



UNIVERSITY
of HAWAII[®]
SYSTEM

Office of Research Compliance
Animal Welfare Program

December 6, 2021

MEMORANDUM

TO: Victoria Rivera
Director for Research Compliance
Office of the Vice President for Research and Innovation

FROM: Diana Blanco
Animal Welfare and Biosafety Programs Manager

SUBJECT: UH Animal Welfare Program
2021 Annual Activity Status Report

Provided is the University of Hawaii's (UH) Animal Welfare Program's Annual Status Report to the Institutional Official (IO).

This document serves as the 2021 internal program report, which summarizes activities executed by the Animal Welfare Program administrative unit and the Institutional Animal Care and Use Committee (IACUC) to meet regulatory requirements of the Public Health Service (PHS) *Policy*; the US Dept. of Agriculture, Animal and Plant Health Inspection Service, *Animal Welfare Act*; State of HI Dept. of Agriculture; and accreditation expectations of the *Association for Assessment and Accreditation of Laboratory Animal Care International* (AAALAC).

Report received: Victoria Rivera 12/7/2021
Victoria Rivera, MPA Date
Director for Research Compliance
Institutional Official, Animal Welfare Program

c: Vassilis Syrmos, Vice President for Research and Innovation

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Animal Welfare Program 2021 Annual Activity Status Report

Animal Welfare Program/Office of Research Compliance:

Program Administrator: Diana Blanco, Manager

Specialist: [REDACTED], IACUC Coordinator, Compliance Officer

Reporting Lines:

The Animal Welfare Program Office and Institutional Animal Care and Use Committee (IACUC) of the Office of Research Compliance (ORC) reported to the following Institutional Official during the 2021 calendar year.

Month Timeline	Institutional Official	Administrative Level
January-December	Victoria Rivera	University System

ORC reports to the Office of the Vice President for Research and Innovation (OVPRI).

Federal Mandates:

The federal charge of the IACUC is 9 CFR 2.31(c)(1) – 8 and 2.31(d)(5)(6) & (7) *Animal Welfare Act*, Animal Plant Health Inspection Service, US Dept. of Agriculture. The program is also responsible for ensuring compliance with the *Public Health Service Policy* IV.B.1-8, Health Extension Act, Dept. of Health and Human Services and their agencies as an institution receiving extramural awards through grants and/or contracts administered by the National Institutes of Health.

- Review, at least once every six months, the research facility's program for the humane care and use of animals.
- Inspect, at least once every six months, all of the institution's animal facilities (including satellite facilities).
- Prepare reports of the IACUC evaluations and submit reports to the IO.
- Review concerns involving the care and use of animals at the institution.
- Make recommendations to the IO regarding any aspect of the animal program, facilities, or personnel training.
- Review and approve, require modifications in, or withhold approval of those components of proposed activities related to the care and use of animals. Continuing review of activities required not less than annually (APHIS requirement).
- Review and approve, require modifications in, or withhold approval of those components of proposed significant activities regarding the care and use of animals.

- Authorized to suspend an activity involving animals in accordance with specifications in IV.C. 6 of the *PHS Policy* (i.e., an activity that is not being conducted in accordance with applicable provision to the *Animal Welfare Act*, the *Guide for the Care and Use of Laboratory Animals*, the institution's *Assurance*, or *PHS Policy*.

In fulfilling the requirements of ensuring research and instructional activities which use vertebrate animals, the IACUC evaluates animal use protocols (proposals) for appropriateness of the activities to determine necessity of the work through scientific justification and the humaneness of the procedures that will be experienced by the animal research or training subjects.

IACUC Composition:

The IACUC members are recruited from different campuses and are representatives from different scientific fields, veterinarians, nonscientists, and representatives from the community-at-large. The majority of the members are faculty with science backgrounds that are currently engaged in or have in the past conducted vertebrate animal research and/or teaching activities.

At the close of 2021, the IACUC membership numbered 32 volunteers, which includes voting members, alternates, non-voting and *ad hoc* members comprise the committee. Eight new members (including alternates) were added during 2021. The member composition and their affiliations are provided pages 10-11.

Animal Protocol Information:

The IACUC reviewed 287 animal use protocol submissions during 2021.

Since 2007, reviews and approval of vertebrate animal use protocols have been conducted using the TOPAZ protocol management system. The use of the electronic system enables investigators to submit applications in real time. The system enables investigators to interface with IACUC reviewers. The Animal Welfare Program staff directs pre-meeting protocol reviews leading to a high success rate of approved protocols at the convened meeting.

The Animal Welfare Program upgraded the Topaz protocol management system to a newer version in January 2021. The upgraded version utilizes a new, more detailed protocol form on an HTML platform that can now be accessed from any computer and any browser. This upgrade makes use of the system easier and more efficient for the researchers and administrative staff. Protocol histories were imported from the older version of Topaz so that historical data dating back to 2007 was not lost.

Protocol Statistics

Category Description	Statistic	%
Number of Applications Received/Processed	287	
Number of Committee Meetings for Year	12	
Average Number of Protocols/Meeting	24	
Number of Applications Approved	267	93
Number of Applications Not Approved	19	7
Number of Applications Deferred (Tabled)	1	
Number of Applications Withdrawn (Prior to Initial IACUC Review, Resubmitted at a Later Date)		
Number of New Protocols	30	
Avg. Number of New Protocols/Meeting	2.5	
Number of Renewed Protocols	163	
Avg. Number of Renewed Protocols/Meeting	14	
Number of Amendments	17	
Avg. Number of Amendments/Meeting	1.5	
Principal Investigators	99	

Education and Certification:

Education and training requirements are fulfilled by personnel completing CITI education modules found at <https://www.citiprogram.org/>.

Personnel are withheld from engaging in live animal activities if they fail to meet this basic requirement prior to the animal use protocol approval. Completion of the education requirement is valid for three years upon which personnel are required to refresh their training to be able to continue work with animals.

Education Description	Number of Trainings Completed
Animal Welfare Regulations	366
Aseptic Training	43
Species Specific Training	497
Compliance Training	107
Total Number of Personnel Certifications	1013

Facility and Laboratory Inspections:

The IACUC is required by federal regulation to conduct inspections and program reviews on a semiannual basis. The inspections are conducted by a minimum of two IACUC members accompanied by at least one representative of the Animal Welfare Program. However, due to the COVID19 pandemic, OLAW reminded assured institutions that they may implement procedures to minimize IACUC and facility personnel infection risks by using one qualified IACUC member to conduct inspections and/or use methods such as virtual imagery, photos, logs and records

reviews to substitute for in-person site visits when appropriate. Until further notice, facilities holding USDA-APHIS covered species are inspected by two members of the IACUC to comply with regulations of the *Animal Welfare Act*. These include the AVS Manoa (Biomedical Sciences) and Kakaako (JABSOM Biosciences Building) vivaria, the Waikiki Aquarium (Hawaiian Monk Seal Program), and the Windward Community College Veterinary Technician Program.

Laboratories and facilities are evaluated on established criteria in accordance to the requirements specified in the *Animal Welfare Act*, and performance standards of the *Guide for the Care and Use of Laboratory Animals* and the *Guide for the Care and Use of Agriculture Animal Used in Research and Teaching*. Site visitors will utilize other reference documents (e.g., guidelines from professional societies or organizations) to assist with the evaluations when visiting facilities housing unusual or uncommon animal species.

Sixty-five (65) facility and laboratory IACUC inspections were conducted in 2021.

The facility and laboratory inspections are mostly concentrated with Manoa campus research affiliated programs. The Hilo campus historically records the second most visits by the IACUC during a reporting period. The Hilo and community college campus nearly have an even distribution of research and educational programs, which utilize vertebrate animal subjects in their programs.

Facility and Laboratory Inspections

Facility, Laboratory, Unit, Building, or Study Site	Reporting Period Jan 1 to June 30, 2021	Reporting Period July 1 to Dec 31, 2021
	January 8	July 8
	January 8	July 8
	January 8	November 9
	January 29	July 29
	January 29*, ***	See below dates
	January 29	July 29
	February 8	August 10
	February 19	August 26
	February 19	August 26
	February 19	<i>moved labs</i>
1	February 19	August 26
	March 4	September 17
	March 4	September 17
	March 4	September 17
	March 30***	October 6***
	April 1**	October 15
	April 1	October 15
	April 1	October 15
	April 1	October 15
	April 1	October 15
	April 12*, ***	**Closed

	April 22	October 26
	April 22	October 26
	April 27	October 29
	April 27	October 29
	April 27	October 29
	May 19	November 12
	May 19	November 14
	May 19	November 12
	May 25	November 9
	May 29***	November 22***
	May 31***	November 15***
	June 1***	November 20***
	Inspection not permitted	August 31***
	Inspection not permitted	August 31***

* Initial Inspection

** Inactive or Closed Facility/Laboratory No Live Animal Activities or Usage

*** Virtual imagery, photos, logs and records inspection conducted due to COVID19 travel restrictions

Post-Approval Monitoring (PAM):

Routine post approval monitoring site visits and assessments were not conducted in 2021 do to a shortage in Animal Welfare Program staff and support as a result of a hiring freeze due to the COVID19 pandemic. Reports would typically be reviewed and approved by the IACUC during convened monthly meetings of the committee. The reports would be distributed to the respective principal investigators following review and approval along with comments and requirements of the IACUC.

Other PAM activities, including animal acquisition and breeding tracking, facility monitoring by facility maintenance personnel, post operative care by trained personnel, and hands-on training in animal procedures, continued in the biomedical vivaria. Continuing protocol review, laboratory inspections, daily observations of animals by trained personnel, communication with veterinary staff, veterinary observation of selected procedures, and external inspections also continued through the program.

Animal care and use monitoring is a significant regulatory requirement of the Public Health Service (PHS) *Policy* and US Dept. of Agriculture *Animal Welfare Act*. Moreover, Post-Approval Monitoring (PAM) is an accreditation standard of AAALAC International of which the University is an accredited member with regard to the John A. Burns School of Medicine.

Specifically, the *Guide for the Care and Use of Laboratory Animals* (p.33) provides examples of Post-Approval Monitoring (PAM) activities, which includes but is not limited to, "continuing protocol review, laboratory inspections, veterinary or IACUC observation of selected procedures,

observations of animals by animal care, veterinary, IACUC staff and members, and external inspections and assessments". The Animal Welfare Program meets the PHS Policy PAM expectation by scheduling IACUC semiannual inspections of facilities and laboratories to also serve the purpose of continuous protocol activity review and monitoring.

An enhanced PAM follow-up program should be conducted by a staff representative ("Specialist") of the Animal Welfare Program. The enhanced program is designed to ensure and confirm observed and reported deficiencies of semi-annual IACUC facility and laboratory inspections are reasonably completed by expected correction schedules determined by the IACUC. Documentation of satisfactorily meeting the IACUC's correction schedules are required by the Office of Laboratory Animal Welfare (OLAW).

The enhanced PAM follow-up program commits a significant effort in time towards continuing protocol activity review. The IACUC conducts a general protocol activity review every six months of those facilities and laboratories on scheduled inspections. The PAM follow-up program conducts protocol activity assessments on a continuous basis regardless of time or location of protocol activity. Of particular interest is study personnel proficiency of animal manipulation procedures according to IACUC expectations of experience and skill level, and protocols which entail experimental procedures that are considered painful or distressful to animals or methods that have resulted in unexpected mortalities.

A new PAM Coordinator is currently being recruited so that the enhanced PAM program may continue in 2022.

Post Approval Monitoring Program Activities

Principal Investigator	Date	Affiliation	Assessment Type*	Rationale for PAM
None Conducted				

Post-Approval Procedures Monitored Previously

¹ Microbubble Administration	¹⁵ Wing Tagging	²⁹ Unilateral Ureteral Obstruction (UUO)
² Ear Punch	¹⁶ Weighing	³⁰ Embryo Transfer
³ IP Injection	¹⁷ Feline Castration	³¹ VIE Tagging
⁴ Cervical Dislocation	¹⁸ Glucose Tolerance Test	³² Echocardiogram
⁵ IM Injection	¹⁹ Fear Conditioning	³³ Ligation of Left Anterior Descending Artery (LAD)
⁶ Tail Venipuncture	²⁰ Barnes Maze Test	³⁴ Digit Amputation
⁷ Intranasal Instillation	²¹ Gavage	³⁵ Testosterone Pellet Insertion
⁸ SQ Injection	²² Decapitation	³⁶ Culling
⁹ Pithing	²³ Footpad Injection	³⁷ Implantation of G2 Transmitter
¹⁰ Anesthesia Machine	²⁴ Intracranial Injection	³⁸ Intragastric Injection
¹¹ Genotyping	²⁵ Sex Determination	³⁹ Cryoablation
¹² Tail Vein Injection	²⁶ Retro-Orbital Bleeding	⁴⁰ Drop Anesthesia
¹³ Ear Tagging	²⁷ Vasectomy	⁴¹ Isoflurane Overdose Euthanasia
¹⁴ IVIS Imaging	²⁸ Submandibular Bleed	

Fish Advisory Committee (FAC):

The Fish Advisory Committee (FAC) was formed in May 2014 as a result of study site, facility, and husbandry management deficiencies reported in a significant number of adverse incidents involving aquaculture and aquaponics projects. Due the number and seriousness of deficiencies over an 18-month span, occurring in 2012-2014, the Office of Laboratory Animal Welfare (OLAW) required the University to develop and adhere to a *Comprehensive Improvement Plan* using state-of-the-art husbandry and management practices for aquatic species used at the University.

The FAC is a subunit of the IACUC and is comprised of practicing scientists that use fish in their protocols for research and/or instruction. Five members with fish expertise comprise the FAC.

The FAC is responsible for conducting site visits at active facility, laboratory, and study sites that involve the use of aquatic species, mainly fish. In conducting assessments, the FAC uses an enhanced modified checklist, which originates from the OLAW guidance document "*Aquatic Animal Housing and Support Areas*". Assessment site visits using the enhanced checklist are reported to the IACUC. Administrative corrective actions originate from the IACUC when there is reason. The FAC representatives also serve as references and consultants to those requesting information on fish-related issues.

Facility and study site visits were previously conducted in the spring semester of alternating years. The FAC met in May 2021 and decided to propose changes to the original Comprehensive Improvement Plan. The proposed changes include the FAC conducting visits in conjunction with the IACUC rather than separately, the FAC conducting visits annually rather than biennially, veterinary site visits twice per year rather than four times per year, discontinuation of inspections for facilities that have not had an incident over a period of 2 years, and removal of the component for annual workshops. The requested changes were submitted to OLAW in June 2021 and are awaiting a decision. The current FAC assessment members are named on page 12 of this report.

Fish Advisory Committee (FAC) Assessment Visits

Facility	Visit Date
[REDACTED]	
[REDACTED]logy	
[REDACTED]	
[REDACTED]	
[REDACTED]	
[REDACTED]	
[REDACTED]	
[REDACTED]	
[REDACTED]	
[REDACTED]	

Adverse Incident:

Two (2) adverse incidents (AI) occurred during 2021.

The IACUC was informed of a break-in at the [REDACTED] on August 2, 2021. The night before, staff received a call from the pump house alarm due to an air pressure drop. When he went to investigate, everything seemed okay, but the internet was noted to be out. There may have been a momentary disruption. During the staff morning check, it was found that tank 5 holding adult, tilapia fish had holes punched in it. The fish in the tank were unharmed, the water had not completely drained, but about half the fish were missing. Other materials appear to have been missing as well. Staff filed a report with campus security and the

police. They believe the suspect got in through the back gate. It had been forced open enough for someone to get in. Staff is looking into placing a camera near the back tanks.

████████████████████ reported to the Veterinarian on October 21, 2021 a 90% die off of juvenile fish. He suspected it was due to a possible inadvertent 4-degree drop in room temperature during the night hours. A drop in temperature lowers immunity and causes susceptibility to disease. Temperature fluctuations in fish are known to stress fish immune systems. The PI worked with the UH Manoa Facilities and Grounds Department to stabilize the temperature in the room during off hours. The PI performed skin scrapings and found an unidentified, white bacteria present in the fish. The remaining fish were treated with antibiotics and their health improved. Tanks were also disinfected.

Composition of IACUC 2021

[illegible]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

- * Chairman
- ^A Alternate for Nonscientist
- ^B Alternate for Scientist
- ^C Alternate for Community Member
- ^{AV} Alternate for Attending Veterinarian
- ^{VC} Vice Chairman

Abbreviations:

CTAHR – College of Tropical Agriculture and Human Resources
JABSOM – John A. Burns School of Medicine
SOEST – School of Ocean and Earth Science and Technology

Composition of Fish Advisory Committee

Name of Member	Credentials	Position Title	PHS Membership Requirements
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	
[REDACTED]	[REDACTED]	[REDACTED]	
[REDACTED]	[REDACTED]	[REDACTED]	
[REDACTED]	[REDACTED]	[REDACTED]	
[REDACTED]	[REDACTED]	[REDACTED]	