



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

April 6, 2020

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

Dr. Jane E. Strasser  
Associate Vice President for Research  
University of Cincinnati  
P.O. Box 210663  
51 Goodman Drive, (b) (4) University Hall  
Cincinnati, OH 45221-0567

Dear Dr. Strasser,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 1, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Cincinnati following up on an initial February 14, 2020 notification by telephone.

According to the information provided, this Office understands that the University of Cincinnati Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: failure of a new training system to register new IACUC users in the institution's Occupational Health and Safety Program (OHSP). The final report states approximately 50 researchers began working with animals after all the other training requirements had been completed but were not enrolled in the OHSP. The corrective actions that were implemented included:

- Informing impacted researchers promptly of the issue and enrolling them in the OHSP.
- ACUC leadership met with IT to develop a corrective action plan.

IT reported the following updates on March 23, 2020:

- ACUC personnel with administrative access can now see when a health questionnaire was submitted by any individual to University Health Services.
- Completion of all occupational health and safety documents is now a prerequisite for training completion in the system.
- Alerts have been added in the training databases that will inform the researcher of outstanding items required to complete their training.

Based on its assessment of this explanation, OLAW understands that the University of Cincinnati 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.

*April 6, 2020*  
*OLAW Case A3295-4M*

Sincerely,

(b) (6)

Jacquelyn T. Tubbs, DVM  
Veterinary Medical Officer  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Contact



Jane Strasser, Ph.D.  
Sr. Associate Vice President for Research  
Institutional Official  
University of Cincinnati  
PO Box 210663  
51 Goodman Drive  
540 University Hall  
Cincinnati, OH 45221-0663

Phone: (513) 558-5034  
Fax: (513) 558-0549  
Jane.Strasser@uc.edu

April 1, 2020

Brent Morse, D.V.M., DACLAM  
Interim-Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500 MSC 6910  
Bethesda, Maryland 20817

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

In accordance with PHS Policy and the terms of our Assurance Statement, we are advising you of an issue of programmatic non-compliance that was discovered and initially reported as an oral preliminary submission on February 14, 2020. Below is the final formal report that includes the corrective action that has now fixed this non-compliance.

#### **Occupational Health and Safety Program Researcher Enrollment Deficiency**

The failure of a new training system to register new IACUC users in our Occupational Health and Safety Program (OHSP) was identified in an audit. These roughly 50 researchers began working with animals after all the other training requirements had been completed but were not enrolled in the OHSP. Prior to this issue staff from the Animal Care and Use Program (ACUP) were not readily able to monitor enrollment in the OHSP, that information was only visible to health care providers.

#### Corrective Actions:

- Impacted researchers were promptly informed of the issue and enrolled in the OHSP..
- ACUP leadership met with IT to develop a corrective action plan. IT committed to implementing the proposed solution as quickly as possible.
- On March 23, 2020 IT reported the following:
  - ACUP personnel with administrative access can now see when a health questionnaire was submitted by any individual to University Health Services.
  - Completion of all occupational health and safety documents is now a prerequisite for training completion in the system.
  - Alerts were added in the training database that will inform the researcher of any outstanding items required to complete their training.

Sincerely,

(b) (6)

Jane E. Strasser, Ph.D.

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

## **Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Thursday, April 2, 2020 9:18 AM  
**To:** Custer, David (custerda)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Letter of Non-Compliance University of Cincinnati D16-00190 (A3295-01)

Thank you for this report, Mr. Custer. We will respond soon.  
Axel Wolff

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**From:** Custer, David (custerda) <custerda@ucmail.uc.edu>  
**Sent:** Wednesday, April 1, 2020 4:43 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** Letter of Non-Compliance University of Cincinnati D16-00190 (A3295-01)

Dear Dr. Morse, *et.al.*,

Attached is a letter from the IO of University of Cincinnati on an issue of non-compliance that was initially submitted by a telephone oral report.

**David A. Custer**  
Interim-Director, Animal Regulatory Compliance  
IACUC Office  
Office of Research Integrity  
University of Cincinnati  
P.O. Box 210572  
Cincinnati, OH 45221-0572  
Tel (b) (6)  
Email [custerda@ucmail.uc.edu](mailto:custerda@ucmail.uc.edu)



## Initial Report of Noncompliance

By: N. Rose, CooperDate: 3-10-20Time: 3:27 PMName of Person reporting: David CusterTelephone #: (b) (6)Fax #: (b) (6)Email: (b) (6)Name of Institution: University of CincinnatiAssurance number: 016-00190Did incident involve PHS funded activity? Programmatic

Funding component: \_\_\_\_\_

Was funding component contacted (if necessary): \_\_\_\_\_

What happened? Programmatic Issue

- Several animal users did not complete the medical health questionnaire over a couple of months due to a change in the OHSR website and were inadvertently enrolled in the OHSR and allowed to use animals

Species involved: rodents

Personnel involved: \_\_\_\_\_

Dates and times: \_\_\_\_\_

Animal deaths: \_\_\_\_\_

Projected plan and schedule for correction/prevention (if known): \_\_\_\_\_

Projected submission to OLAW of final report from Institutional Official: \_\_\_\_\_

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Case # \_\_\_\_\_