



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

May 10, 2021

Re: Animal Welfare Assurance  
A3031-01 [OLAW Case 1I]

Dr. Andrew S. Weyrich  
Vice President for Research  
The University of Utah  
(b) (4) Park Building  
Salt Lake City, UT 84112

Dear Dr. Weyrich,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 4, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Utah, following up on an initial report on April 22, 2021. According to the information provided, OLAW understands that breeding and research activities continued to be conducted on zebrafish after the protocol had expired. The activities continued from January 23, 2021 to April 13, 2021.

The corrective actions consisted of transferring the fish to a holding protocol and having the Principal Investigator submit a new protocol. Expiration dates of protocols will be tracked electronically by the PI and the Institutional Animal Care and Use Committee (IACUC) will send reminders of pending expirations to all investigators. The Centralized Zebrafish Core Director will also track protocol expiration dates monthly. The PI reported the incident to the NIH funding component.

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 IACUC to comply with the PHS Policy. Note that the grant is not to be charged for any unauthorized animal activities and data acquired during the lapse period usually cannot be published. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

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

cc: IACUC Chair



**VICE PRESIDENT FOR RESEARCH**  
**THE UNIVERSITY OF UTAH**

A3031-17

May 4, 2021

Brent C. Morse, DVM  
Department of Health and Human Services  
Rockledge, Suite 360, MSC 7982  
6705 Rockledge Drive  
Bethesda, MD 20892-7982

Dear Dr. Morse,

Under provision of IV.F.3 of the Animal Welfare Assurance Policy and as the Institutional Officer at the University of Utah (U of U), I am providing OLAW with a full explanation of circumstances in regard to an adverse event. This event was initially reported to OLAW in a preliminary report emailed to you on April 22, 2021.

Name of Institution: University of Utah  
Assurance Number: A3031-01

The Centralized Zebrafish Core (CZAR) Director submitted an amendment on April 10, 2021 (Saturday) to request a transfer of fish to the CZAR husbandry protocol. The protocol, in which the fish would be transferred from, expired on January 23, 2021. The IACUC Director received the transfer request on April 12, 2021 and immediately notified the Attending Veterinarian of the expired protocol with fish currently on study. The IACUC Director requested that the fish be transferred to the veterinary holding protocol and not the CZAR husbandry protocol. The fish were transferred to the veterinary holding protocol in which no research can be conducted on April 13, 2021. A replacement protocol was submitted to the IACUC by the Principal Investigator on April 13, 2021. The IACUC Director discussed the potential protocol non-compliance with the IACUC Chair on April 20, 2021 and it was determined that this would be reviewed at the next convened IACUC meeting to be held on April 28, 2021. In addition, it was determined that a preliminary report would be sent to OLAW. As mentioned above, the IACUC Director sent a preliminary report via email to OLAW on April 22, 2021.

The following is a summary of the protocol non-compliance:

1. Protocol number: 18-01003
2. Protocol title: *Zebrafish as a Model Organism for the Study of Human Cardiac Disease*
3. Funding agency: NIH
4. Animal species: Zebrafish (*Danio rerio*)
5. Age of animal(s): *embryos to 2 year old fish (animals include fish that were bred to maintain the colonies as well as to undergo the research procedures)*
6. Date(s) that the event occurred: *Breeding (2/9/21, 2/25/21, 3/30/21) – Research procedures (2/3/21)*
7. Overview of the adverse event (as provided by the Principal Investigator):  
*Animals were used for breeding and research procedures after the protocol expiration date.*
8. Was there inadvertent pain involved in the adverse event (more than momentary)?: *No*
9. Describe the corrective actions to avoid future problems:  
*-The PI will add the date of renewal into his Outlook Calendar. The IACUC office will email out notification of impending renewal.*  
*-Please note that when I was notified that the protocol was expired, the fish were immediately transferred to the veterinary holding protocol in which no research can be conducted. Moreover, a replacement protocol was submitted to the IACUC office on April 13, 2021, within one week of my notification.*



**VICE PRESIDENT FOR RESEARCH**  
THE UNIVERSITY OF UTAH

10. Provide a conclusion:

*To the best of my knowledge, I did not receive an email notification that the protocol was nearing expiration, nor was I aware that the process of notification had changed. I have since learned that courtesy notifications of expiration have resumed and thus I am confident that future non-compliance will not occur.*

As mentioned above, the IACUC Chair, in consultation with the IACUC Director, determined that a preliminary report should be sent to the Office of Laboratory Animal Welfare (OLAW) to meet the requirement of prompt reporting. The Institutional Official agreed, and a preliminary report was sent to OLAW on April 22, 2021 by the IACUC Director.

The IACUC, at a convened meeting, on April 28, 2021, discussed the details of the potential protocol non-compliance that was provided by the PI as detailed above. The IACUC discussed that the Principal Investigator is responsible for renewing the protocol prior to expiration. However, unknowingly, the courtesy protocol expiration notices previously sent by the IACUC office were discontinued by the previous IACUC Director. This was discovered in January 2021. The sending of courtesy protocol expiration notifications by the IACUC office was immediately re-instated at that time (January 2021). In addition, the IACUC office and the Centralized Zebrafish Core have developed a plan to identify protocols approaching expiration several months in advance to prevent recurrence. The CZAR Director will check all protocols on a monthly basis to ensure that all protocols are current. Furthermore, every month, the IACUC office will send the CZAR Director a list of any zebrafish protocols for which protocol expiration letters will be sent to PI's by the IACUC office.

In conclusion, the IACUC agreed with the corrective actions and determined that this protocol non-compliance is serious. The Principal Investigator is ultimately responsible for regulatory compliance and must maintain compliance with animal use regulations. A replacement protocol was approved via Designated Member Review on May 3, 2021. The committee voted unanimously to report the protocol non-compliance to the Office of Laboratory Animal Welfare (OLAW) since it is federally funded. The Principal Investigator was requested to report this to the agency that is funding this research. No further actions are requested by the IACUC.

The IACUC Director met with the Institutional Official on May 3, 2021 and determined that the corrective actions presented by the Principal Investigator and the IACUC were adequate, and no additional action is required.

Sincerely,

(b) (6)

Andrew Weyrich, Ph.D.  
Vice President for Research  
Institutional Official

cc. Derek Dosdall, Ph.D.  
IACUC Chair

Alton Swennes, DVM, MS, DACLAM  
Attending Veterinarian

U of U IACUC Office Files

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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, May 5, 2021 7:33 AM  
**To:** Andrew S Weyrich  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Event Notification - Protocol 18-01003

Thank you for this report, Dr. Weyrich. We will send a response soon.

Axel Wolff, M.S., D.V.M.  
Deputy Director, OLAW

**From:** Clarisa Depari <clarisa.depari@utah.edu> **On Behalf Of** Andrew S Weyrich  
**Sent:** Tuesday, May 4, 2021 2:11 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Alton Swennes <aswennes@ocm.utah.edu>; Derek Dosdall <derek.dosdall@utah.edu>; iacuc@ocm.utah.edu  
**Subject:** Event Notification - Protocol 18-01003

Dear Dr. Morse,

Under provision of IV.F.3 of the Animal Welfare Assurance Policy and as the Institutional Officer at the University of Utah, I am providing OLAW with a full explanation of circumstances regarding an adverse event for protocol number 18-01003. I have attached the summary letter in this email. This event was initially reported to OLAW in a preliminary report emailed to you on April 22, 2021.

The Principal Investigator was also requested to report to the agency that is funding this research.

Please let me know if you need additional information.

Thank you,  
**Andrew S. Weyrich, Ph.D.**  
Vice President for Research  
Professor of Internal Medicine  
The University of Utah  
P: (b) (6)

Please contact (b) (6) for scheduling requests (including events and presentations)



## Preliminary Report

### Name and contact information of person reporting

(b) (6)



### Name of Institution

University of Utah

### Assurance Number

A3031-01

### Funding component and if contacted (for situations related to PHS-supported activities)

NIH/NHLBI

NIH not contacted as of the time of this report

### Brief description of incident (e.g., species, category of personnel involved, dates, times, animal deaths)

Dates: January 24-April 12, 2021  
Personnel: Principal Investigator  
Species: Zebrafish (*danio rerio*)  
Description: Embryos to 2 year old fish (animals include fish that were bred to maintain the colonies as well as to undergo the research procedures) were used for breeding and research procedures after the protocol expiration date.  
12 fish for breeding, 70 fish for research procedures

### Plan and schedule for correction and prevention (if known)

The fish were immediately placed on the veterinary holding protocol in which no research can be conducted. A replacement protocol was submitted to the IACUC office on April 13, 2021. The Principal Investigator will set reminder dates for protocol renewal going forward. The IACUC office and the Centralized Zebrafish Core have developed a plan to identify protocols approaching expiration several months in advance to prevent reoccurrence. These corrective actions will be discussed at a convened IACUC meeting. Any additional corrective actions will be included in the final report to OLAW.

### Timeframe for final report from the Institutional Official

The full IACUC will review this non-compliance at the next convened meeting scheduled to be held on April 28, 2021. After the IACUC meeting, the non-compliance and the proposed corrective actions will be discussed and will be further developed with the Institutional Official. A final report should be submitted to OLAW by mid- May 2021.

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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, April 23, 2021 8:02 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: U of U Preliminary Non-compliance Report

Thank you for this preliminary report, (b) (6). We will open a new case and look forward to receiving the final report from the IO after the IACUC has completed its investigation.

Axel Wolff, M.S., D.V.M.  
Deputy Director, OLAW

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**From:** (b) (6)  
**Sent:** Thursday, April 22, 2021 4:22 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>  
**Cc:** Andrew S Weyrich <andy.weyrich@utah.edu>; Derek Dosdall <derek.dosdall@utah.edu>; Alton Swennes <aswennes@ocm.utah.edu>  
**Subject:** U of U Preliminary Non-compliance Report

Dear Dr. Morse,

Please find attached a preliminary report concerning potential protocol non-compliance at the University of Utah.

Sincerely,

(b) (6)

*(Please use the iacuc email ([Link](#)) to provide the department with comments and suggestions concerning office procedures and services.)*