



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

May 25, 2021

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

Dr. Mark Suto  
President and CEO  
Southern Research  
2000 Ninth Avenue South  
Birmingham, AL 35205

Dear Dr. Suto,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 18, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Southern Research (SR). This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the SR Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: failure to adhere to the IACUC-approved protocol. The final report states a protocol deviation occurred on March 15, 2019 and April 11, 2019. It is stated amendment #6 approved the addition of 110 animals for blood collection. However, it was determined that 113 animals were used for the approved procedure. It is also stated the study protocol approved use of 11 dams and 88 pups, but it was discovered that 102 pups were indeed used for an approved procedure.

It is understood that the study director for this project at the time the deviations occurred is no longer at Southern Research. The deviations were identified by the newly assigned study director and he reported them to the IACUC chairperson. In response to the findings, updates to ACUP animal numbers will be made by the new study director. Also, the new study director has been trained on animal ordering and amending a protocol if more animals are required.

It is noted that this study is supported by PHS funds. Based on its assessment of this explanation, OLAW understands that the Southern Research has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy.

We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

Jacquelyn T. Tubbs -S

Digitally signed by  
Jacquelyn T. Tubbs -S  
Date: 2021.05.25  
15:21:49 -04'00'

Jacquelyn T. Tubbs, DVM, DACLAM  
Animal Welfare Program Specialist  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Contact



Solving the world's hardest problems.

A3046-1f

OLAW  
Division of Compliance Oversight  
Office of Laboratory Welfare, NIH  
Rockledge 1, Suite 360 MSC 7982  
Bethesda, MD 20892-7982

18 MAY 2021

To Whom It May Concern,

In accordance with Assurance #D16-00025 and PHS Policy IV.F.3, Southern Research (SR) provides this report of non-compliance regarding ACUP 16-08-035B-*Historical Control Study of Hematology Parameters in Harlan Sprague Dawley Rats* (HC2019DevHemR) Southern Research Study No: 14140.11.20 Contract No.: (b) (4)

A deviation from ACUP 16-08-035B Amendment# 6 (approved 04 March 2019) occurred on 15 March 2019 and 11 April 2019. Amendment #6 approved the addition of 110 animals (10 pregnant dams and their pups) to be used for blood collection, Classified under Column D. In actuality, 11 dams and 102 pups were added to the study and used for blood collection for a total of 113 rats. A deviation also occurred against the study protocol. The study protocol approved the use of 11 dams and 88 pups for blood collection. The number of animals actually used for blood collection was 11 dams and 102 pups. The in-vivo portion of this study ended on 11 April 2019. (Note: ACUP 16-08-035B later became ACUP 19-07-034B. No animals were used on ACUP 19-07-034B and this ACUP has since been termed).

The study director for this study at the time these deviations occurred no longer works at Southern Research. The newly assigned study director discovered the deviations as he was preparing the final report, and reported them to our IACUC Chairperson. As this is a PHS funded study, we wanted to report these deviations to OLAW.

Updates to ACUP animal numbers will be made by the new study director. The new study director has also been trained on animal ordering and amending a protocol if more animals are needed.

Southern Research is committed to protecting the welfare of all animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact Dr. Jill Mann, IACUC Chairperson @ [jmann@southernresearch.org](mailto:jmann@southernresearch.org).

Regards,  
(b) (6)

Dr. Mark J. Suto  
Vice President, Life Sciences

SouthernResearch.Org  
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**Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Thursday, May 20, 2021 12:13 PM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Please see attached correspondence

Thank you for this report. We will send a response soon.

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

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**From:** (b) (6)  
**Sent:** Thursday, May 20, 2021 12:05 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** Please see attached correspondence

Please let me know if you have any questions. Thank you!



[www.southernresearch.org](http://www.southernresearch.org)

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