



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

December 14, 2022

Re: Animal Welfare Assurance
#A3272-01 [OLAW Case 2R]

Dr. Denis Wirtz
Vice Provost for Research
Johns Hopkins University
(b) (4) Garland Hall
3400 N. Charles St.
Baltimore, MD 21218

Dear Dr. Wirtz,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 30, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Johns Hopkins University, following up on an initial telephone report on June 12, 2022. According to the information provided, OLAW understands that one pig was used in a research activity after the protocol had expired. The animal was not on a PHS funded study and the investigator subsequently left the institution.

The corrective actions consisted of placing the second pig ordered for this study on an approved, active protocol. Institutional procedures were modified to ensure accurate tracking of protocol expiration dates to allow intervention to prevent animal purchases for procedures without an active protocol in place.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy. Unless informed to the contrary, OLAW assumes that the pig used in the study was euthanized. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair
Robert Gibbens, D.V.M., USDA-APHIS-AC



November 30, 2022

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare
National Institutes of Health
Bethesda, Maryland 20892-6910

RE: Animal Welfare Assurance #A3272-01, OLAW Case 2R

Dear Dr. Wolff:

Please accept this letter as the final report on a finding of serious noncompliance with the Public Health Service (PHS) *Policy on Humane Care and Use of Laboratory Animals*. In accordance with federal guidelines, the circumstances in question were described to you in a prompt report from Dr. Brendan Canning, Chair of the Johns Hopkins University (JHU) Animal Care and Use Committee (ACUC) on June 12, 2022 (OLAW Case #A3272-2R).

A researcher using swine for cardiac ablation studies failed to submit a renewal application for an active but expiring protocol. Just prior to expiration, 2 pigs were ordered for the project. An experiment was performed on one of the pigs after protocol expiration. The PI was informed of this serious noncompliance. The second pig was immediately transferred to an active protocol supporting the investigator's research.

An ACUC Compliance Subcommittee was convened on May 17, 2022. The Compliance Subcommittee voted unanimously that the circumstances represented serious noncompliance with PHS policy. Following the May 17, 2022 meeting, the Compliance Subcommittee confirmed that the second pig had in fact been transferred to an active protocol, and the case was closed during the October 20th ACUC meeting.

This research was not supported by federal funding. The PI has since left JHU. Corrective actions implemented focused on identifying census software shortcomings that allowed the purchase of animals for soon to be expired protocols and on earlier interventions to prevent use of any animals associated with expired protocols. A parallel spreadsheet documenting actual expiration dates has been maintained and a system for contacting investigators as these deadlines approach has been implemented to address shortcomings in the software. The JHU ACUC considers this matter closed.

Please do not hesitate to contact me if you have additional questions.

Sincerely,

(b) (6)


Denis Wirtz, Ph.D.
Vice Provost for Research



JOHNS HOPKINS
UNIVERSITY

cc: AAALAC International

Brendan J. Canning, Ph.D., Chair, Johns Hopkins University Animal Care and Use Committee

Eric Hutchinson, D.V.M., DACLAM, Attending Veterinarian and Assistant Vice Provost for Animal Research and Resources, Johns Hopkins University

(b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, December 12, 2022 8:03 AM
To: Brendan Canning
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Final reports

Good morning Dr. Canning,

Thank you for sending us these three final reports and we will send official responses soon.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

From: Brendan Canning <bjc@jhmi.edu>
Sent: Friday, December 9, 2022 1:16 PM
To: Wolff, Axel (NIH/OD) [E] <WolffA@OD.NIH.GOV>; Denis Wirtz <wirtz@jhu.edu>; Eric Hutchinson <ehutchi8@jhmi.edu>; (b) (6)
Subject: [EXTERNAL] Final reports

Dear Dr. Wolff,

Please find attached the final reports on cases 2R, 2S and 2U.

Thanks in advance for confirming receipt. Contact me directly if you have any questions.

Regards,

Brendan J. Canning, Ph.D.
Professor of Medicine
Chair, Johns Hopkins University Animal Care and Use Committee
Johns Hopkins Asthma and Allergy Center
5501 Hopkins Bayview Circle
Baltimore, Maryland 21224
(b) (6)

e-mail: bjc@jhmi.edu



Initial Report of Noncompliance

By: (b) (6)

Date: 6/12/22

Time: 4:20

Name of Person reporting: *Mendenham*

Telephone #: (b) (6)

Fax #: (b) (6)

Email:

Name of Institution: Johns Hopkins U

Assurance number: A3272-2R

Did incident involve PHS funded activity? No

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

Pig studies done on expired protocol

Species involved: *Pigs*

Personnel involved:

Dates and times:

Animal deaths:

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

Other pig transferred to active protocol

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____