

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

January 30, 2023

Re: Animal Welfare Assurance
A3172-01 [OLAW Case L]

Morris Foster, Ph.D.
Vice President for Research
Old Dominion University
4111 Monarch Way, (b) (4)
Norfolk, VA 23508

Dear Dr. Foster,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt in this office on January 23, 2023, of your November 22, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Old Dominion University (ODU). Your letter supplements the information contained in the preliminary phone report to this office on October 14, 2022. According to the information provided, OLAW understands that on August 23, 2022, your institution noted that the number of fish captured and euthanized for the reporting period of August 2021 to August 2022 for an approved protocol was 10,429 fish. This exceeded the 3-year approved total of 6,000 fish. This activity was funded by NSF Project Number 1743711, "PIRE: Centennial Genetics and Species Transformations in the Epicenter of Marine Biodiversity".

Corrective and preventive actions included:

1. The IACUC will close the IACUC protocol, and two new protocols must be submitted for review. Separate protocols are required for each of the specimen collection expeditions detailed in the NSF grant. Expeditions for fish collection cannot restart until approval is granted.
2. When the new protocols are submitted for review, the IACUC requests the presence of the PI at the IACUC meeting.
3. The CITI courses for all personnel listed on the new protocols will need to be retaken.
4. The PI will need to attend a conference or workshop relating to IACUC education and animal welfare.
5. A Project Implantation Meeting (PIM) will need to occur for all the PI's active protocols. This is a meeting to ensure that everyone is clear on their knowledge of the protocol.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken by Old Dominion University to investigate this incident and prevent recurrence. OLAW concurs that the incident warranted reporting. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse -S

Brent C. Morse, DVM
Director

Division of Compliance Oversight
Office of Laboratory Animal Welfare

Digitally signed by Brent C.

Morse -S

Date: 2023.01.30 10:19:46 -05'00'

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cc: IACUC contact
NSF Animal Welfare Officer

Physical Address

4111 Monarch Way, Suite 203
Norfolk, Virginia 23508

Mailing Address

Office of Research
1 Old Dominion University
Norfolk, Virginia 23529
Phone (757) 683-3460
Fax (757) 683-5902

November 22, 2022

Brent Morse., D.V.M.
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institution of Health
RKL1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, Maryland 20892-7982

Subject: Non-Compliance Report

Assurance Number A3172-01

Dear Dr. Morse,

The purpose of this letter is to submit a final report regarding an issue of non-compliance on an NSF-funded project that was first reported to your office by phone on 10/14/22. This matter involves NSF Project Number 1743711, "PIRE: Centennial Genetics and Species Transformations in the Epicenter of Marine Biodiversity" (PI – Kent Carpenter).

The possibility of a protocol deviation first came to our attention with the submission of an annual report on 8/23/22. Initial administrative review of this report noted that the number of fish captured and euthanized for the reporting cycle had greatly exceeded the 3-year approved total of 6,000 fish. The report indicated that a total of 10,429 fish had been collected via rotenone stations from the reporting period of August 2021 to August 2022.

An initial request for more information was emailed to the PI on August 25th. Communications were somewhat delayed due to the PI still being in the field in the Philippines and having limited internet access. The information and explanations given by the PI were shared with the IACUC at a convened meeting on 9/22/22. The IACUC requested further information from the PI and held a subsequent meeting on 9/30/22 and determined a meeting with the PI was necessary since answers to questions were not direct or clear. The IACUC met again on 10/11/22, and while the PI attempted to join the virtual meeting, was ultimately unable to connect from the Philippines. The project administrator and one of the PhD students were able to connect and log in and offered some clarification to the unanswered questions.

Ultimately, the project administrator admitted to estimating the total number of fish (6,000) when drafting the original protocol, and the student admitted that the members of the lab did not double check the documents that were submitted to the IACUC and originally approved on

August 24, 2020.

The IACUC met again on October 27th to discuss the outcome of this investigation took the following points into consideration:

1. Lack of adherence to the IACUC protocol – While the NSF grant allowed for more open-ended numbers concerning specimen collection, the IACUC protocol did not. The protocol that was submitted to the IACUC and subsequently approved had limits on numbers and specific descriptions concerning how collection would occur. This specimen collection plan was within the scope of the NSF grant. While the research team noted that their collection did not contradict the NSF grant aims, exceeding the limits in the IACUC protocol resulted in non-compliance.
2. Uncaught error on sample size calculation – During our meetings concerning this event, the IACUC was informed by the project administrator that he performed calculations that were erroneous and led to a low sample size being listed in the protocol. While the IACUC understands that this was unintentional, the fact remains that it was an error that should have been caught by other members of the research team if there had been communication and sharing of information concerning the submitted protocol. Research team members indicated that they were aware that the actual number should have been higher but missed the fact that lower numbers were used. Opportunities for members of the research team catching this error should have existed during the initial protocol submission process, subsequent renewals, and when familiarizing other research team members with the approved protocol.
3. Knowledge of approved protocol by research team members – All members of a research team should be familiar with the approved IACUC protocol for a study. This ensures that everyone is aware of the approved procedures and boundaries of the study. This did not appear to be the case as nobody recognized the non-compliant situation developing when numbers greater than that in the approved protocol were being collected.
4. Overlap in protocol between the Smithsonian and Albatross replications – When this protocol last received full-board review, it was presented to the IACUC in a way that implied the majority of fish being collected would come from markets. This appears to be the case for one of the project replications but not the other. The IACUC doesn't question the use of different methods but believes that trying to combine two different methods into one protocol submission contributed to the errors that entered the protocol concerning sample sizes.

Given the above findings and the fact that the non-compliance was unintentional in a research group with no history of non-compliance, a primarily educational approach was taken. The IACUC decided upon the following remediation:

1. The IACUC will close the IACUC protocol and two new protocols must be submitted for review. Separate protocols are required for each of the specimen collection expeditions detailed in the NSF grant. Expeditions for fish collection cannot restart until approval is granted.
2. When the new protocols are submitted for review, the IACUC requests the presence of the PI at the IACUC meeting. This was specifically requested as the PIs travel schedule often has him out of the country.
3. The CITI courses for all personnel listed on the new protocols will need to be retaken.
4. The PI will need to attend a conference or workshop relating to IACUC education and animal welfare. Options were provided to the PI as well as the opportunity for him to identify a training opportunity of his own.

5. A Project Implantation Meeting (PIM) will need to occur for of the PIs active protocols. This is a meeting that typically takes place between research team members and animal care staff to ensure that everyone is clear on their knowledge of the protocol.
6. The IACUC discussed and determined that the number of fish that were collected beyond the approved 6,000 can still be used for data collection, as the act of recapturing these specimens would go against the efforts of reduction and conservancy.

Please feel free to contact me by e-mail (mfoster@odu.edu) or phone [REDACTED] (b) (6) should you have any questions or require additional information.

Sincerely,

[REDACTED] (b) (6)

Morris W. Foster, Ph.D
Vice President for Research

Cc:

[REDACTED] (b) (6)

Dr. Eric Walters, IACUC Chair
Dr. Donna Webb, ODU Attending Veterinarian

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Monday, January 23, 2023 4:00 PM
To: (b) (6)
Subject: RE: final non-compliance report - A3172-01

Follow Up Flag: Follow up
Flag Status: Flagged

Thank you for this follow-through (b) (6) I'll check on the status of your case and send an official response soon.

Best regards, 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: Monday, January 23, 2023 11:30 AM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Subject: [EXTERNAL] final non-compliance report - A3172-01

Dear Dr. Morse,

Attached to this e-mail is a final report concerning a non-compliance matter we discussed over the phone in October. We had thought it had been sent to you at the end of November but I just discovered that it had gotten saved as an outgoing draft on a machine I had used while on vacation for Thanksgiving. I am very sorry for the delay this led to in sending the final report.

Please feel free to contact me if you need any additional information or wish to discuss this matter further.

Best regards,

(b) (6)

A3172-L



Initial Report of Noncompliance

By: BCM

Date: 10/14/2022

Time: 2:30

Name of Person reporting: (b) (6)
 Telephone #: (b) (6)
 Fax #:
 Email:

Name of Institution: Old Dominion Univ
 Assurance number: A3172

Did incident involve PHS funded activity? NSF
 Funding component: _____
 Was funding component contacted (if necessary): _____

What happened? Foreign field study. Fish species collected beyond target specie approved in protocol (bicatch). No permit violation.

Species involved: ??
 Personnel involved: PI
 Dates and times: ?
 Animal deaths:

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

Early in investigation. Many species involved. Expect more information in follow-up written preliminary report from institution. Institution told to provide NSF grant #.

Projected submission to OLAW of final report from Institutional Official:

< 60 days

OFFICE USE ONLY
 Case # _____