



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive – MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

June 6, 2017

Re: Animal Welfare Assurance
A3632-01 [OLAW Case 1D]

Dr. Robert E.W. Fyffe
Vice President for Research
Wright State University
3640 Colonel Glenn Highway
202 University Hall
Dayton, OH 45435

Dear Dr. Fyffe,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 5, 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Wright State University. According to the information provided, OLAW understands that sixteen rats were subjected to cardiocentesis under CO2 anesthesia although this activity had not been included in the approved protocol. Seven of the rats died or were euthanized due to weight loss, weakness, and dehydration. These rats had also undergone an approved minor surgical procedure before the blood was taken and it was determined post-mortem that poor maternal care and cardiac dysfunction contributed to the death.

The corrective actions consisted of the Institutional Animal Care and Use Committee (IACUC) requiring the investigator to undergo retraining and to ensure that the laboratory staff use approved procedures, is adequately trained, and has access to the protocols. All morbidity and mortality on this protocol must be reported to the veterinarians for the next six months after which time only unexpected health problems must be reported.

OLAW understands that the protocol involved was not PHS-supported, but concurs that the incidents were serious and supports the actions taken by the IACUC. The establishment and application of policies and practices that are consistent with the provisions of the PHS Policy at Wright State University are commendable and avoid the perception of a double standard. Thank you for informing OLAW about this matter.

Sincerely,

Axel Wolff, M.S., D.V.M.
Director
Division of Compliance Oversight

cc: IACUC Chair



June 5, 2017

Robert E.W. Fyffe, Ph.D.
Vice President for Research
and Dean of the Graduate School
3640 Colonel Glenn Hwy.
Dayton, OH 45435-0001
(937) 775-3336
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Axel V. Wolff, M.S., D.V.M.
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Reference: Animal Welfare Assurance Number D16-00383 (A3632-01)
Wright State University

Dear Dr. Wolff:

In compliance with *The PHS Policy on Humane Care and Use of Laboratory Animals* (Policy), "Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals" [NOT-OD-05-034, February 24, 2005, Office of Laboratory Animal Welfare (OLAW), Office of Extramural Research], and Wright State University's Animal Welfare Assurance (D16-00383/A3632-01), the purpose of this letter is report an occurrence of noncompliance with the PHS Policy and the result of the initial investigation. The research described in this report is not supported by an NIH grant.

On May 24, 2017, an investigator was found to be using an unapproved animal procedure in her laboratory. The procedure involved taking a non-terminal blood sample while under CO₂ anesthesia from 16 rats using a cardiocentesis method. Blood sampling had been approved by the IACUC using the tail vein or cheek bleed method but not by cardiocentesis, and not while using CO₂ anesthesia. An amendment for the new method of blood sampling had been submitted by the investigator to the IACUC for approval, but was still under review by the IACUC at the time the procedures were performed.

Of the 16 animals that underwent cardiocentesis with CO₂ anesthesia, seven died or were euthanized due to weight loss, weakness, and dehydration. All seven of these animals also underwent an approved minor surgical procedure 24 hours prior to blood sampling. Necropsy examination of two euthanized animals revealed a multi-factorial cause of death which included poor maternal care and cardiac dysfunction. The other nine animals that underwent cardiocentesis had no apparent clinical effects.

Axel V. Wolff, M.S., D.V.M.

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A subcommittee of the IACUC was formed immediately upon notification of the protocol violation and met on May 31, 2017. The following corrective actions were recommended to, and approved by the IACUC on June 1, 2017, and formally communicated to the investigator:

- The investigator must undergo additional training in IACUC procedures and ethics. The following training modules available through citiprogram.org must be completed by June 30, 2017:
 - Working with the IACUC (Basic Course)
 - Responsible Conduct of Research (RCR) (Basic Course)
- The investigator must address the importance of using approved procedures and proper training with the members of her laboratory by June 30, 2017. The investigator must ensure that each lab member has access to and reviews all protocols that they will be working on.
- The investigator must report ALL animal morbidity and mortality on the affected animal use protocol to the University veterinarians until December 31, 2017. After that time, the investigator will continue to report unexpected or significant health problems as required.

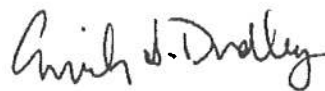
The investigator was also notified that any further violations that occur on any of her animal use protocols will result in further sanctions that could include stringent oversight or termination of the protocol.

Wright State University regrets this unfortunate deviation from the requirements of the PHS policy. If you have any additional questions or need clarification, please contact Dr. Gregory P. Boivin, Director of Laboratory Animal Resources telephone # [REDACTED] or Dr. Emily S. Dudley, Chair of the Institutional Animal Care and Use Committee telephone # [REDACTED] at Wright State University.

Sincerely,



Robert E. W. Fyffe, Ph.D.
Institutional Official
Vice President for Research and
Dean of the Graduate School



Emily S. Dudley, D.V.M.
Chair, WSU-IACUC

cc: James Swearengen, D.V.M., AAALAC

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, June 06, 2017 7:36 AM
To: Secondary individual
Subject: RE: Wright State University Report of Noncompliance

Thank you for this report. Secondary individual We will respond soon.

Axel Wolff

From: Secondary individual [mailto:Secondary individual@wright.edu]
Sent: Monday, June 05, 2017 4:24 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Wright State University Report of Noncompliance

Dr. Wolff,

Please see the attached letter regarding an issue of noncompliance on a Wright State University approved protocol. Let me know if you have any questions or concerns.

Best,

**WRIGHT STATE
UNIVERSITY**

Secondary individual Compliance Coordinator

3640 Colonel Glenn Hwy Room # Dayton, OH 45435
Phone: telephone # Secondary individual@wright.edu