



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

February 14, 2022

Re: Animal Welfare Assurance
#A3272-01 (OLAW Case 20]

Dr. Denis Wirtz
Vice Provost for Research
Johns Hopkins University
3400 N. Charles Street
Baltimore, MD 21218

Dear Dr. Wirtz,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 8, 2022 letter responding to my November 8, 2021 request for an assessment of allegations of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Johns Hopkins University which had been submitted by People for the Ethical Treatment of Animals (PETA). According to the information provided, OLAW understands the following:

- 1) The two allegations regarding a study involving pigs had been appropriately reported to OLAW (case A3272-2K), the corrective/preventive measures had been accepted, and the case was closed.
- 2) The allegation involving headcap infections in rhesus monkeys, including one which lead to euthanasia, was determined by the Institutional Animal Care and Use Committee (IACUC) to have constituted a reportable incident. The IACUC investigated and found that some personnel involved with the headcap surgeries were not proficient in applying aseptic surgical technique. The IACUC and Attending Veterinarian put corrective measures in place which included extensive retraining of the laboratory staff involved and allowing only proficient personnel to perform surgery. Subsequent surgeries were performed successfully. Because the IACUC determined that this matter should have been promptly reported to OLAW, a new standard operating procedure was developed which provides additional guidance on reportable events.
- 3) The allegation regarding provision of expired heparin and sodium chloride to a rabbit was sustained and the matter has been corrected. Policies and procedures are in place to ensure that expired materials are not used in animal activities. The laboratory staff involved was counseled and the animals involved were evaluated and found not to have been negatively impacted by use of the agents.

Based on its assessment of these explanations, OLAW understands that measures have been implemented in each situation to correct and prevent recurrence of the problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy and will inform PETA of this assessment. Thank you for your comprehensive response to this inquiry.

Sincerely,

 (b) (6)

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

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



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February 14, 2022

Re: Animal Welfare Assurance
#A3272-01 (OLAW Case 20]

(b) (6)

(b) (6)

The Office of Laboratory Animal Welfare (OLAW) has concluded its investigation of the allegations of noncompliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy) at Johns Hopkins University which you submitted on behalf of People for the Ethical Treatment of Animals on November 3, 2021 and determined the following:

- 1) The two allegations regarding a study involving pigs had been appropriately reported to OLAW by the institution, the corrective/preventive measures had been accepted, and the case was closed.
- 2) The allegation involving headcap infections in rhesus monkeys, including one which lead to euthanasia, was determined by the Institutional Animal Care and Use Committee (IACUC) to have constituted a reportable incident. The IACUC investigated and found that some personnel involved with the headcap surgeries were not proficient in applying aseptic surgical technique. The IACUC and Attending Veterinarian put corrective measures in place which included extensive retraining of the laboratory staff involved and allowing only proficient personnel to perform surgery. Subsequent surgeries were performed successfully. Because the IACUC determined that this matter should have been promptly reported to OLAW, a new standard operating procedure was developed which provides additional guidance on reportable events.
- 3) The allegation regarding provision of expired heparin and sodium chloride to a rabbit was sustained and the matter has been corrected. Policies and procedures are in place to ensure that expired materials are not used in animal activities. The laboratory staff involved was counseled and the animals involved were evaluated and found not to have been negatively impacted by use of the agents.

Because the incidents have all been corrected there was no need to suspend or revoke the grant. Johns Hopkins University is in compliance with the Animal Welfare Assurance and the provisions of the PHS Policy and no further actions will be taken. Thank you for your interest in animal welfare.

Sincerely,

(b) (6)

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



February 8, 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 2O

Dear Dr. Wolff:

Please accept this letter in response to your letter dated November 8, 2021, regarding the above captioned case. The circumstances referenced in your letter were summarized in a citation issued by the USDA after a routine inspection of our facilities on the 23rd of August 2021. We appreciate the extension of time you granted to us to respond. Your letter requested that the Johns Hopkins Animal Care and Use Committee (ACUC) review the citations issued by the USDA to determine whether the underlying facts and circumstances represented serious noncompliance that should have been reported to OLAW under the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (the "Policy"). A summary of the ACUC's findings is presented below.

- 1) With respect to items 1 and 4 in your letter, the ACUC found that these matters were properly investigated and reported to OLAW in a timely manner in accordance with the Policy. As a reminder, my letter to you dated June 21, 2021, summarizes the ACUC's suspension of a protocol focused on cardiopulmonary resuscitation techniques performed in pigs. After the unexpected death of an animal associated with that protocol, and in accordance with PHS policy, a prompt report was delivered by phone to your office on March 20, 2021. The ACUC followed its procedures for addressing potential serious noncompliance, and the ACUC's decision to suspend the protocol and associated corrective actions are outlined in that June 21, 2021 letter to you. Your office acknowledged by letter dated June 28, 2021 the prompt report which you assigned OLAW Case #2K and supported the corrective actions put in place. All faculty and staff still working on this project have been retrained and the corrective actions were adopted and have been fulfilled. The ACUC considers this matter closed.
- 2) With respect to item 2 in your letter, the ACUC found: (i) that the matter was properly investigated by the ACUC with regards to animal safety and welfare and that appropriate and effective corrective actions were adopted and implemented; and (ii) the ACUC concluded that the matter should have been reported to OLAW, and the failure to timely report constituted serious noncompliance with the Policy.

During a recent routine inspection of Johns Hopkins facilities, the USDA noted in our ACUC meeting minutes a summary of the corrective actions put in place to address welfare concerns in a lab utilizing headcaps on rhesus monkeys for neuronal recordings. In brief, several animals associated with this protocol had developed infections in and around the headcaps at various times after surgery. The cause of the infections were initially thought to be a consequence of the approved recording procedures. However, after a severe infection prompted an unscheduled euthanasia in June 2021, the ACUC Chair and JHU attending veterinarians reviewed the surgical

Office of the Provost

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Obtained by Rise for Animals.
Uploaded to Animal Research Laboratory Overview (ARLO) on 07/11/2022



practices within the lab and concluded that some personnel involved lacked proficiency with aseptic surgical technique. The ACUC Chair and JHU attending veterinarian immediately intervened and put in place a corrective action plan to ensure that only study team members with demonstrated proficiency would perform surgery. Extensive retraining of team members was also scheduled and provided. This welfare concern and the corrective actions put in place were both discussed during an ACUC meeting held in July 2021. In that meeting the ACUC primarily focused on the corrective actions and safety and welfare of the animals in the study and did not at that time render a decision regarding whether the circumstances represented a reportable event to OLAW. A successful surgery was completed later that month in accordance with the corrective actions adopted by the study team. The ACUC considered the case closed at its next scheduled meeting in August 2021. Again in accordance with the corrective actions put in place, an additional surgery was performed in December with no complications. Both animals associated with this protocol that have undergone surgeries since the corrective actions were put in place remain in good health.

Prompted by the USDA citation issued in September 2021, the ACUC convened a subcommittee to revisit the circumstances in that laboratory, the corrective actions adopted, and to specifically review the ACUC procedures for determining if an event represents a reportable matter to OLAW. The subcommittee's findings were consistent with the earlier actions taken, and additionally agreed with the USDA findings that a member of the study team had inadequate training/ proficiency with aseptic technique. Noting that the animals associated with this protocol that have undergone surgeries since the corrective actions were implemented remain in good health, the subcommittee also agreed that the corrective action plan implemented previously was appropriate. The subcommittee subsequently discussed the definition of serious noncompliance and expectations regarding prompt reporting to OLAW. The subcommittee concluded that this event should have been reported to OLAW when these concerns were first identified. The findings of the subcommittee were presented to the ACUC at its meeting on January 20, 2022, and a quorum of committee members voted unanimously in agreement with the subcommittee findings. We are confident that the corrective actions implemented in this instance were in accordance with PHS Policy for the Care and Use of Animals. We acknowledge, however, that we failed to provide a prompt report of this situation as required. Consequently, please accept this letter as our report of an instance of serious noncompliance and associated corrective actions. This finding relates to Grant Number 5R01DC002390. The corrective actions with respect to the failure to report by the ACUC will include development of an updated SOP for evaluating reportability of events, which will be developed by the ACUC office and Attending Veterinarian and will be reviewed and approved at an upcoming ACUC meeting. With the completion of that task, the ACUC will consider this matter to be closed.

3. With respect to item 3 in your letter, the ACUC reviewed the specific instance of expired drugs in the laboratory reported by the USDA and determined that the circumstances did not present serious or continuing noncompliance with the Policy or a serious deviation from the Guide and was therefore not reportable to OLAW.

During their visits to JHU laboratories in August 2021, USDA inspectors observed that expired supplies of both heparin and sodium chloride were inadvertently in use during a surgery performed on rabbits. Use of expired supplies is a primary focus of JHU ACUC oversight. All deficiencies identified by the USDA inspectors, including the deficiency related to use of expired reagents referenced in the USDA citation, have been corrected. The importance of monitoring expiration dates on drugs and supplies is emphasized to JHU faculty and staff involved in animal research. Prior to each semi-annual inspection a list of commonly reported deficiencies is provided to each lab, including mention of continued storage of expired supplies. A flier providing guidance to researchers has been circulated and posted in animal areas detailing our expectations regarding expiration dates and disposal of expired supplies. Guidelines posted on



our website also provide detailed descriptions of procedures for discarding expired drugs including anesthetics and analgesics. In this specific instance, the ACUC agreed with the Attending Veterinarian that there was no likely threat to the health and safety of these animals from the use of these materials, an assertion corroborated by post-surgical assessments of animal health. Directed training was provided to the laboratory in question.

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

Sincerely,

(b) (6)

Denis Wirtz, Vice Provost for Research Institutional Official

cc:

(b) (6)

Wolff, Axel (NIH/OD) [E]

From: Wolff, Axel (NIH/OD) [E]
Sent: Friday, February 11, 2022 7:11 AM
To: Brendan Canning
Subject: RE: Response to Case# 20

Thank you for this report, Dr. Canning. I will send a response shortly.
Axel Wolff

From: Brendan Canning <bjc@jhmi.edu>
Sent: Thursday, February 10, 2022 3:28 PM
To: Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>; Denis Wirtz <wirtz@ihp.edu>;
Subject: [EXTERNAL] Response to Case# 20

(b) (6)
(S) (S)

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Dear Dr. Wolff,

Attached please find our response to your letter sent on November 8, 2021.

Please contact us directly if any additional information is required.

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
Phone: (b) (6)
e-mail: bjc@jhmi.edu



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November 8, 2021

Re: Animal Welfare Assurance
#A3272-01 (OLAW Case 2O)

Dr. Denis Wirtz
Vice Provost for Research
Johns Hopkins University
3400 N. Charles Street
Baltimore, MD 21218

Dear Dr. Wirtz,

The Office of Laboratory Animal Welfare (OLAW) has received from the People for the Ethical Treatment of Animals (PETA), a list of allegations of potential noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Johns Hopkins University. PETA had obtained citations issued by the US Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) which describe animal welfare concerns. Minimal information was provided other than species and a brief description of the violation. Please direct the Institutional Animal Care and Use Committee (IACUC), avoiding any conflicts of interest to evaluate the allegations, and if noncompliance is identified that should have been reported to OLAW, please provide an explanation as to why it was not reported. Note that OLAW currently has jurisdiction over animal activities supported by the Public Health Service (National Institutes of Health, Centers for Disease Control and Prevention, Food and Drug Administration), US Department of Veterans Affairs, National Science Foundation, National Aeronautics and Space Administration, and the Biomedical Advances Research and Development Authority. Also, any noncompliance which impacts such funded activities or is programmatic in nature needs to be reported even if not directly funded. The allegations submitted are as follows:

- 1) Analgesia was withheld from pigs due to investigator concerns about the impact on recovery from anesthesia. The veterinary staff had not been consulted.
- 2) Inadequate aseptic technique resulted in cranial implant contamination and chronic antibiotic resistant infections in some rhesus monkeys, requiring euthanasia.
- 3) Expired heparin and sodium chloride were given to rabbits in the Traylor Laboratory.
- 4) Another incident involving a pig injury had been promptly reported to OLAW and was successfully closed. This was Case A3272-2K and requires no additional input.

Please provide a final or interim report by **December 10, 2021**. Feel free to contact me should you have any questions.

Sincerely,

(b) (6)

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

cc: IACUC contact



November 3, 2021

Brent Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892

Via Email: morseb@mail.nih.gov

Dear Dr. Morse,

Thank you in advance for your time. I'm writing on behalf of People for the Ethical Treatment of Animals—PETA entities have more than 9 million members and supporters globally, and PETA U.S. is the largest animal rights organization in the world.

Based on the alarming violations of the Animal Welfare Act at Johns Hopkins University (JHU; Public Health Service Approved Animal Welfare Assurance #A3272-01), as described in detail below, we urge the Office of Laboratory Animal Welfare (OLAW) at the National Institutes of Health (NIH) to investigate these critical and deadly non-compliances and levy all appropriate penalties against JHU.

According to federal records obtained by PETA, JHU has been cited by the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), for negligence and compromising the welfare of the animals whom the university uses in experiments.¹ The APHIS inspection report reveals that:

- A JHU principal investigator deviated from an Institutional Animal Care and Use Committee (IACUC)-approved protocol by failing to provide analgesia to pigs, claiming that recovery from anesthesia was better without the use of analgesics. JHU veterinary staff were also not consulted on this matter.
- A pig who was used in a JHU cardiac experiment had a difficult recovery from anesthesia and was later found to be severely injured. The necropsy revealed that this pig sustained two broken elbows, which occurred when transitioning from the transport cage to another

¹ United States Department of Agriculture, Animal and Plant Health Inspection Service. Inspection Report. <https://www.peta.org/wp-content/uploads/2021/10/210823-jhu-ir-pig-monkeys.pdf>

PEOPLE FOR
THE ETHICAL
TREATMENT
OF ANIMALS

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1536 16th St. N.W.
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202-483-PETA

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2154 W. Sunset Blvd.
Los Angeles, CA 90026
323-644-PETA

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Alliaries:

- PETA Asia
- PETA India
- PETA France
- PETA Australia
- PETA Germany
- PETA Netherlands
- PETA Foundation (UK)

location. The JHU senior laboratory technician failed to report this pig's injury to the JHU veterinary staff.

- A JHU laboratory displayed a significant lack of aseptic technique and failed to maintain a sterile workspace—nearly 50% of cranial implants embedded in rhesus macaques by one JHU experimenter resulted in contamination and chronic antibiotic-resistant infections in these monkeys. As a result, the experimenter euthanized these animals.
- Experimenters in JHU's Traylor Laboratory used expired compounds during experiments on rabbits. Two bottles of heparin—one expired in 2017, and the other in 2018—and one bottle of sodium chloride that expired in 2019, were actively being used in these experiments.

You can contact me directly by e-mail at (b) (6). Thank you for your consideration of this important matter, and we look forward to your response.

Sincerely yours,

(b) (6)

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Thursday, November 4, 2021 10:34 AM
To: (b) (6)
Subject: RE: For Dr. Brent Morse, from PETA—complaint re AWA violations at Johns Hopkins

Follow Up Flag: Follow up
Flag Status: Completed

Good morning,

This email is to acknowledge receipt of your letter. OLAW will investigate the allegations and inform you of those results upon conclusion.

Sincerely, Brent Morse

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

From: (b) (6)
Sent: Wednesday, November 3, 2021 10:49 AM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Subject: For Dr. Brent Morse, from PETA—complaint re AWA violations at Johns Hopkins

Dear Dr. Morse,

Please find enclosed a letter on behalf of People for the Ethical Treatment of Animals—PETA entities have more than 9 million members and supporters globally—regarding disturbing violations of the Animal Welfare Act (AWA) at Johns Hopkins University (JHU).

Thank you, and we look forward to your response.

Sincerely yours,

(b) (6)

