



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

Office of Laboratory Animal Welfare
Bethesda, Maryland 20892

Telephone: (301) 496-7163
Home Page: <https://olaw.nih.gov>

June 10, 2026

Re: Animal Welfare Assurance
A3272-01 [OLAW Case 3X]

Jonathan M. Links, Ph.D.
Vice Provost and Chief Risk Officer
Johns Hopkins University
3400 N. Charles St., (b) (4)
Baltimore, MD 21218

Dear Dr. Links,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 29, 2026, letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Johns Hopkins University (JHU) following up on an initial April 22, 2026, notification by email. It is noted that the research project is not supported by PHS funding.

According to the information provided, this Office understands that the JHU Institutional Animal Care and Use Committee (IACUC) determined that instances of noncompliance occurred with respect to protocol suspension. The final report states that the approved protocol includes development of new therapies for treating necrotizing enterocolitis (NEC). It is understood that these projects involve piglets being fed formula with bacteria recovered from a patient with NEC for experimental study and treatment. The report states that within 1-2 days following the first feeding, most of the animals receiving the formula containing bacteria using the IACUC-approved modified feeding paradigm presented clinically in poor health and either died or required euthanasia.

Following a review by the IACUC and JHU veterinarians, it was determined that the lab failed to seek veterinary support as required in a timely manner when the animals exhibited a decline in health and the lab chose to administer care on their own. Per the report, lab personnel primarily responsible for performing the procedures and the post-procedure monitoring were inadequately trained to work with the species and were not directly supervised by the more experienced research staff. The fully convened IACUC met on April 16, 2026, and voted to suspend the protocol and pursue corrective measures from the lab and JHU veterinarians.

It is stated that the Principal Investigator and their research staff developed corrective actions in conjunction with JHU veterinarians. The corrective actions include the following:

- Enhanced monitoring of the piglets throughout the study.
- Objective assessments of health status (respiratory rate, blood gases, temperature, hematocrit, electrolytes).
- Overnight monitoring by veterinarians and vet techs.
- A pilot study evaluating the impact of bacterial load on outcomes.
- Refined criteria for humane endpoints based on clinical findings and daily x-rays.
- Limiting the number of piglets to 15 in any given study.
- Mandatory training (feeding, handling, euthanasia) for all personnel involved.
- Using a better equipped and situated laboratory for the studies.

The report states on May 21, 2026, the IACUC was presented with the corrective action plan and voted to approve the corrective actions and lift the protocol suspension. It is understood that no studies will be conducted until personnel have finished the mandatory training and the lab is fully equipped. This Office recognizes that this laboratory has successfully performed these studies over a dozen times in the past. OLAW recommends the IACUC consider conducting post-approval monitoring visit(s) for this laboratory to assess compliance.

Based on its assessment of this explanation, OLAW understands that Johns Hopkins University has implemented appropriate measures to correct and prevent recurrence 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.

Sincerely,

JACQUELYN
T. TUBBS -S

Digitally signed by
JACQUELYN T. TUBBS -S
Date: 2026.06.10
11:54:31 -04'00'

Jacquelyn Tubbs, DVM, DACLAM
Acting Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

Louis DiVincenti, Senior Veterinary Medical Officer – Research



A3272-3X

May 29, 2026

Office of Laboratory Animal Welfare
National Institutes of Health
Bethesda, Maryland 20892-6910

RE: Notification of protocol suspension, OLAW Case A3272-3X

To Whom It May Concern:

Please accept this letter as a notification of protocol suspension that was necessitated by serious noncompliance with the Public Health Service (PHS) *Policy on Humane Care and Use of Laboratory Animals*. In accordance with federal guidelines, the circumstances leading to this suspension were described to you in a prompt report (b) (6) the Johns Hopkins University (JHU) Animal Care and Use Committee (ACUC), on April 22, 2026 (OLAW Case # A3272-3X).

The ACUC-approved protocol has the overarching goal of developing new therapies for treating necrotizing enterocolitis (NEC), a serious condition occurring in preterm infants. In these studies, piglets are fed formula that contains bacteria recovered from a patient with NEC and the course of disease is monitored in untreated animals and in animals receiving experimental treatments. The lab had successfully performed these studies over a dozen times previously. Prior to the most recent attempt, the lab amended their protocol to change the timing and frequency of feedings, changes that were supported by both scientific and veterinary care rationales. Unfortunately, within hours or 1-2 days after the first feeding, most of the animals receiving the formula containing bacteria using the modified feeding paradigm presented clinically in poor health and either died or were humanely euthanized.

The ACUC and JHU veterinarians reviewed the circumstances associated with these poor outcomes. It was determined that the lab had not sought timely veterinary support as required when the animals experienced deteriorating health, but instead administered care on their own. It was also noted that the lab members primarily responsible for carrying out the procedures and the subsequent monitoring of the animals were inadequately trained to work with the species and not directly supervised by the more experienced lab members. A compliance subcommittee of the ACUC was convened on April 15th and voted by majority to recommend protocol suspension. Given the serious noncompliance that had been identified, the fully convened ACUC met on April 16th and voted by majority to suspend the protocol and seek corrective actions from the lab and JHU veterinarians.

After the protocol was suspended, the PI and his research team worked closely with JHU veterinarians to develop corrective actions. The corrective actions include enhanced monitoring of the piglets throughout the study, objective assessments of health status (respiratory rate, blood gases, temperature, hematocrit, electrolytes), overnight monitoring by veterinarians and vet techs, a pilot study evaluating the impact of bacterial load on outcomes, refined criteria for humane endpoints based on clinical findings and daily x-rays, limiting the number of piglets to 15 in any given study, mandatory training (feeding, handling, euthanasia) of all personnel involved, and using a better

equipped and situated laboratory for the studies. These corrective actions were presented to the committee during an ACUC meeting held on Thursday, May 21st. The committee voted by majority to approve the corrective actions and lift the suspension of the protocol. No studies will be performed until personnel have completed their mandatory training and the lab is fully equipped.

The ACUC considers this matter closed.

Although the lab is federally funded, this study was supported by a non-federal-funding mechanism.

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

Sincerely,

(b) (6)

Jonathan M. Links, PhD
Vice Provost and Chief Risk Officer
Institutional Official for the Animal Care and Use Program
Professor, Public Health, Medicine, Education, Engineering, and Business

cc: (b) (6)
Brendan J. Canning, Ph.D., Chair, Johns Hopkins University Animal Care and Use Committee,
Jason Villano, D.V.M., Attending Veterinarian, Johns Hopkins University

Ware, Teagan (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, May 29, 2026 10:48 AM
To: 'Jon Links'
Cc: Brendan Canning; Jason Villano; OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: A3272-3X

Good morning,

Thank you for providing this final report for OLAW case **A3272-3X**. We will send an official response soon.

***Disclaimer:** Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected, or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.*

Best,
Teagan

Teagan Ware, MS, PMP
Animal Welfare Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
6705 Rockledge Drive (RKL 1), MSC 7983

Phone: 301-435-2390

Email: teagan.ware@nih.gov

From: Jon Links <jlinks1@jhu.edu>
Sent: Friday, May 29, 2026 10:35 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: accredit@AAALAC.org; Brendan Canning <bjc@jhmi.edu>; Jason Villano <jvillano@jhmi.edu>
Subject: [EXTERNAL] A3272-3X

Please see attached follow-up letter.
Thanks,
Jon

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Ware, Teagan (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, April 22, 2026 12:15 PM
To: (b) (6) Jon Links; Jason Villano
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Prompt report from Johns Hopkins (Welfare Assurance #A3272)

Good afternoon,

Thank you for providing this preliminary report, which has been assigned as OLAW case **A3272-3X**. Please reference this case ID when providing updates or submitting the final report.

***Disclaimer:** Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected, or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.*

Best,
Teagan

Teagan Ware, MS, PMP
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6705 Rockledge Drive (RKL 1), MSC 7983

Phone: 301-435-2390

Email: teagan.ware@nih.gov

From: (b) (6)
Sent: Wednesday, April 22, 2026 11:18 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Jon Links <jlinks1@jhu.edu>; Jason Villano <jvillano@jhmi.edu>
Subject: [EXTERNAL] Prompt report from Johns Hopkins (Welfare Assurance #A3272)

To Whom It May Concern:

(b) (6) at Johns Hopkins University (JHU). Our animal welfare assurance number is **A3272**. In accordance with federal guidelines, I am writing to report serious noncompliance with our expectations for the care and use of piglets in the laboratory of a JHU investigator.

The ACUC-approved protocol has the overarching goal of developing new therapies for treating necrotizing enterocolitis (NEC), a serious condition occurring in preterm infants. In these studies, piglets are fed formula that contains bacteria recovered from a patient with NEC and the course of disease is monitored in untreated animals and in animals receiving experimental treatments. The lab had successfully performed these studies over a dozen times previously. Prior to the most recent attempt, the lab amended their protocol to change

the timing and frequency of feedings, changes that were supported by both scientific and veterinary care rationales. Unfortunately, within hours or 1-2 days after the first feeding, most of the animals receiving the formula containing bacteria using the modified feeding paradigm presented clinically in poor health and either died or were humanely euthanized.

The ACUC and JHU veterinarians reviewed the circumstances associated with these poor outcomes. It was determined that the lab had not sought timely veterinary support as required when the animals experienced deteriorating health but instead administered care on their own. It was also noted that the lab members primarily responsible for carrying out the procedures and the subsequent monitoring of the animals were inadequately trained to work with the species and not directly supervised by the more experienced lab members. A compliance subcommittee was convened on April 15th and voted by majority to recommend protocol suspension and to seek corrective actions from the lab and JHU veterinarians. On April 16th, the fully convened ACUC voted by majority to suspend the protocol and seek corrective actions given these instances of serious noncompliance.

As soon as we are able, we will be sending a formal letter to OLAW acknowledging protocol suspension. The protocol suspension will remain in effect until the ACUC receives, reviews, and approves the corrective actions and subsequently confirms they are implemented.

Although the lab is federally funded, this study was supported by a non-federal-funding mechanism.

If you would like to discuss with me in the interim, I can be reached at (b) (6)

(b) (6)

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