Office of Research Compliance Animal Welfare Program



June 18, 2021

MEMORANDUM

Director for Research Compliance
Office of the Vice President for Research and Innovation Diana Blanco Animal Welfare and Biosafety Program Manager
UH IACUC Semiannual Report to the Institutional Official Reporting Period January – June 2021

Provided is the University of Hawaii's (UH) Animal Care and Use Committee (IACUC) Semiannual Report to the Institutional Official (IO).

The Public Health Service (PHS) *Policy on Humane Care and Use of Laboratory Animals* section IV.B.3 requires the IACUC prepare and submit a report of their semiannual evaluation to the IO. The US Department of Agriculture (USDA) also requires the reports to be reviewed and signed by the majority of the IACUC members.

The report to the IO includes the required information (OLAW Semiannual Report Template):

- Description of the nature and extent of the University of Hawaii's adherence to the Guide for the Care and Use of Laboratory Animals (Guide) and the PHS Policy.
- Identification of deficiencies in the program or facility, including classification as either significant or minor and a reasonable and specific plan for correction.
- Minority views of the IACUC.
- Identification of facilities accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC).
- Signature of a majority of the IACUC members.

Report received:

0-28-21 MPA Date

Victoria Rivera, MPA Director for Research Compliance Institutional Official, Animal Welfare Program

c: Vassilis Syrmos, Vice President for Research and Innovation

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

Memorandum to:	Director for Research Compliance, Animal Welfare Program Institutional Official
From:	Institutional Animal Care and Use Committee
Subject:	Semiannual Report of the Program Review and Facility Inspections (Semiannual Reporting Period January – June 2021)
Date:	June 18, 2021

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This report summarizes the IACUC's results of its most recent program review and facility inspection, as required by the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (<u>Policy</u>), Section <u>IV.B.1.-3.</u>, the *Guide for the Care and Use of Laboratory Animals* (<u>*Guide*</u>), and the Animal Welfare Act (<u>AWA</u>) regulations, as applicable. Submission of semiannual reports to the Institutional Official is a condition of this institution's Animal Welfare Assurance with the NIH Office of Laboratory Animal Welfare (OLAW).

Since the last review, the following changes have occurred in the institution's program for animal care and use (PHS Policy <u>IV.A.1.a.-i.</u>):

Dr. Axel Lehrer accepted and started his new position as IACUC Chair. Dr. Jenee Odani accepted and started her new position as IACUC Vice Chair. Diana Talerico Blanco accepted and started her new position as the Animal Welfare Program Manager. All were previously regular IACUC members. Five new members were appointed.

I. Description of the Nature and Extent of the Institution's Adherence to the PHS Policy, the *Guide*, and the AWA

Departures from the PHS Policy, the *Guide*, and the AWA. Select A or B:

[x] A. There were no departures during this reporting period.

[] B. The following departures have been reviewed and approved by the IACUC:

None. Although impacted by the COVID-19 pandemic, the IACUC dld not deviate from regulations. IACUC managed to conduct all inspections within the reporting period.

II. Deficiencies in the Institution's Animal Care and Use Program

Animal Care and Use Program Review Date(s):

Select A or B:

[X] A. There were no deficiencles in the program during this reporting period.

] B. The following deficiencies have been identified:

Attached

III. Deficiencies in the Institution's Animal Facility

Animal Facility Inspection Date(s): Select A or B:

- [] A. There were no deficiencies in the animal facility during this reporting period.
- [X] B. The following deficiencies have been identified: [describe each deficiency, identify each deficiency as either minor or significant, and provide a reasonable and specific plan and schedule for the correction of each deficiency, deficiencies may be recorded on a separate table and attached, the last page of OLAW's Sample Semiannual Program Review and Facility Inspection Checklist provides a sample table]

Refer to (#1 - 32) Semiannual Animal Facility Inspection Checklist Tables attached. Inspections #5, 14, 20, 30, 31, 32 were done virtually (imagery, photos, logs, and records) and not inperson inspections due to the COVID-19 pandemic, personnel health concerns, and local travel restrictions. Inspections # 26, 27, 28 were performed by one IACUC member on the same island as the facilities. A regular subcommittee was not present due to State, COVID travel restrictions.

IV. Minority Views

Select A or B:

- [X] A. No minority views were submitted or expressed.
- [] B. The following minority views were expressed: [insert minority views here or attach]

V. Status of AAALAC Accreditation [identify accredited facilities, if applicable]

The University of Hawaii has three AAALAC accredited facilities during this reporting period. These facilities renewed accreditation in February 2019. Biomedical Sciences Vivarium – Manoa Campus Institute for Biogenesis Research – Manoa Campus JABSOM Biosciences Building Vivarium – Kaka'ako Campus **VI. Signatures** [signatures of a majority of the IACUC members required by AWAR (§2.31, c, 3), if applicable]

Names of IACUC Members

Signatures

REDACTED

II. Animal Care and Use Program Review

March 18, 2021



Office of Research Compliance Animal Wetfare Program

15 April 2021

MEMORANDUM

TO: Dr. Sylvia Kondo Veterinarian and Manager Animal and Veterinary Services

FROM: Victoria G. Rivera Yim, C. King _____ Interim Program Manager, Animal Welfare and Biosafety Programs

SUBJECT: UH IACUC Semiannual Review of the Program of Humane Care and Use

Please find a copy of the report for the semiannual Review of the Program of Humane Care and Use which was conducted on 18 March 2021. The full committee reviewed and approved the report during its 15 April 2021 business meeting.

There were no noncompliant items identified.

Your cooperation and consideration are appreciated.

c: Victoria G. Rivera, Director, ORC, Institutional Official Axel T. Lehrer, Chair, UH IACUC IACUC File

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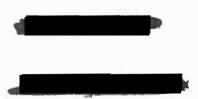
IACUC INSPECTION REPORT

FACILITY: Review of the Program of Humane Care and Use

DATE OF INSPECTION: 18 March 2021

REPORTING PERIOD: 01 January 2021 – 30 June 2021

INSPECTION MEMBERS:





MEMBER

Victoria G. Rivera

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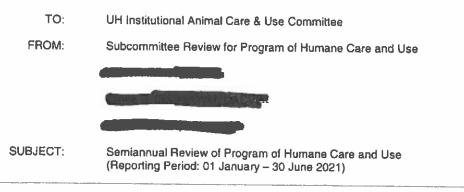




Office of Research Compliance Animal Welfare Program

25 March 2020

MEMORANDUM



On 18 March 2020, IACUC Chair, Dr. Axel Lehrer., along with members the second and interviewed Dr. Sylvia Kondo, UH Veterinarian, Dr. Michael Wong, AVS Staff Veterinarian and Ms. Diana (Talerico) Blanco, AVS Operations Manager for the Semiannual Review of the Program of Humane Care and Use. In attendance and assisting with the program review was Ms. Denise Yee, Research Compliance Staff.

The subcommittee was provided with the previous semiannual Review conducted on 17 September 2020. The subcommittee used as references, the *NIH Guide for the Care and Use of Laboratory Animals (8th Edition)*, the OLAW Semiannual Program Review Checklist and the USDA-APHIS Animal Welfare Act (AWA).

The following categories were inspected pursuant to the Guide for the Care and Use of Laboratory Animals, 8th Edition.

I. Institutional Policies and Responsibilities:

Animal Care and Use Program

The primary oversight for the Program is the responsibility of the Institutional Official (IO), the Attending Veterinarian (AV), and the Institutional Animal Care and Use Committee (IACUC). However, animal well-being is the responsibility of all members of the Program. Resources to manage the Program and veterinary care are allocated by the IO on an annual budgeted basis, then communicated to the AV and AWBP Manager. As of 1 February 2016, the Office of Research Compliance has been reorganized under the Office of the Vice President for Research and Innovation. The Animal Welfare and Biosafety Program (AWBP) and the Animal and Veterinary Services (AVS) Managers meet with the IO monthly or as needed. As of 1 July 2012, regulations training, species specific training, and IACUC training are completed through the CITI program. As of 03 October 2018, in revised Policy 13 Requirement for Personnel Training, training completed at other institutions within the current triennium, will be accepted on a case-by-case basis to satisfy CITI training requirements. Protocol specific procedures training is accomplished for individuals working in the AVS-operated vivariums by watching training videos and passing the corresponding online quizzes. In addition, personnel listed on protocols involving the faxitron, non-standard ultrasound, microbubbles, and other procedures, may be required to demonstrate proficiency during post approval monitoring and/or on a case by case basis. Other protocol specific procedures training may be accomplished by the UH veterinarian, designees or the investigator who has the expertise. Occupational Health and Safety training is site specific. Zoonoses training is provided by 2425 Campus Road, Sinclair 10

Honolulu, Hawaii 96822

Phone: (808) 958-4552 Fax: (808) 956-9150 An Equal Opportunity/Affirmative Action Institution the University Veterinarian's Office. When a full time veterinarian is not available on-site at any of the program facilities, specific managers are responsible for daily animal care and facility management, and communicate as needed with the UH veterinarians in the case of animal injuries and/or illnesses. Memorandums of Understanding (MOUs) are on file for non-UH entities (mostly private biotechnology companies) that use UH facilities. These agreements address the responsibilities for off-site animal care and use, animal ownership and IACUC review and oversight.

Disaster Planning and Emergency Preparedness

Disaster planning and emergency preparedness plans and SOPs, previously IACUC approved, are in place for the vivaria located at the Kaka'ako and Manoa campuses. Depending on the type of natural disaster and time permitting, provisions have been made to relocate valuable strains of rodents to safe areas and euthanize all other strains. Investigators are provided the option of cryopreserving valuable animal strains in advance. Building managers have been provided copies of disaster planning and emergency preparedness plans and are listed in communication "trees". Disaster and Emergency Preparedness Plans for AAALAC accredited facilities were re-evaluated and updated in preparation for the AAALAC site visit on 25-26 February 2019. An AVS Emergency Response Plan/SOPs and a general system-wide checklist have been drafted to provide guidelines during the recent COVID -19 pandemic. The IACUC approved two (2) provisions of the AVS plan on 16 April 2020; 1) to extend the expiration date of emergency stockpiled non-medicated feed beyond 6 months of its mill date if stored properly and 2) based on research, extend the interval between mouse cage changes.

Disaster Plans and Emergency Preparedness Plans are in place for all facilities. The Disaster Plan/Emergency Preparedness Plans are based on a template developed by the AWBP staff for facilities to use in developing their emergency preparedness plans. Facilities have revised their current preparedness plans to include contingencies for pandemic diseases.

IACUC

The IACUC meets once a month to review protocols and discuss other business. Emergency meetings are convened when necessary. Due to government mandates for social distancing during COVID-19, meeting have been held via teleconferencing. Records of committee meetings and deliberations are maintained. IACUC members that are PIs or are project personnel on a protocol recuse themselves during committee deliberations and voting. As of December 2019, the Animal Care and Use Program has been without a post-approval monitor on staff to continue oversight after protocol approval. Due to a state-wide hiring freeze the post-approval monitor position will remain open. The effectiveness of training programs can be evaluated by the UH veterinarians certifying individuals in animal procedures.

IACUC Protocol Review – Special Considerations

Special consideration for humane endpoints is given to studies that involve tumor models, infectious disease, vaccine challenge, pain modeling, trauma, production of monoclonal antibodies, assessing toxicological effects, organ or organ system failure, and models of cardiovascular shock. Weight loss, as well as symptoms of morbidity (emaciation, impaired ambulation, lack of physical or mental alertness, difficulty breathing, or ability to remain upright) are required to be monitored closely (2 times daily). The AVS animal care staff monitors animals daily and institutes a twice a day monitoring system when possible. A Veterinary Assistant works closely with the AVS Veterinarians and the researchers to communicate and resolve animal health concerns.

For pilot studies, a minimal number of animals are approved and the PI is usually required to report findings to the IACUC before being allowed to continue.

Although infrequent, studies that involve more than minor restraint, multiple surgical procedures, or food/fluid restriction require justification and a consideration of alternatives. If IACUC approved, these types of studies require more frequent monitoring of animal subjects. Animals that have particular phenotypical traits have enhanced monitoring. Any unexpected phenotypical traits observed in the vivariums, are reported to the IACUC. Twice a day monitoring is required for studies where animals are placed in Pain and Distress Category E.

Aseptic surgery standards are required for survival surgeries whether the species is regulated or non-regulated. In field situations, aseptic surgery standards are followed as closely as possible. These standards are covered during the aseptic surgery module within CITI training. Investigators and their staff

who work with rodents within the AVS vivariums are also required to complete on-line veterinary training modules. These modules and quizzes are available on Laulima and must be completed prior to gaining access to the vivarium, or prior to refresher orientation. Pursuant to revised Policy 13 Requirement for Personnel Training (revised and approved on 19 March 2020), personnel performing biomedical research techniques, including aseptic surgery must complete the online training videos and pass the corresponding online quizzes before working independently on survival surgery protocols. They must demonstrate proficiency to the UH veterinary staff or designee during post-approval monitoring.

Pharmaceutical grade chemicals/drugs are used as a rule. When non-pharmaceutical grade chemicals are used they must be described in detail, be fully justified in the protocol application and are subject to IACUC approval.

A non-pharmaceutical grade chemical policy, including the use of Avertin or TBE, was initially approved on 16 May 2013 and updated on17 January 2019.

Investigators that conduct field studies or are involved in an IACUC exempt activity that involves exposure to potential zoonoses are required to complete zoonoses training, provided by the University Veterinarian or designee, pursuant to revised Policy 13 Requirement for Personnel Training. A Standard Operating Procedures per Appendix 6 - Fieldwork Safety Guidelines (Departmental Health and Safety Guide) is available from the Environmental Health and Safety Office (EHSO@hawaii.edu).

Management protocols that reduce populations of invasive wild vertebrates follow AVMA Guidelines for Euthanasia. Sick or injured animals removed from the wild as part of Research or Teaching Protocols are required to receive veterinary care or be humanely euthanized.

Toe clipping is an alternative method of identification that is only permitted when scientifically justified and ethical considerations have been discussed by the IACUC. An IACUC policy was approved on 17 November 2015, revised and approved on 06 December 2018

A policy for retro-orbital bleeding was approved by the IACUC on 15 September 2016.

IACUC Membership and Functions

The IACUC consists of 19 members [11 scientists, 5 veterinarians (four DVMs with UH program authority), 1 (UH) nonscientist, 2 nonaffiliated (non-UH) members and 1 non-voting member. All members are appointed by the Institutional Official (IO). The IACUC organizationally reports to the IO. The IACUC conducts semiannual reviews of the Program of Vertebrate Animal Humane Care and Use, semiannual inspections of animal facilities where animals are housed or used, and reviews and investigates concerns about animal care and use. Policies and guidelines are posted on line for reporting animal welfare concerns. The IACUC meets to review, approve, and/or suspend activities if warranted.

The use of the policy for specific significant changes to animal activities, referenced by NIH Notice NOT-OD-14-126, was IACUC approved on 19 February 2015, revised and approved multiple times with an amended version approved 17 October 2019. The policy permits specific changes on previously approved IACUC protocols to be administratively resolved without full IACUC review. The UH Veterinarian's office serves as the subject matter expert to verify compliance with IACUC reviewed and approved policy. Other significant changes to approved activities are reviewed and approved by the full committee prior to the activities taking place.

Other protocol changes such as a change in PI, change or addition of a species that does not change the objectives of the study, addition of anesthesia, sedation or analgesia that improves animal well-being or addition of a procedure that does not result in greater pain, distress, or degree of invasiveness (limited to Cat. C and D) are reviewed through Designated Member Review (DMR) process. The UH IACUC Policy on Conditions for Designated Member Review was IACUC approved on 16 August 2018. The IACUC voted on 19 March 2020 to approve DMR of annual renewals for pain category C protocols only.

Special procedures for genetically modified animals, restraint, multiple survival surgeries, food and fluid regulation, field investigations, and agricultural animals are reviewed individually by the IACUC. Genetically modified animal use is also reviewed by the AWBP Biosafety Officer. The AVS veterinary staff has instituted a rodent phenotype monitoring system and reports health concerns related to phenotypes to the IACUC.

If a request to perform multiple major survival surgery on a covered species is received, the APHIS Administrator will be contacted.

IACUC Training

All IACUC members receive orientation. Newly appointed members are required to complete the CITI training module for IACUC members. New members observe meeting proceedings and read inspection reports for a period of 6 months before being assigned to conduct inspections or review protocols on their own. Members are provided with inspection checklists and previous reports for every facility inspections and checklists for reviewing protocols. New members are often paired with a more experienced member to assist them in learning how to conduct reviews and inspections. Continuing education is ongoing usually during meetings. IACUC 101/301 training was held at the University of Hawaii 3-4 September 2015. Another IACUC 101 and higher training is planned for May or June 2021.

IACUC Records and Reporting Requirements

Semiannual inspection and Program review reports are generated after each inspection. The reports are reviewed and approved by the full IACUC committee prior to being submitted to the IO. Minority views are always welcomed. Deficiencies are described and a plan and schedule for correction are included. Minor deficiencies are distinguished from significant deficiencies.

The annual report to OLAW documents program changes, dates of the semiannual program reviews and facility inspections and includes any minority views. OLAW is promptly advised of serious and/or ongoing deviations from *the Guide* or PHS Policy noncompliance. OLAW is promptly notified of any suspension of an animal activity by the IACUC.

The annual report to the USDA contains the number of regulated species used as well as any IACUC approved exceptions/exemptions to USDA requirements. Reports are filed within 15 days for failure to adhere to the timetable for correction of significant deficiencies. Suspension of activities by the IACUC is promptly reported to the USDA and any federal funding agency.

IACUC meeting minutes and semiannual reports to the IO are maintained for a minimum of 3 years. IACUC reviews of animal activities include required information such as considering alternatives to pain and distress and assurance that the animal activities do not unnecessarily duplicate previous experiments. Records of IACUC reviews are maintained for 3 years after the completion of the study.

Veterinary Care

Although not board-certilied in Laboratory Animal Medicine, the AV and AVS Program Manager, Dr. Sylvia Kondo and AVS staff veterinarian, Dr. Michael Wong are experienced in laboratory animal medicine. Dr. Wong provides primary daily veterinary care. Dr. Kondo has direct or delegated authority over all aspects of animal care and use. Veterinary access to all animals is provided. Pursuant to IACUC policy 15.0, PIs are required to involve the AV or his/her designee in the planning of their vertebrate animal use protocols. Animal use protocol applications are not approved without confirmation that consultation has taken place. Regular communication occurs between the IACUC and the AV. Dr. Kondo provides the IACUC with an activities report at each monthly IACUC meeting. The veterinarians have experience and training in mostly small laboratory animals. When they do not have the training and experience needed for other species of animals, or if the animal are being used at sites not easily accessible to the UH veterinarians, consulting veterinarians are used. All animal use protocols are required to designate either the UH veterinarians or a consultant veterinarian for veterinary care. Justification is required whenever a request for veterinary care is not applicable. All facilities are required to have a program of veterinary care.

Personnel Qualifications and Training

All personnel, veterinary staff, animal care staff, research investigators, instructors, technicians, trainees, and students are required to complete the CITI training modules for the regulations for using vertebrate animals. In addition, species specific training is required. For those individuats that perform surgery, the aseptic technique training module is required. Procedures that further specify training for volunteers, students and workshop participants was approved on 16 April 2015 and 03 October 2018. The AVS animal care staff is highly motivated and many have completed or in the process of completing

AALAS certification. All vivarium users are required to be on a protocol, complete the Laulima vivarium orientation module, vet training modules, the occupational health module, and the Health History Questionnaire forms to be enrolled in the Occupational Health and Safety Program. Researchers are required to demonstrate proficiency of biomedical research procedures during post-approval monitoring. All training is documented.

More recently, the JABSOM Library has provided rodent on-line training videos from JOVE. This is available to Manoa campus users. This has been discussed earlier under Policy 13 Personnel Training.

All vertebrate animal users are required to complete the CITI recertification module every three years to refresh their understanding of the regulations.

Training to report animal concerns is covered in the CITI regulations for animal use module. Procedures to report animal concerns are described in the IACUC website Policy 7.0 Reporting Concerns of Animal Misuse or Abuse

Occupational Health and Safety of Personnel

An occupational health and safety program (OHSP) consistent with federal, state, and local regulations for the vertebrate animal program is posted at the Office of Research Compliance, Animat Resource Center Services site https://researchcompliance.hawaii.edu/programs/animal-veterinaryservices/occupational-health-safety-program/. The OHSP covers personnel affiliated with JABSOM, UH Cancer Center, AVS, the JABSOM Biocontainment Facility and individuals that don't work directly with, but may be exposed to animals. To enroll in the program, individuals must complete a Health History Questionnaire (HHQ) and complete the AVS OHSP training. Protected health information of enrollees is treated in a manner consistent with UH's applicable standards of privacy and confidentiality. AVS management works closely with the Environmental Health and Safety Office and Biosafety staff to identify and manage hazardous waste. A medical surveillance program for individuals that work with animals is described on-line, as well as in the AVS Occupational Health and Safety Program manual. Based on AAALAC requirements, the OHSP was revised March 2019 with assistance from an OHS professional. The IACUC approved the original version of the OHSP on 03 December 2015. Additional revisions, including the review of HHQ for AVS staff and students by UH Straub Occupational Health Services and TB testing were IACUC approved on 21 April 2016. Since then, the OHSP process has been revised to incorporate Straub Occupational Health Services' health professional (HP) to provide reviews of HHQs. On 17 September 2020, the IACUC approved some minor changes and for short term vivarium users, such as community college students and visiting scholars, the option of completing the HHQ instead of it being a requirement.

AVS staff have all successfully completed their HHQs and been medically cleared by a HP at Straub to be exposed to animals in the vivaria. Vivaria users had until 30 June 2019 to complete the HHQ and training to be enrolled in the OHSP, or be denied access.

When reviewing non-biomedical IACUC protocols, the reviewers remind PIs to have a written site-specific OHSP available upon request during IACUC semi-annual reviews and/or veterinary reviews of their facilities.

Risks associated with the use of non-human primates (NHP) are not considered because NHP have not been used for more than 15 years. There currently are no plans to use NHPs. Occupational health SOPs are required for field study projects. Any NHP tissues from outside sources that may be used are done so under the direction of the Biosafety Program.

Personnel Security

Preventive measures such as pre-employment criminal background screening are done for new regular AVS hires. Contingency plans for deliberate acts of human destruction are described in the Emergency Operations Plan for the Kaka'ako and Manoa vivariums.

Investigating & Reporting Animal Welfare Concerns

IACUC approved Policy 7 Reporting Concerns of Animal Misuse or Abuse and Policy 9 Guidelines and Procedures for Conducting Inquiries and Investigations into Non-compliances, Deviations, and Cases of Animal Misuse or Abuse establishes the methods for reporting and investigating animal welfare concerns. These policies are posted at https://researchcompliance.hawaii.edu/programs/animal-welfare/aw-policies/. All reported concerns and corrective actions are documented. Policy 7 lists multiple contacts and provides for anonymity, and protection against discrimination and reprisals.

II. Veterinary Care:

Clinical Care and Management

The UH veterinarian and staff veterinarian oversee the well-being and clinical care of all animals used in research, testing, teaching and production in the Program of Animal Care and Use. The veterinary program offers a high quality of care and ethical standard. Pursuant to Policy 15.0, investigators are required to involve the AV or his/her designee in the planning of their vetebrate animal use protocols. Animal use protocol applications are not approved without confirmation that consultation has taken place. Investigators are also required to provide documentation of training and/or demonstrate proficiency in procedures such as CO₂ euthanasia, cervical dislocations, rodent anesthesia and surgery. The AVS veterinary and animal care staff monitor animals at least once a day and twice daily if possible. If problems are observed the veterinary staff (veterinarian or veterinary assistant who is in contact with a veterinarian) are notified. If multiple problems/situations occur, the veterinarian will triage the situations and provide an objective assessment to determine a course of action with the PI. The IACUC approved the Vivarium Incident Policy on 20 November 2012, which provides a mechanism for reporting incidents. A revised Vivarium Incident Policy was approved on 18 July 2013.

The UH veterinary staff conducts a veterinary review of all facilities in the Program semiannually. At the time of inspection, medical and animal health records are reviewed. During the inspections, facility personnel are reminded to report animal health concerns to the veterinary staff in a timely manner so that assessments, treatments or euthanasia recommendations can be made. During protocol review, clearly delineated scientific and humane endpoints ensure that contingency plans are in place should problems arise during a study. SOPs may be developed for recurrent health conditions to expedite treatment. Recurrent or significant problems are communicated to the IACUC during the UH Veterinarian's monthly report.

The UH Veterinarian is authorized to treat, relieve pain and/or euthanize animals.

Animal Procurement and Transportation/Preventative Medicine

All rodents housed in the vivaria are either bred in-house or procured through legitimate vendors. Ordering and use of vertebrate animals is not allowed unless a protocol has been reviewed and approved by the IACUC. Computer software is used in the ordering and tracking of animal usage in the vivarium. Animals received from other institutions are required to be linked to an approved protocol, have health certificates and transfer authorization by the UH Veterinarian, AWBP Compliance Officer and Biological Safety Officer. Every effort is made to accommodate investigators with space to house animals. A space committee reviews and prioritizes investigator's animal housing requests. Priority is given to investigators associated with the University over private biotechnology companies requesting use of vivarium space.

Appropriate records are maintained for all animals acquired through ordering. Animals are bred only for the minimum amounts and genotypes needed. An inventory of in-house bred animals is kept and tracked on the investigator's protocol. In addition, the investigator is required to justify animal use numbers and address the principle of reduction in the 3 R's.

Random source dogs and cats from local animal shelters are used in a cooperative effort with the Windward Community College's (WCC) Veterinary Technician Program for teaching purposes. A small number of animals are transported to WCC for sterilization surgery and returned the same day. The surgeries are performed by licensed veterinarians that are also veterinary technician program instructors. MOU's between WCC and the shelters are in place. In most cases of wildlife projects, procurement is not an option.

Transportation of ordered animals, usually rodents, is through airlines that follow federal regulations as well as professional ground transportation companies. Dates of arrival are always scheduled to ensure animals are not delivered during non-business hours. Upon arrival at the vivarium, the shipping crates containing animals from commercial vendors are decontaminated and recommended conditioning period of 72 hours prior to use is followed. Rodents from other institutions are pre-screened

before shipment, and upon arrival quarantined in a separate quarantine holding area until PCR negative for Specific Pathogens excluded from the vivarium. Animals are accompanied with health certificates. Animals are kept separated by species, source, health status, and shipments. Personnel are trained in zoonoses prevention and must provide documentation. Animals transported between facilities are accompanied by animal care staff and have the proper intrastate transportation permits. An SOP for transporting animals and procedures to follow if problems develop has been IACUC approved. Transportation of other species such as birds and fish are described in the investigator's protocol.

Sentinel animal programs are in place for the surveillance, diagnosis, treatment and control of disease for facilities where laboratory animals are housed. Sentinel animals are sacrificed every 6 months and analyzed for the presence of disease and parasites. Diagnostic laboratories are used in the preventative health program.

Surgery

Pursuant to Policy 15.0, investigators are required to involve the AV or his/her designee in the planning of their vertebrate animal use protocols including presurgical plans, use of anesthetics/analgesics, and peri-operative care. Researchers are required to provide documentation of training or certify their surgical technique proficiency with the UH veterinarian. Aseptic surgery is required for survival surgeries and performed in dedicated facilities or spaces, unless an exception is justified and IACUC approved. The investigator is required to describe how asepsis will be maintained. Surgical procedures are categorized as major (entering a body cavity) or minor. Researchers are also required to describe how anesthesia will be monitored and name the individuals responsible for post-operative monitoring and care.

Pain, Distress, Anesthesia and Analgesia

Pursuant to Policy 15.0, investigators are required to involve the AV or his/her designee in the planning of their vertebrate animal use protocols. At that time, the investigator and the AV should discuss the use of anesthetics or analgesics and the many factors involved such as the species used, type and degree of pain, the nature and length of the pain-inducing procedure and the safety of the agent. Investigators are asked to describe in their protocols the symptoms of pain/distress that may be observed and what measures will be taken to alleviate pain/distress, how the animal will be monitored and who will do the monitoring. Procedures are in place to assure analgesia before surgery begins. The UH Policy on Use of Non-Pharmaceutical Grade Drugs/Agents in Research Animals was approved by the IACUC on 16 May 2013 and revised multiple times. An updated version was approved on 17 January 2019. The Policy addresses the requirements of the *Guide* for the use of pharmaceutical grade chemicals and substances when available. Use of non-pharmaceutical grade agents such as Avertin or TBE, are required to be described, justified, and approved by the IACUC. Procedures that utilize paralytic agents are closely reviewed by the veterinary staff and the IACUC.

A rodent and rabbit anesthesia and analgesia policy was approved by the IACUC on 21 March 2016, revised and approved 18 April 2019.

Euthanasia

Methods of euthanasia are consistent with the 2020 AVMA Guidelines on Euthanasia unless approved by the IACUC. Standardized methods, e.g., isofluorane prior to decapitating mouse pups, are developed and approved by the veterinarian and IACUC that avoid distress and consider animal age and species. In general, chemical agents are preferable to physical methods of euthanasia. Training and proficiency certification is required for certain methods of euthanasia, e.g., CO₂, cervical dislocation, and decapitation. A secondary method of euthanasia, e.g., thoracotomy is often used to ensure death. The Policy was revised on 20 February 2020 to reflect changes in the 2020 AVMA Guidelines on Euthansia.

Drug Storage and Control

The Animal Care and Use Program complies with federal regulations for human and veterinary drugs. Drug records, storage procedures, and expiration dates are reviewed during facility inspections. Anesthetics and analgesics are acquired, stored and their use and disposal are recorded legally and safely. Some investigators have their own DEA license for acquiring controlled substances. The use of pharmaceutical grade drugs is required whenever possible.

III. Other Space, Facility, and Program Issues

Animal and Veterinary Services (AVS)

- AVS reported the cagewasher in the Manoa vivarium is aging and in general doesn't work 3 months out of the year. The cost for repairs has been \$32000 since 2018. The Technoplast technician flies in from Hawaii Island for troubleshooting repairs and maintenance. Often maintenance can be scheduled concurrently with other facilities on island. The cost of parts for the machine is \$5200. The cagewasher at Kaka'ako occasionally needs repair as well but the Manoa cagewasher is more complex.
- The ABSL3 facility will soon be used again for animal activities. Training will be needed for all staff to work in the ABSL3.

Feral Cats

 Discussion with the UH-Hilo Farm regarding feral cats has been delayed due to the pandemic. Feral cats may transmit zoonotic diseases and therefore should not freely reside with animals used for teaching at the farm. If the cats are to remain on the farm, they must be approved on a protocol and be provided routine veterinary care, pursuant to the *Guide*. The Farm wants to maintain the cats in a feral cat colony for vermin control without IACUC oversight. Prior to restarting discussions with UHH, a policy for feral cats will be drafted and presented to UHH Farm representatives for their input.

Waikikik Aquarium (WAQ)

- The WAQ is short staffed due to pandemic related layoffs and staff leaving for other opportunities. Presently, animals are receiving the minimum level of care. There is concern that animal care could be impacted should staff become sick or go on vacation. The IACUC Chair and UH Veterinarian will meet with the WAQ Director to discuss how the IACUC may be of assistance.
- The Hawaiian Monk Seal (HMS) front pool is delaminating again and needs repair. The WAQ has the option of moving the HMS to an off exhibit tank in the back of the facility or shipping him temporarily to a California institution for research while the repairs are performed. The timing for relocating the HMS is at issue since the off exhibit tank needs some plumbing and equipment fixes and another HMS needs to return to Hawaii before the WAQ HMS can fly out. The USDA-APHIS will be informed of the situation.

No noncompliant items were reported.

CA:JO:AL:dy

III. Animal Facility Inspection Dates

January – June 2021

III. Semiannual Program Review and Facility Inspection Report REPORTING PERIOD: JANUARY – JUNE 2021

Deficiency Category*	√ Location		Deficiency a Plan for Corre	Responsible Party	Correction Schedule and Interim Status	Date Complete
NA		NA				NA
* A = accep M = mino	table deficiency					

Deficiency Category*	/ Location		Deficienc Plan for Co	y and rrection	Responsible Party	Correction Schedule and Interim Status	Date Complete
NA		NA	1917 - A		4		NA

S = significant dericiency (is or may be a threat to animal health of safety)
 C = change in program (PHS Policy <u>IV.A.1.a.-i.</u>) (include in semiannual report to IO and in annual report to OLAW)
 NA = not applicable
 ✓ Check if repeat deficiency

Deficiency Category*	√	Location	Deficiency and Plan for Correction	Re	sponsible Party	Correction Schedule and Interim Status	Date Complete
A		NA					NA
A = accept							

Deficiency Category*	√ Location		Deficiency an Plan for Correc		Responsible Party	Correction Schedule and Interim Status	Date Complete
4		(Khanal). The protocol is ree expiration dated		n Dec 5, 2020. The ed on or prior to the ppliance . Submit		Corrected. Protocol was submitted 2/17/21.	2/17/21
S = signifi	· deficiency cant deficiency (is e in program (PH) applicable	s or may be a threa S Policy <u>IV.A.1.ai.</u>	t to animal health or safety) (include in semiannual rej) port to IO and in annual report	to OLAW)		

Deficiency Category* √ Lo	ocation	ncy and Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
A	NA				NA

✓ Check if repeat deficiency

Deficiency Category*	√	Location		Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
NA			NA				NA
							in Malanti
 * A = accep M = minor S = signifi 	defi	ciency deficiency (is	s or may be a threat to	animal health or safety) aclude in semiannual report to IO a			

Deficiency Category*	√ Location		Deficiency and Plan for Correction		Responsible Party	Correction Schedule and Interim Status	Date Complete
A		NA					NA
 A = accept M = minor S = signific C = change NA = not a 	deficiency ant deficiency (i a in program (PF	is or may be a threat IS Policy <u>IV.A.1.ai.</u>)	to animal health or safety) (include in semiannual report to	IO and in annual rep	ort to OLAW)		

#7 FACILITY: WINDWARD COMMUNITY COLLEGE VETERINARY TECHNICIAN PROGRAM

Semiannual Checklist

Deficiency Category* \checkmark Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
M I.11	A bottle of Stress Coat and a bottle of Ovaprim were expired. <i>Minor non-compliance</i> - the expired products were discarded during the inspection. <i>Corrected</i>		Corrected	2/19/21
 * A = acceptable M = minor deficiency S = significant deficiency (is 	s or may be a threat to animal health or safety) S Policy <u>IV.A.1.ai.</u>) (include in semiannual report to IO and in annual repor			

Deficiency Category*	\checkmark	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
M I.11			The protocol that covers the animal activities 06-062- 12 expired October 17, 2020. The protocol is required to be renewed on or prior to the expiration date. <i>Minor non-compliance</i> . A current approved protocol is required. <i>Correction schedule</i> - submit the annual renewal application prior to animal activities taking place.		Protocol submitted	5/4/21
A = accept M = minor S = signific C = change NA = not a Check if re	defi cant e in j appli	ciency deficiency (i: program (PH cable	s or may be a threat to animal health or safety) S Policy <u>IV.A.1.ai.</u>) (include in semiannual report to IO and in annual report to	to OLAW)		
Semiannual Ch	eckli	st	v3/8/2012	17		

Deficiency Category*	√	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
1 I.12			Two (2) bottles of Tricaine were expired. <i>Minor non-</i> <i>compliance</i> . Removed from inventory during the inspection. <i>Corrected</i> .		Corrected	2/19/21
	able					
 A = accept M = minor S = signifie C = change NA = not a 	defi ant e in p	ciency deficiency (i: program (PH	s or may be a threat to animal health or safety) S Policy <u>IV.A.1.ai.</u>) (include in semiannual report to IO and in annual report	to OLAW)		

Semiannual Checklist

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v3/8/2012

#11 FACILITY: NONOCLONAL ANTIBODY SERVICE FACILITY AND TRAINING CENTER (MASFTC)

Date: March 4, 2021, Responsible Party: Dr.

cation	Deficiency and Plan for Correct	ion	Responsible Party	Correction Schedule and Interim Status	Date Complete
NA					NA
ram (PHS Policy <u>IV.A.1.a.</u> 2	eat to animal health or safety) -i.) (include in semiannual rep	ort to IO and in annual re	port to OLAW)		
	cy ziency (is or may be a thre ram (PHS Policy <u>IV,A.1.a.</u>	cy ciency (is or may be a threat to animal health or safety) ram (PHS Policy <u>IV.A.1.ai.</u>) (include in semiannual rep	cy ciency (is or may be a threat to animal health or safety) ram (PHS Policy <u>IV.A.1.ai.</u>) (include in semiannual report to IO and in annual re	CY ciency (is or may be a threat to animal health or safety) ram (PHS Policy <u>IV.A.1.ai.</u>) (include in semiannual report to IO and in annual report to OLAW)	Cy iency (is or may be a threat to animal health or safety) ram (PHS Policy IV.A.1.ai.) (include in semiannual report to IO and in annual report to OLAW)

Semiannual Checklist

v3/8/2012

Deficiency Category*	\checkmark	Location		eficiency and a for Correction	Responsible Party	Correction Schedule and Interim Status	Date Compiete
A			NA				NA
A = accep M = minor				ealth or safety)			

#13 FACILITY: WAIKIKI AQUARIUM HAWAIIAN MONK SEAL AND FISH MAINTENANCE PROGRAMS

Date: March 4, 2021, Responsible Party: Dr. Members in Attendance:

Deficiency Category*	V	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
4 II.13			The updated Disaster and Emergency Preparedness Plan to include contingencies for COVID-19 and other pandemic diseases was not received. This is a now a <i>Minor non-compliance. Correction schedule</i> – submit revised plan no later than 30 days from receipt of this report (~April 19, 2021).			NA
A = accept M = minor S = signific C = change NA = not a Check if re	defic ant c e in p applic	ciency deficiency (is program (PH cable	s or may be a threat to animal health or safety) S Policy <u>IV.A.1.ai.</u>) (include in semiannual report to IO and in annual report	to OLAW)		
Semiannual Ch			v3/8/2012	17		

Deficiency Category*	v	Location	-	Deficiency an Plan for Correc		Responsible Party	Correction Schedule and Interim Status	Date Complete
NA			NA					NA
 A = accept M = minor S = signifit C = chang NA = not a 	defi ant e in p	ciency deficiency (is program (PHS	s or may be a the S Policy <u>IV.A.1.a</u>	reat to animal health or safety i.) (include in semiannual rej) port to IO and in annual	report to OLAW)		

Deficiency Category* √	Location	D Pla	eficiency and n for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
A		NA				NA
A = acceptable M = minor def						

Deficiency Category*	~	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
A		NA				NA
* A = accep M = mino						

eficiency ategory* √ Lo	cation	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
Ą	NA				NA
A = acceptable					

Deficiency Category* √ Location		Deficienc Plan for Co	Responsible Party	Correction Schedule and Interim Status	Date Complete
NA	NA		Por Li dise karala Li		NA

Semiannual Checklist

Deficiency Category*	√ Location		Deficiency and Plan for Correction	Responsi Party	ble Correction Schedul and Interim Status	
NA		NA				NA

#20 FACILITY: USDA NATIONAL WILDLIFE RESEARCH CENTER

Date: April 12, 2021, Responsible Party: Dr.

Members in Attendance:

Deficiency Category*	√	Location	Deficiency and Plan for Correction		Responsible Party	Correction Schedule and Interim Status	Date Complete
NA		NA					NA
 A = accept M = minor S = signific C = chang NA = not a 	defi cant e in p appli	ciency deficiency (is or may be a thre program (PHS Policy <u>IV.A.1.a</u> cable	at to animal health or safety) <u></u>) (include in semiannual report to IO	and in annual repor	t to OLAW)		

✓ Check if repeat deficiency

Semiannual Checklist

Deficiency Category*	√ Location	-	Deficience Plan for Co		Responsible Party	Correction Schedule and Interim Status	Date Complete
A		NA				1	NA
 A = accept M = minor S = signific C = chang NA = not a 	deficiency cant deficiency (is e in program (PHS	s or may be a thr S Policy <u>IV.A.1.a.</u>	eat to animal health or si i.) (include in semiannu	afety) al report to IO and in annual	report to OLAW)		

Deficiency Category*	V	Location	ficiency and for Correction	Re	sponsible Party	Correction Schedule and Interim Status	Date Complete
NA		NA					NA
	 :						

NA = not applicable
 ✓ Check if repeat deficiency

Semiannual Checklist

#23 FACILITY: HAWAII INSTITUTE OF MARINE BIOLOGY (FISH PROGRAMS)

Date: April 27, 2021, Responsible Party: Dr. 🖤

Members in Attendance

Deficiency Category*						Responsible Party	Correction Schedule and Interim Status	Date Complete
M I.11				02-5 (Toonen) is exp ubmit the renewal a y 5, 2021.			Corrected	5/4/21
* A = accept								
M = minor S = signific C = chang NA = not a	ant e in p	deficiency (is program (PH)	s or may be a threat to S Policy <u>IV.A.1.ai.</u>) (i	animal health or safety) nclude in semiannual report t	o IO and in annual report	to OLAW)		

✓ Check if repeat deficiency

#24 FACILITY: WAIMANALO RESEARCH STATION LIZARD BEHAVIOR PROJECT

Date: April 27, 2021, Responsible Party: Dr. Members in Attendance

Deficiency Category*	√ Location		Deficiency and Plan for Correction		Responsible Party	Correction Schedule and Interim Status	Date Complete
NA		NA					NA
					<u> </u>		
C = change NA = not a	deficiency cant deficiency (is e in program (PH:	s or may be a threat to ar S Policy <u>IV.A.1.ai.</u>) (incl	nimal health or safety) ude in semiannual report to	IO and in annual report	to OLAW)		

#25 FACILITY: WAIMANALO RESEARCH STATION AQUAPONICS PROJECT

Deficiency Category* √ Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
NA	NA			NA
 A = acceptable M = minor deficiency 				

Semiannual Checklist

#26 FACILITY: UH HILO AGRICULTURE TEACHING FARM - LIVESTOCK PROGRAM

Date: May 19, 2021, Responsible Party: Dr. Members in Attendance:

Deficiency Category*	√	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
NA		NA				NA

S = significant deficiency (is or may be a threat to animal health or safety)
 C = change in program (PHS Policy <u>IV.A.1.a.-i.</u>) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

✓ Check if repeat deficiency

#27 FACILITY: PACIFIC AQUACULTURE AND COASTAL RESOURCE CENTER (KEAUKAHA)

Date: May 19, 2021, Responsible Party: Dr.

Members	in Attendance:	

Deficiency Category*			Deficiency and Plan for Correction	1	Responsible Party	Correction Schedule and Interim Status	Date Complete
NA		NA					NA
		2					
S = signi C = chan NA = noi	or deficiency ficant deficiency (is	s or may be a threat to S Policy <u>IV.A.1.ai.</u>) (ii	animal health or safety) nclude in semiannual report	to IO and in annual repo	ort to OLAW)		

#28 FACILITY	: UH HILO	AQUACULTURE	EXPERIMENTAL	- FACILITY
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Deficiency Category* √	Location	Defici Plan fo	iency and r Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
NA	NA					NA
 A = acceptable M = minor defici S = significant d 	eficiency (is or may be a	threat to animal health	or safety) annual report to IO and in a			

Deficiency Category*	√	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
I I.11			A student that serves as backup animal caregiver is required to be added to the protocol. Submit an amendment to add the student and any other students that will work on the project. Correction Schedule – Submit an amendment to add the backup student within 10 days of receipt of this report. Submit an amendment to add the student prior to him/her working with animals.			
A - 20000	-					
A = accept M = minor S = signific C = change NA = not a Check if rep	defic ant (e in p ipplic	ciency deficiency (is program (PH: cable	s or may be a threat to animal health or safety) S Policy <u>IV.A.1.ai.</u>) (include in semiannual report to IO and in annual report	to OLAW)		
Cneck ir rej iemiannual Ch			v3/8/2012	17		

#30 FACILITY: GOAT PROGRAM- KAUAI AGRICULTURE RESEARCH AND EDUCATION CENTER Date: May 29, 2021, Responsible Party: Dr. Norman Strengthere Members in Attendance:

Deficiency Category*	\checkmark	Location		Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
NA			NA				NA
* A = accept							

C = change in program (PHS Policy IV.A.1.a.-i.) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

✓ Check if repeat deficiency

Semiannual Checklist

v3/8/2012

Deficiency Category* √ Location		Deficiency and Plan for Correction		Responsible Party	Correction Schedule and Interim Status	Date Complete
NA	NA				l	A

#31 FACILITY: UNIVERSITY OF HAWAII MAUI COLLEGE - AQUPONICS GREENHOUSE

C = change in program (PHS Policy IV.A.1.a.-1.) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

✓ Check if repeat deficiency

Semiannual Checklist

v3/8/2012

Deficiency Category*	√	Location	Deficiency and Plan for Correction	onsible arty	Correction Schedule and Interim Status	Date Complete
A		NA				NA
A = accept M = minor	defi	ciency	reat to animal health or safety)			