

## 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 7, 2022

Re: Animal Welfare Assurance #A3423-01 (OLAW Case 2H)

Ms. Victoria G. Rivera
Director for Research Compliance
Institutional Official for Animal Welfare Program
University of Hawaii-Manoa
2425 Campus Road, (b) (4)
Honolulu, HI 96822

Dear Ms. Rivera,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 28, 2021 letter. As required in OLAW's letter dated April 28, 2014, the University of Hawaii provided to OLAW a Comprehensive Plan for your Aquatics Research Program on May 30, 2014. The requirement for the plan came as a result of repetitive fish mortality incidents between 2013 and 2014. At the time the plan was implemented, the University of Hawaii had seventeen aquatic research facilities. The program has since reduced to nine facilities over the last seven years. Eleven of the original seventeen facilities have closed, three of which were facilities that had a history of animal welfare and compliance incidents. Several new facilities have also started aquatics research activities. Of the nine facilities that are in operation today, two are under new administrative leadership and/or under the direction of new Principal Investigators.

OLAW understands that you are proposing the following changes to the Comprehensive Plan:

- The revised plan would have members of the Fish Advisory Committee (FAC) visit facilities in conjunction with the IACUC inspections rather than independently. The Principal Investigator or designated Lab Manager will be required to attend the inspection.
- The FAC currently conducts inspections on a *biennial* basis. The revised plan would have the FAC join IACUC inspectors *annually* to ensure that there are members present with the required expertise to thoroughly evaluate each facility. The FAC will continue to utilize the detailed FAC Inspector's Worksheet from the original plan to assess facility mechanical system monitoring and maintenance, environmental monitoring, staffing, response to alarms, availability of parts and services, stocking densities, resources to address emergencies, standard operating procedures, and alternative plans for animals if compliance cannot be met as detailed in the Worksheet. The IACUC will schedule longer inspections for these facilities to allow enough time for the more in-depth reviews.
- 3) The original plan stated Veterinarians would perform four inspections each year. The revised plan would include two veterinary inspections each year.

Page 2 — Dr. Rivera February 7, 2022 OLAW Čase A3423-2H

- 4) The FAC will offer incentives for facilities that have not had an incident or major non-compliance for a period of two years or more. Those facilities would not require the annual FAC inspection and would only host regular, semi-annual IACUC and Veterinary inspections.
- 5) Annual workshops will not be held, but the FAC will inspect and provide guidance to all new Principal Investigators and new laboratories that wish to begin aquatics research at the University of Hawaii.
- 6) If the IACUC, FAC and Veterinarians observe no major fish mortalities or non-compliances for a period of two years, the FAC would discontinue the additional inspections for existing facilities and only inspect new facilities. The FAC would continue to act as an advisory committee to provide guidance to researchers and the IACUC as needed.

OLAW appreciates the program transparency by the University of Hawaii regarding this matter. The results of your Plan are consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that the proposed changes to your Comprehensive Plan for your Aquatics Research Program will continue to be effective at reducing animal welfare concerns. OLAW would expect an increase in the frequency and intensity of oversight of the Aquatics program, or individual aquatics research facilities, if there are increased frequencies of incidents. We appreciate being updated regarding this matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse -S Digitally signed by Brent C. Morse -S Date: 2022.02.07 08:27:47 -05'00'

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact







June 28, 2021

To:

Dr. Brent Morse, DVM

Director, Division of Compliance Oversight Office of Laboratory Animal Welfare

From:

Victoria Rivera

Director, Office of Research Compliance

University of Hawaii System

(b)(6)

Re:

University of Hawaii animal Welfare Assurance #A3423-01

Comprehensive Plan for Aquatics Programs COMM-OLAW-2014-6 (OLAW Case 10)

As required in the Office of Laboratory Welfare's (OLAW) letter dated April 28, 2014, the University of Hawaii provided to OLAW a Comprehensive Plan for our Aquatics Research Program on May 30, 2014 (attached). The requirement for the plan came as a result of repetitive fish mortality incidents between 2013 and 2014. Our University of Hawaii Fish Advisory Committee (FAC) has been meeting and inspecting our aquatic facilities according to the schedule outlined in our plan since 2014, with the exception of delayed inspections during 2020 due to the COVID-19 pandemic. The FAC convened on Wednesday, May 12, 2021 to discuss the inspections needed, and determine whether we would inspect the facilities virtually or in person.

The committee discussed the changes that have taken place since the committee was formed in 2014. At the time this plan was implemented, the University of Hawaii had seventeen aquatic research facilities. The program has since reduced to nine facilities over the last seven years, which operate on the islands of Oahu, Maui, and Hawaii Island. Eleven of the original seventeen facilities have closed, three of which were facilities that had a history of animal welfare and compliance incidents. Several new facilities have also started aquatics research activities. Of the nine facilities that are in operation today, two are under new administrative leadership and/or under the direction of new Principal Investigators.

We reviewed the Veterinary, IACUC and FAC inspection reports for our aquatic facilities since 2014. There were thirteen incidents of fish mortalities since 2015. One incident was likely caused by an unidentified, pathogenic agent, two involved shipping stress, and two involved vandalism and/or malicious activity. Eight of the incidents across six different facilities were either a result of staff error or mechanical failure. Three of those six problematic facilities are now closed and of the three that are still in operation today, each had only one incident in the last seven years.

The committee requests to modify our Comprehensive Plan. We are proposing the following changes for your consideration.

- The FAC currently conducts inspections independent of the IACUC. The revised plan would have 1) members of the FAC visit facilities in conjunction with the IACUC inspections rather than independently. The Principal Investigator or designated Lab Manager will be required to attend the inspection.
- The FAC currently conducts inspections on a biennial basis. The revised plan would have the FAC join 2) IACUC inspectors annually to ensure that there are members present with the required expertise to thoroughly evaluate each facility. The FAC will continue to utilize the detailed FAC Inspector's Worksheet from the original plan to assess facility mechanical system monitoring and maintenance, environmental monitoring, staffing, response to alarms, availability of parts and services, stocking densities, resources to address emergencies, standard operating procedures, and alternative plans for animals if compliance cannot be met as detailed in the Worksheet. The IACUC will schedule longer inspections for these facilities to allow enough time for the more in-depth reviews.

2425 Campus Road, Sinclair 10 Honolulu, Hawaii 96822 Phone: (808) 956-4552 Fax: (808) 956-9150 An Equal Opportunity/Affirmative Action Institution

- 3) The original plan stated Veterinarians would perform four inspections each year. The revised plan would include two veterinary inspections each year.
- The FAC will offer incentives for facilities that have not had an incident or major non-compliance for a period of two years or more. Those facilities would not require the annual FAC inspection and would only host regular, semi-annual IACUC and Veterinary inspections.
- Annual workshops will not be held, but the FAC will inspect and provide guidance to all new Principal Investigators and new laboratories that wish to begin aquatics research at the University of Hawaii.
- 6) If the IACUC, FAC and Veterinarians observe no major fish mortalities or non-compliances for a period of two years, the FAC would discontinue the additional inspections for existing facilities and only inspect new facilities. The FAC would continue to act as an advisory committee to provide guidance to researchers and the IACUC as needed.

We hope that OLAW finds the University of Hawaii's proposed revisions to the plan satisfactory, as this matter is very important to the institution's aquatics programs. Please contact me at (b) (6) or riveravg@hawaii.edu with any questions.

(b) (6)

C:

Axel Lehrer, Chair, UH Institutional Animal Care & Use Committee

(b) (6)

## Morse, Brent (NIH/OD) [E]

From:

(b) (6)

Sent:

Tuesday, July 6, 2021 7:01 PM Morse, Brent (NIH/OD) [E]

To: Cc:

Victoria Rivera

Subject:

Attachments:

University of Hawaii - Request to Modify Compliance Plan for Fish Facilities OLAW Acquatics Programs Plan original.pdf; OLAW Acquatics Programs Plan

Revision\_signed.pdf

Hello Dr. Morse,

I hope this email finds you well. I'd like to start by introducing myself. I am the new Animal Welfare and Biosafety Program Manager for the University of Hawaii, a position previously held by Norman Magno. I'm reaching out to you today on behalf of our Institutional Official, Victoria Rivera, and our Fish Advisory Committee (FAC).

As required in the Office of Laboratory Welfare's (OLAW) letter dated April 28, 2014, the University of Hawaii provided to OLAW a Comprehensive Plan for our Aquatics Research Program on May 30, 2014 (attached). The requirement for the plan came as a result of repetitive fish mortality incidents between 2013 and 2014. The FAC convened on Wednesday, May 12, 2021 and proposed some modifications to the original plan, which I am forwarding now for OLAW's consideration.

Please feel free to contact me with any questions or further discussion. We look forward to hearing OLAW's response on the proposed changes.

Thank you, Diana

Diana Talerico Blanco, MS, LVT, LATG, CMAR University of Hawaii, Office of Research Compliance Manager, Animal Welfare and Biosafety Program 2425 Campus Road, (b) (4) Honolulu, HI 96822

Office: (b) (6)

Email: <u>dtaleric@hawaii.edu</u>

A3423

## Morse, Brent (NIH/OD) [E]

From:

(b) (6)

Sent:

Friday, January 7, 2022 1:00 PM

To:

Morse, Brent (NIH/OD) [E]

Cc:

Victoria Rivera; Wolff, Axel (NIH/OD) [E]

Subject: Re: [E]

Re: [EXTERNAL] Re: University of Hawaii - Request to Modify Compliance Plan for Fish

**Facilities** 

Follow Up Flag:

Follow up

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Dr. Morse,

Thank you very much.

Diana

On Jan 7, 2022, at 4:38 AM, Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov> wrote:

Hello,

Thank you for the follow-up message. I will send an official response to your modified compliance plan soon, but OLAW is in general agreement with the plan as outlined.

Best regards, Brent Morse

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

(b) (6)

Sent: Thursday, January 6, 2022 5:28 PM

To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>

Cc: Victoria Rivera <riveravg@hawaii.edu>; Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>

Subject: [EXTERNAL] Re: University of Hawaii - Request to Modify Compliance Plan for Fish Facilities

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Hello Dr. Morse,

Happy New Year and I hope you had a nice holiday.

I wanted to check in with you on this request we submitted in June regarding proposed changes to our Comprehensive Plan for our Aquatics Research Program. Can you let me know if OLAW has had a chance to review it and if the proposed changes are acceptable? Thank you,