocol. The technician responsible for the oversight reread the protocol on 5/25/22.

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

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Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, June 16, 2022 7:00 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: 6.15.22 Self-report to OLAW

Thank you for this report, (b) (6) We will send a response soon.

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

From: (b) (6)
Sent: Wednesday, June 15, 2022 6:46 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] 6.15.22 Self-report to OLAW

Dear Sir/Madam:

Enclosed is the written report of an incident initially reported to Dr. Morse on 6/2/2022.

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,

(b) (6)

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