



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) 402-7065

March 12, 2019

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

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 March 8, 2019 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 that 34 rats were subjected to an additional retro-orbital bleed without first undergoing a two week rest between survival bleeds from the same eye as stated in the approved protocol. This occurred due to incomplete information in the blood collection schedule.

The corrective actions consisted of counseling the Principal Investigator, the Toxicology Services Director, and technical staff to ensure that all blood collection schedules list the route and method of blood collection, the time points, and the identification numbers of the animals.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair

SRI International

March 8, 2019

Brent Morse, D.V.M.
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:

SRI would like to report an incident which happened on January 22, 2019.

The incident involved 34 rats on a study being conducted for the National Institute for Allergy and Infectious Diseases (NIAID), contract # Contract HHSN2722018000011, Task Order No. HHSN27200003. Rats underwent survival retro-orbital (RO) bleeds (1st and 2nd timepoints), one bleed from each eye, on day 1 of the study. On day 7 the route/method of collection for the 3rd and 4th timepoints (tail bleed and terminal RO bleed respectively) were inadvertently reversed, resulting in the rats undergoing another survival RO bleed without the two-week minimum rest period (between survival RO bleeds from the same eye) required by the IACUC protocol. This error was traced to the study's blood collection schedule missing critical information such as the planned route and method of blood collection at each time point, and identification numbers of animals that will be involved for each method of collection.

To prevent such noncompliance from recurring, the IACUC Chair and Attending Veterinarian met with the PI, the Toxicology Services Director, and technical staff to ensure that all future studies will have blood collection schedules specify the route and method of blood collection at each timepoint and identification numbers for the animals that will be involved.

The incident was reported to the sponsor on February 13, 2019.

SRI fully understands all the implications of deviations from the Guide 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
General Counsel
Institutional Official
Tel.: (b) (6)
Fax: (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: Monday, March 11, 2019 7:07 AM
To: Esther Judith Tran
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: self-report to OLAW (A3025-01; D16-00012)

Thank you for this report, Ms. Maniago-Tran. We will send a response soon.

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

From: Esther Judith Tran <judith.maniago-tran@sri.com>
Sent: Friday, March 8, 2019 5:16 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: self-report to OLAW (A3025-01; D16-00012)

Dear Sir/Madam:

Enclosed is the written report of a recent incident in SRI.

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.

Regards,

Judith Maniago-Tran, M.B.A., C.P.I.A.

IACUC and IRB Chairperson

Program Director, Research Integrity

SRI International

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Menlo Park, CA 94025

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