



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

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Office of Laboratory Animal Welfare
Rockledge One, Suite 360
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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

November 20, 2017

Re: Animal Welfare Assurance
A3295-01 [OLAW Case 4C]

Dr. Jane E. Strasser
Associate Vice President
University of Cincinnati
Office of Research Compliance and
Regulatory Affairs
P.O. Box 210567
Cincinnati, OH 45221-0567

Dear Dr. Strasser,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 9, 2017 letter reporting several noncompliance incidents with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Cincinnati, which had not been preceded by a preliminary report to OLAW. According to the information provided, OLAW understands that the IACUC suspended an animal use protocol as a result of a series of violations including the performance of a surgical procedure by an unauthorized research associate whose animal use privileges were temporarily revoked by the IACUC; inappropriate drug records maintenance; shared storage of expired and in-use drugs and expired anesthetic drug use. A total of thirteen mice were involved in the noncompliant surgical event and all animals from the suspended protocol were transferred to an IACUC approved holding protocol which allows for continued colony breeding. It was also identified that previously there have been concerns associated with the aforementioned protocol. The associated animal activities in question were funded by PHS grants 5R01HL087861 and 5R01GM112930.

The corrective actions consisted of the following:

- 1) Revoking the Principal Investigator (PI) and laboratory personnel's access into the housing facilities for the duration of the protocol suspension period, with the exception of the maintenance of the critical breeding colony by one research associate while under direct Laboratory Animal Medical Services supervision.
- 2) Retraining the PI and laboratory staff on appropriate controlled drug records management, securing in-date drugs and disposal of expired drugs.
- 3) The Institutional Official issuing a letter of reprimand to the PI which indicates that continuing noncompliance will result in escalating sanctions.
- 4) OLAW recommends that the PHS funding components be notified directly to determine the allowability of charges against the grant during the period of noncompliance for the suspended animal activities. Please be advised that institutions should promptly notify OLAW of noncompliance issues,

with submission of a follow-up thorough report once the IACUC has established a plan and schedule for correction. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct and prevent recurrence of the noncompliance. We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,



Neera V. Gopee, DVM, PhD, DACLAM, DABT
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Chair

Gopee, Neera (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, November 16, 2017 5:00 PM
To: Secondary Individual OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report of Non-Compliance from University of Cincinnati A3295-01

Thanks for the clarification, I appreciate it.

Neera

From: Secondary Individual [mailto:Secondary Individual@ucmail.uc.edu]
Sent: Thursday, November 16, 2017 1:41 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: RE: Report of Non-Compliance from University of Cincinnati A3295-01

Hi Neera,

- 1) The PI's colony of mice were transferred to an IACUC approved veterinary holding protocol that describes that species appropriate husbandry care is provided by LAMS staff.
- 2) The same holding protocol describes that and breeding colony maintenance is permitted under prior arrangement with LAMS veterinary staff. The PI and lab staff, except the one designated lab member performing colony maintenance under LAMS veterinary staff escort/oversight, had their facility access temporarily revoked during the suspension.

Dave

From: OLAW Division of Compliance Oversight (NIH/OD) [mailto:olawdco@od.nih.gov]
Sent: Thursday, November 16, 2017 11:17 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Secondary Individual
Secondary Individual@ucmail.uc.edu>
Subject: RE: Report of Non-Compliance from University of Cincinnati A3295-01

Hi Secondary Individual

In reviewing your memo I am would like to request additional clarification of the following two items:

- (1) Were mice held on an approved holding protocol or maintained according to IACUC-approved standard operating procedures (SOPs) for housing and routine animal care during the period of the protocol suspension?
- (2) If yes, is breeding allowed on holding protocols or established SOPs?

Neera

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, November 15, 2017 4:07 PM
To: Secondary Individual @ucmail.uc.edu>; OLAW Division of Compliance Oversight (NIH/OD)
<olawdco@od.nih.gov>
Subject: RE: Report of Non-Compliance from University of Cincinnati A3295-01

Thank you Secondary Individual for your prompt response in providing the requested information.

Please see the attached letter of non-compliance from the Institutional Official of the University of Cincinnati.

[Redacted]
Secondary Individual

Research Compliance Specialist
IACUC Office
Office of Research Integrity
University of Cincinnati
P.O. Box 210572
Cincinnati, OH 45221-0572
Tel [Redacted] Phone Number
Fax [Redacted] Phone Number
Email [Redacted] dary Indi@ucmail.uc.edu



Jane Strasser, PhD
 Associate Vice President for Research
 Institutional Official
 University of Cincinnati
 PO Box 210567
 51 Goodman Drive
 300 University Hall
 Cincinnati, OH 45221-0567

Phone: (513) 558-5034
 Fax: (513) 558-4111
 Jane.Strasser@uc.edu

November 9, 2017

Axel Wolff, M.S., D.V.M.
 Director, Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 Rockledge 1, Suite 1051
 6705 Rockledge Drive, MSC 7982
 Bethesda, Maryland 20852

RE: PHS Assurance No. A3295-01 / D16-00190

In accordance with PHS Policy and the terms of our Assurance Statement, we are advising you of an issue of continued non-compliance discussed at the October 12, and November 9, 2017 meetings of University of Cincinnati Institutional Animal Care and Use Committee (IACUC).

The findings were that a lab member while under an IACUC mandated 30 day personal suspension performed surgery; additional concerns involved drug record keeping, storing expired and in-date drugs in the same location, and the use of an expired anesthetic drug. This was not the first time that concerns arose with this protocol. The IACUC voted to suspend the PI's animal use protocol for a 30 day period for continued non-compliance.

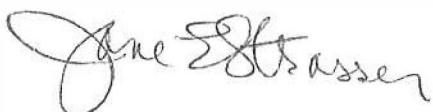
Corrective Actions:

- The PI and lab staff's access to LAMS housing facilities have been revoked for the duration of the suspension period. The IACUC agreed to allow one lab member to perform critical breeding colony maintenance while under LAMS direct supervision but prohibited experimental procedures during the suspension.
- The PI and lab staff were retrained on controlled substance drug record keeping and best practice procedures for securing in-date drugs and sequestration/disposal of expired substances. The PI has submitted a plan to the IACUC describing additional measures to prevent further non-compliance.

- A letter was sent from the IO to the PI acknowledging the corrective actions and indicating that any further non-compliance would result in strict and more progressive actions.

Species: mouse / rat
NIH Funding: 5 R01 HL087861
5 R01 GM112930

Sincerely,

A handwritten signature in black ink, appearing to read "Jane E. Strasser". The signature is fluid and cursive, with the first name "Jane" being more prominent.

Jane E. Strasser, Ph.D.
Associate Vice-President for Research and Institutional Official

cc: George F. Babcock, Ph.D., Chair, Institutional Animal Care and Use Committee

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, November 13, 2017 9:43 AM
To: Secondary Individual OLAW Division of Compliance Oversight (NIH/OD)
Cc: Babcock, George (babcocgf); Strasser, Jane (strassje)
Subject: RE: Report of Non-Compliance from University of Cincinnati A3295-01

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

Regards, Brent Morse

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

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From: Secondary Individual [mailto:Secondary Individual@ucmail.uc.edu]
Sent: Thursday, November 09, 2017 3:49 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Babcock, George (babcocgf) <babcocgf@ucmail.uc.edu>; Strasser, Jane (strassje) <strassje@ucmail.uc.edu>
Subject: Report of Non-Compliance from University of Cincinnati A3295-01

Dear Dr. Wolff, *et.al.*,

Please see the attached letter of non-compliance from the Institutional Official of the University of Cincinnati.

Secondary Individual

Research Compliance Specialist
IACUC Office
Office of Research Integrity
University of Cincinnati
P.O. Box 210572
Cincinnati, OH 45221-0572
Tel: Phone Number
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Email: Secondary Individual@ucmail.uc.edu