



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

February 6, 2019

Re: Animal Welfare Assurance  
#A3025-01 (OLAW Case R)

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 January 31, 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 36 rats were bled from the tail vein in the animal housing room, rather than the procedure room, without prior approval from the Institutional Animal Care and Use Committee (IACUC).

The corrective actions consisted of retraining the technicians on adhering to the protocol and on contacting the Attending Veterinarian or IACUC regarding any animal concerns.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC 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

January 31, 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:

This letter is the written report of the incident discussed on the phone between SRI's Attending Veterinarian (AV), Dr. Kenneth López, and Dr. Neera Gopee on January 11, 2019.

The incident involves 36 rats on a study being conducted for the National Cancer Institute (NCI), contract # HHSN261200800001E. The rats were bled from the tail vein in the housing room, a practice that is not allowed without previous IACUC approval. The lead technician felt the normally used procedure room was too warm for the animals and staff members and decided to perform blood withdrawal on the animals in the housing room without first consulting the AV or anyone else in the IACUC regarding authorization prior to the procedure. In fact, the procedure room had remained within the temperature and humidity guidelines specified in The Guide. The IACUC has a policy requiring IACUC approval whenever invasive procedures (or procedures expected to cause more than slight/momentary pain/distress) will be performed in housing rooms. The noncompliance was performance of the experimental procedure of blood withdrawal in an animal housing room without prior permission from the IACUC. All other aspects of the blood withdrawal procedure were performed according to the IACUC protocol.

To prevent such noncompliance from recurring, the PI, the Study Director, and the Toxicology Services Director, will be involved in retraining the technicians in the Contract Services department on the need to adhere to the IACUC-approved protocol and at the very least, consult the Attending Veterinarian or the IACUC if there are questions/appear to be any issues (e.g. concerns on animal welfare, HVAC etc.).

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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**Morse, Brent (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Thursday, January 31, 2019 3:41 PM  
**To:** Esther Judith Tran; OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** IACUC Correspondence; John McIntire  
**Subject:** RE: 1.31.19 Self-report to OLAW

Thank you for providing this report Ms. Tran. We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM  
Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

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**From:** Esther Judith Tran [mailto:judith.maniago-tran@sri.com]  
**Sent:** Thursday, January 31, 2019 2:46 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:** 1.31.19 Self-report to OLAW

Dear Sir/Madam:

Enclosed is the written report of the incident discussed over the phone with Dr. Gopee on 1/11/2019.

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.*  
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Program Director, Research Integrity  
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