



DEPARTMENT OF HEALTH & HUMAN SERVICES

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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) 402-7065

February 26, 2019

Re: Animal Welfare Assurance
#A3046-01 (OLAW Case 1D)

Dr. Arthur J. Tipton
President and CEO
Southern Research
2000 Ninth Avenue South
Birmingham, AL 35205

Dear Dr. Tipton,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of a February 19, 2019 email from Dr. Mann and acknowledged by you reporting an adverse event within the animal care and use program at Southern Research. According to the information provided, OLAW understands that a rat that had undergone CO2 toxicosis as a euthanasia method was found to be gasping and had regained consciousness during necropsy despite having been checked by two individuals for lack of consciousness. It was returned to the CO2 chamber and fully euthanized. The animal was supported by PHS funding.

To prevent a recurrence, ethanol will be applied to the fur around the neck as an additional stimulus to confirm unconsciousness and a pneumothorax will be performed as soon as the testis is removed during the necropsy.

The prompt consideration of this matter by Southern Research was consistent with the philosophy of institutional self-regulation. Similarly, the actions taken to resolve the issue and prevent recurrence were appropriate. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

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Hi Art,

I did not realize that I needed to get your signature on this report. Please send acknowledgement to Dr. Morse at OLAW Division of Compliance Oversight (NIH/OD) [mailto:olawdco@od.nih.gov] .

Thanks,

Jill

Jill F. Mann, D.V.M., DACVP
IACUC Chairperson
Senior Pathologist
Toxicology and Pathology Services Department
Southern Research
2000 Ninth Avenue South
Birmingham, AL 35205

(b) (6)

jmann@southernresearch.org

From: OLAW Division of Compliance Oversight (NIH/OD) [mailto:olawdco@od.nih.gov]

Sent: Wednesday, February 20, 2019 9:26 AM

To: Mann, Jill <jmann@southernresearch.org>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Cc: IACUC <IACUC-BIRMINGHAM@sriemail.sri.org>

Subject: RE: Report of an adverse event regarding the ACUP 18-07-024B, Southern Research study 14140.25.01

CAUTION: This email originated from outside of the organization. Carefully examine the content before you open any links or attachments.

Thank you for providing this report Dr. Mann. We require acknowledgement of the report by the Institutional Official by signature or other means. We will hold the case file open until then.

Best regards, Brent Morse

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

From: Mann, Jill <jmann@southernresearch.org>

Sent: Tuesday, February 19, 2019 2:09 PM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Cc: IACUC <IACUC-BIRMINGHAM@sriemail.sri.org>

Subject: Report of an adverse event regarding the ACUP 18-07-024B, Southern Research study 14140.25.01

Dear Dr. Morse,

In accordance with Assurance #D16-00025 (A3046-01) and PHS Policy IV.F.3, Southern Research (SR) provides a report of an adverse event regarding the ACUP 18-07-024B, Southern Research study 14140.25.01, Sponsor Study No.: C10127, Contract No.: HHSN273201300010C *Subchronic Study of Acetaminophen (APAP, CAS# 103-90-2) in Harlan Sprague Dawley Rats Following Exposure on Gestation Days 14-18 (C10127).*

This adverse event was reported to the Veterinarian, Study Director and the IACUC Chair on Friday, February 15 2019 and an investigation was initiated. A male Sprague Dawley rat (animal 13077) was scheduled for euthanasia via CO2 to be followed by necropsy and tissue collection. The In-Life technician removed the rat from the CO2 chamber and checked for an eye reflex, toe pinch response, and respirations. There were no signs of life. Prior to the initiation of necropsy, the necropsy technician also checked the rat for a palpable heartbeat in the chest and for a toe pinch response. The necropsy technician also detected no signs of life and proceeded to pin the animal to the necropsy board, again the animal did not react to the pinning of the feet. The necropsy was started and the left testis removed for sperm analysis when the animal began gasping and regained consciousness. The In-Life technician had stepped out of the room momentarily to hand off the testis to be analyzed. As soon as the In-Life technician stepped back in the room the rat was returned to the CO2 chamber and fully euthanized. After removal from the CO2 chamber the second time there were no signs of life and the necropsy technician completed the necropsy.

Normal Southern Research necropsy processes require the creation of a pneumothorax to ensure the effectiveness of the euthanasia procedure (all non-necropsied animals go through similar secondary verification steps to ensure the effectiveness of the euthanasia procedure) however in this particular instance the urgency of the tissue collection (testis and epididymis) required this step to be completed first. In an effort to prevent this from occurring again, in addition to checking for an eye reflex response, toe pinch response, respirations and a palpable heartbeat, Southern Research will have the necropsy technician apply ethanol to the fur around the neck area to provide additional stimulus to potentially rouse the animal if it is not fully euthanized. A pneumothorax will be performed as soon as the testis has been removed and handed off to the In Life technician.

Thank you,
Jill F. Mann

Jill F. Mann, D.V.M., DACVP
IACUC Chairperson
Senior Pathologist
Toxicology and Pathology Services Department
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