



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

October 15, 2021

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

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 the September 27, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals within the animal care and use program at the University of Utah. The letter supplemented information contained in an initial email report to this office on September 15, 2021. According to the information provided, OLAW understands that four species of passerines were captured and processed during a field study in numbers exceeding the approved number of animals in the Institutional Animal Care and Use Committee (IACUC) protocol. The Principal Investigator (PI) holds multiple federal and state permits allowing for the capture and release of an unlimited number of passerines. The laboratory members who conducted the field study were confused about the number of animals they could collect because of the discrepancy in allowed numbers between the IACUC protocol and the permits. The PI reported the inconsistency when they became aware of the issue. The birds involved in this incident were supported (b) (4) funding.

Several corrective and preventive measures were enacted by the PI and the IACUC: 1) The PI retrained the responsible laboratory members that the maximum number of birds is determined by the IACUC protocol. 2) The IACUC required the PI and all laboratory staff to repeat the IACUC Common Compliance Issues training module. 3) A copy of the approved protocol will be provided to each laboratory member, and 4) the IACUC strongly suggested that the PI incorporate flexibility into the IACUC protocol to facilitate consistency with applicable permits.

OLAW appreciates the consideration of this matter by the University of Utah which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident and prevent recurrence. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Robyn M. Engel -S

Digitally signed by Robyn M.
Engel -S
Date: 2021.10.15 14:36:39 -04'00'

Robyn M. Engel, DVM
Animal Welfare Program Specialist
Office of Laboratory Animal Welfare

cc: IACUC contact
Edda Thiels, NSF Animal Welfare Officer



VICE PRESIDENT FOR RESEARCH
THE UNIVERSITY OF UTAH

September 27, 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 Official at the University of Utah (U of U), I am providing OLAW with a full explanation of circumstances in regard to a protocol non-compliance. This event was initially reported to OLAW in a preliminary report sent to olawdco@od.nih.gov on September 15, 2021.

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

The Principal Investigator (PI) notified the IACUC of a potential protocol non-compliance via a non-compliance notification form concerning the below mentioned protocol on September 13, 2021. The IACUC Director notified the IACUC Chair and the Attending Veterinarian of the potential non-compliance on September 14, 2021. Upon discussion with the IACUC Chair and the Attending Veterinarian, it was determined that this would be reviewed at the next convened IACUC meeting to be held on September 22, 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 September 15, 2021.

The following is a summary of the protocol non-compliance as provided by the Principal Investigator:

1. Protocol number: 20-10007
2. Protocol title: *Bird-parasite Biodiversity*
3. Funding agency: NSF
4. Animal species: *Orange-crowned warblers (Vermivora celata)*, *MacGilivray's Warblers (Geothlypis tolmiei)*, *Spotted Towhees (Pipilo maculatus)*, and *Green-tailed Towhees (Pipilo chlorurus)*.
5. Age of animal(s): *not applicable*
6. Number of animals involved in the non-compliance: *These are the number of animals beyond the 25 individuals per species limits in the original protocol (the total number of each species is listed in A 9.0 above): 31 Orange-crowned warblers (Vermivora celata), 8 MacGilivray's Warblers (Geothlypis tolmiei), 22 Spotted Towhees (Pipilo maculatus), and 1 Green-tailed Towhees (Pipilo chlorurus).*
7. Date(s) that the non-compliance occurred: *June-July 2021*



8. Overview of the non-compliance:

*We processed 46 species of birds during our field season this summer. Our IACUC protocol allows us to process up to 25 individuals of each of these species. However, due to a miscommunication, we processed more than 25 individuals of four species. Specifically, we processed 56 Orange-crowned warblers (*Vermivora celata*), 33 MacGillivray's Warblers (*Geothlypis tolmiei*), 47 Spotted Towhees (*Pipilo maculatus*), and 26 Green-tailed Towhees (*Pipilo chlorurus*). These birds were searched for ectoparasites, and the birds were banded and released, unharmed, at the site of capture.*

As PI on this project, I trained two graduate students in the approved procedures on this protocol. I also discussed keeping the sample-size within our allowed limits. It is now apparent, however, that I did not make this latter point clear enough. The mix-up concerned the complexity of the permits on this project. Our research team has several federal and state permits that allow us to capture, remove parasites from, band and release an unlimited number of passerines (all four of these species belong to the avian order Passeriformes, and are "passerines"). Indeed, one of the graduate students has a Master-Banding permit from the USGS Bird Banding Laboratory, which allows him permission (as an individual) to process an unlimited number of passerines. However, since this is a project that is being conducted as part of his graduate research at the University of Utah, it is my understanding that the IACUC limits should be applied. Thus, I am filing this non-compliance notification form, and have filed an amendment to rectify the problem.

Scientifically, the reason for capturing many birds is that, it turns out, very few of the birds in Utah were infested with lice. About 10% of the birds were infested, whereas parasites are much more common in other areas our lab has sampled in the past (e.g. about 75% of the birds in the Bahamas are infested with ectoparasites like lice and mites). This low prevalence was unanticipated, and means that we need to sample many more individual birds than originally planned in order to get enough lice for our molecular work (as outlined in the original protocol).

9. Did the animal(s) experience inadvertent pain as a result of the non-compliance (more than momentary)?: No

10. Describe the corrective actions to avoid future non-compliance:

As PI, I have explained to the personnel involved in this project that the number of individuals allowed on our IACUC protocol is less than what is permitted by our federal and state permits, thus the maximum number of birds we can process for our research goals is set by the IACUC protocol.

11. Provide a conclusion: *In the future, I will be more clear with all participants about the maximum numbers of individuals that can be processed (based on our government and institutional permits and protocols).*

As mentioned above, the IACUC Chair, in consultation with the IACUC Director and the Attending Veterinarian, discussed the potential protocol non-compliance and 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 September 15, 2021 by the IACUC Director.

The IACUC, at a convened meeting on September 22, 2021, discussed the details of the protocol non-compliance that was provided by the PI as detailed above. The committee discussed and determined that the inadvertent protocol non-compliance did not jeopardize animal welfare and that the state and



VICE PRESIDENT FOR RESEARCH
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federal permits were not violated. However, the number of animals captured and processed for the indicated 4 species exceeded the approved animal use number in the IACUC protocol for these species.

The IACUC further reviewed the corrective actions proposed by the PI, and in addition, required that the PI and all laboratory staff again complete the IACUC Common Compliance Issues training module. Further, a copy of the approved protocol must be provided to each laboratory member. The committee also strongly suggested that the PI consider ways to incorporate flexibility in the IACUC approved protocol to facilitate consistency with the applicable federal and state permits.

In conclusion, the IACUC determined that the state and federal permits were not violated. However, the committee determined that this was a serious protocol non-compliance due to an inadvertent unfortunate oversight and that it should be reported to OLAW since it is federally funded. The committee voted unanimously to report the protocol non-compliance to OLAW and agreed with the corrective actions as described above. The committee further required that the approved protocol be followed going forward and that the PI must provide adequate oversight of the study and protocol contents. The PI was requested to report this to the agency that is funding this research.

The IACUC Director met with the Institutional Official on September 27, 2021, and it was determined that the corrective actions presented by the PI and the IACUC were adequate and that no additional action is required.

Sincerely,

(b) (6)

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

cc. Jill Shea, Ph.D.
IACUC Chair

(b) (6)

Alton Swennes, DVM, MS, DACLAM
Attending Veterinarian

U of U IACUC Office Files

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, September 29, 2021 7:44 AM
To: Andrew S Weyrich
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Event Notification - Protocol 20-10007

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

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

From: (b) (6) **On Behalf Of** Andrew S Weyrich
Sent: Monday, September 27, 2021 12:43 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Jill Shea <Jill.Shea@hsc.utah.edu> (b) (6) Alton Swennes
<aswennes@ocm.utah.edu>; iacuc@ocm.utah.edu
Subject: Event Notification - Protocol 20-10007

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 a protocol non-compliance for protocol number 20-10007. I have attached the summary letter in this email. This event was initially reported to OLAW in a preliminary report sent to olawdco@od.nih.gov on September 15, 2021.

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

Please let me know if you need any additional information.

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



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)

NSF-DEB#1926738

NSF 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: June-July 2021

Personnel: Laboratory personnel

Species: Orange-crowned warblers (*Vermivora celata*), MacGillivray's Warblers (*Geothlypis tolmiei*), Spotted Towhees (*Pipilo maculatus*), and Green-tailed Towhees (*Pipilo chlorurus*)

Description: The Principal Investigator self-reported the potential protocol non-compliance upon discovery. The IACUC approved protocol allows processing of up to 25 individuals of each of these species. However, due to a miscommunication, more than 25 individuals of four species were processed. Specifically, 56 Orange-crowned warblers (*Vermivora celata*), 33 MacGillivray's Warblers (*Geothlypis tolmiei*), 47 Spotted Towhees (*Pipilo maculatus*), and 26 Green-tailed Towhees (*Pipilo chlorurus*). These birds were searched for ectoparasites, and the birds were banded and released, unharmed, at the site of capture. The mix-up concerned the complexity of the permits on this project. The research team has several federal and state permits that allow them to capture, remove parasites from, band and release an unlimited number of passerines (all four of these species belong to the avian order Passeriformes, and are "passerines").

Plan and schedule for correction and prevention (if known)

An amendment has been submitted to request an increase in sample size. This will be discussed at the next 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 at the next convened meeting scheduled to be held on September 22, 2021. After the IACUC meeting, the event and the proposed corrective actions will be discussed and will be further developed with the Institutional Official and a final report should be submitted to OLAW by mid- October 2021.

IACUC

Email: iacuc@ocm.utah.edu

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, September 17, 2021 7:40 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: University of Utah A3031-01 Preliminary Report

Thank you for this preliminary report, (b) (6) We will start a new case file and look forward to receiving the final report from the IO after the IACUC has completed its investigation. Please confirm in that report, that all required wildlife permits were active and in place throughout the conduct of the study.

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

From: (b) (6)
Sent: Wednesday, September 15, 2021 4:02 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Jill Shea <jill.shea@hsc.utah.edu>; Andrew S Weyrich <andy.weyrich@utah.edu>; Alton Swennes <aswennes@ocm.utah.edu>
Subject: University of Utah A3031-01 Preliminary Report

To whom it may concern,

Please find attached a preliminary report concerning a 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.)