

STATE OF HAWAI'I
UNIVERSITY OF HAWAI'I
OFFICE OF THE PRESIDENT
OFFICE OF THE VICE PRESIDENT FOR RESEARCH AND INNOVATION

FUNCTIONAL STATEMENT

INTRODUCTION

The Office of the Vice President for Research and Innovation has the system-wide leadership responsibility for planning, developing and coordinating research policies and procedures of the University of Hawai'i (UH). The Vice President for Research and Innovation serves as chief research policy advisor to the UH President and other UH executives.

MAJOR FUNCTIONS

- Provides policy leadership and administrative support to UH System research institute and programs. Fosters and monitors inter-campus collaborative research efforts.
- Develops system-wide research plans, goals, policy and objectives in consultation with campus senior executives. Coordinates system-wide policies reflecting research priorities and direction in consultation with senior campus executives.
- Develops system-wide research policies and procedures, including long-range and planning studies.
- Develops and maintains an international standard of research excellence. The Vice President for Research and Innovation serves as the UH's expert on research policy matters.
- Coordinates and monitors research efforts of statewide concern.
- Monitors and assesses UH's research compliance and recommends revisions as necessary.
- Represents UH in system-wide policy research issues involving governmental, private, international and other external agencies.
- Assures efficient and effective financial management of all extramural research and training contracts and grants that are entered into by UH.
- Facilitates and encourages technology transfer and economic development activities at UH on a system-wide basis.

Fiscal and Administrative Operations

The Fiscal and Administrative Operations unit provides fiscal and administrative support services to the entire OVPRI organization. Functional responsibilities include:

- Provides oversight and guidance on business operations;
- Develops, implements and ensures compliance with business and personnel operating procedures;
- Provides fiscal functions and fiscal support services, including, but not limited to, budget projection and preparation, financial managerial report preparation and budget monitoring;
- Provides administrative support for all personnel functions including, but not limited to, payroll, recruitment, position classification (e.g., preparation of position description and reclassification actions), labor relations, processing of personnel transactions, preparation of personnel documents (e.g., PNFs and SF-1s), maintaining and updating the Human Resource Information System, and providing information and assistance regarding personnel matters and employee benefits;
- Provides desktop computer and telephony support, end user training, diagnostics, updates, patches and administration.
- Administers, maintains and updates the webpages for OVPRI.
- Assists with financial, accounting and facility planning when necessary;

- Prepares system-wide monthly, quarterly and annual extramural award financial reports;
- Prepare special reports as may be requested.

STATE OF HAWAII
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OFFICE OF THE PRESIDENT
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OFFICE OF RESEARCH SERVICES

FUNCTIONAL STATEMENT

INTRODUCTION

The Office of Research Services (ORS) is a University of Hawai'i (UH) System office responsible for providing efficient and effective administration and management for all extramural research and non-research awards entered into by UH.

ORS is administratively responsible for review and approval of proposals and offers to extramural sponsors (referred to herein as "sponsors"); acceptance of grants, contracts, subcontracts, cooperative agreements and all other extramural award agreements (collectively referred to herein as "extramural awards") on behalf of UH; negotiation of extramural award terms and conditions; resolution of disputes and other issues with sponsors; development of system-wide administrative policies and procedures relating to extramurally-funded programs; and the provision of training and coordination services in these matters.

ORS is also responsible for ensuring that all extramural awards are in compliance with governmental laws and regulations, as well as institutional and sponsor policies and procedures. To achieve this, ORS provides oversight and monitoring functions that include ongoing reviews of departmental and system-wide internal controls; coordination of required actions to correct deficiencies; post-audit activities; coordination and resolution of audit findings and questioned costs with sponsors; and the provision of counsel and guidance directly to UH executives, administrators, principal investigators, and fiscal staff on all matters relating to extramurally-funded programs, including the interpretation of application of extramural award terms and conditions, provided, however, that ORS involves the UH Office of General Counsel should such interpretation be legal in nature.

ORS has overall financial reporting responsibilities that include billing and financial reporting to sponsors; developing and maintaining necessary accounting systems and records that comply with federal cost principles and financial management standards; and preparing facilities & administrative cost (referred to herein as "F&A") proposals and other special analytic studies as may be periodically required.

ORS SECTIONS

ORS consists of seven (7) sections, each with varying areas of responsibility. A description of each ORS section follows below.

Office of the Director

The ORS Office of the Director directs and manages system-wide UH extramurally-funded research support services. Functional responsibilities include:

- Creating the vision for system-wide research support services and providing leadership to develop long- and short-range strategic planning for effective research service programs -- and to ensure responsive and quality services to the UH research community;
- Interpreting, applying and ensuring compliance with federal, state and county (collectively, "governmental") laws, rules and regulations, and UH and sponsor-specific policies and procedures applicable to extramural awards and sponsored research administration;
- Interpreting, applying and ensuring compliance with UH and UH Board of Regents policies and procedures applicable to extramural awards and sponsored research administration;

- Interpreting, applying and ensuring compliance with extramural award terms and conditions imposed by sponsors;
- Making recommendations to the Vice President for Research and Innovation and other UH executives on system-wide sponsored research administration policies, procedures and practices;
- Directing research support services through subordinate level subject matter experts;
- Overseeing research financial management support systems and the system of internal controls to meet federal criteria and external audit standards;
- Executing extramural awards on behalf of UH via delegated authority;
- Negotiating F&A rates, implementation procedures and compliance requirements with federal agencies;
- Assisting auditors in the conduct of scheduled and non-scheduled audits and initiating appropriate remediation actions for audit findings;
- Advising the Vice President for Research and Innovation and other UH executives on research support services between UH and the Research Corporation of the University of Hawai'i (RCUH);
- Collaborating with faculty researchers to establish and maintain a communication network (i.e., ORS Faculty Advisory Council) for the dissemination of essential extramural award management and other information; and
- Planning and conducting, through various ORS sections, other UH offices and RCUH, periodic training and workshops in research administration for research personnel throughout the UH System.

Information Systems Services

The ORS Information Systems Services section provides information technology support to ORS and coordinates electronic research administration (eRA) services for investigators and others across the UH System. Functional responsibilities include:

- Installing and maintaining the UH system-wide electronic research extramural award tracking system, database, and related modules (referred to herein as "*myGRANT*");
- Developing and designing adaptations and customization of *myGRANT* to conform the software to UH requirements and desired functionality;
- Collaborating with *myGRANT* system users to identify business requirements and suggested program modifications;
- Coordinating testing and maintaining operation and functionality of *myGRANT*;
- Providing training and workshops to the UH research community on the use of *myGRANT* and any sponsor-specific eRA systems;
- Establishing and maintaining a database for extramural proposals, awards and related subawards;
- Providing a mechanism for the tracking of the status of extramural proposals, awards and related subawards;
- Generating system-wide extramural proposal and award statistics and reports for the ORS Director, UH executives and UH Board of Regents;
- Preparing other special reports as requested by the ORS Director, UH executives or UH Board of Regents
- Providing helpline support for *myGRANT* and sponsor-specific systems for proposal submission to faculty and staff across the ten UH campuses;
- Providing technical support for ORS training sessions and workshops;
- Developing and managing the ORS website and web reports;
- Providing information technology support to ORS staff;
- ing and maintaining the ORS exchange server;
- Performing project management for future system enhancements and new tools for ORS staff;
- Providing graphic design for ORS training or informational materials;

- Making recommendations for update or revision to UH policies and procedures to meet governmental mandates, or as otherwise may be necessary; and
- Advising the ORS Director as to information system and technology tools and upgrades that may be necessary to comply with governmental or sponsor requirements, or UH policies and procedures.

Contracts and Grants Administration – Service Centers

There are five (5) contracts and grants administration service centers within ORS. Although each service center works collaboratively with their other service center counterparts and is responsible for consistent implementation of ORS standard operating procedures, each service center also functions independently and has independent authority in accordance with parameters set forth by the ORS Director.

Functional responsibilities of each service center include:

- Collaborating with sponsors to identify possible funding opportunities and initiatives;
- Serving as subject matter experts and assisting principal investigators with reviewing potential funding opportunities for UH eligibility or other issues;
- Reviewing proposals for compliance with statutory, regulatory, UH and sponsor policy and procedural requirements, as applicable;
- Identifying proposal deficiencies, if any, and the cooperative measures necessary to remediate those deficiencies;
- Providing guidance as to statutory, regulatory, UH and sponsor policy and procedural requirements for proposal submission; and developing, modifying and implementing procedures to ensure that UH-submitted proposals are in compliance with these guidelines;
- Through delegated authority, acting as UH's authorized organizational representative to endorse and submit proposals, and to review, approve & endorse post-award requests for modifications;
- Ensuring the timely processing and submission of UH-submitted proposals;
- Exercising considerable knowledge and expertise in the use of federally-mandated electronic research administration systems;
- Keeping abreast of applicable proposal submission requirements;
- Providing training and workshops for UH faculty and staff on proposal preparation and submission;
- Ensuring that extramural award terms and conditions are consistent with UH policy requirements, including but not limited to policies on liability, indemnity, insurance, choice of laws and jurisdiction;
- Reviewing and negotiating extramural award agreements between UH and sponsors to ensure conformity with statutory, regulatory and UH policy and procedural requirements;
- Ensuring the timely processing and execution of extramural awards and modifications thereto;
- Developing, implementing and maintaining system controls for administrative management of extramural awards;
- Ensuring compliance with statutory, regulatory, UH and sponsor policy and procedural requirements;
- Making recommendations for update or revision to UH policies and procedures to meet governmental mandates, or as otherwise may be necessary; and
- Conducting periodic training and workshops to familiarize appropriate UH personnel with procedural changes and/or to discuss and resolve problem areas.

The following are brief descriptions of the primary area(s) of responsibility for each service center.

Contracts and Grants Administration – Mānoa Service Center. The Mānoa Service Center provides extramural proposal and award administration and support services primarily to the UH Mānoa campus (excluding the John A. Burns School of Medicine and the University of Hawai'i Cancer Center).

Contracts and Grants Administration – Kaka'ako Service Center. The Kaka'ako Service Center provides extramural proposal and award administration and support services primarily to the John A. Burns School of Medicine (JABSOM) and the University of Hawai'i Cancer Center.

Contracts & Grants Administration – Maui Service Center. The Maui Service Center provides extramural proposal and award administration and support services primarily to the UH Maui College.

Contracts & Grants Administration – West O'ahu Service Center. The West O'ahu Service Center provides extramural proposal and award administration and support services primarily to the UH West O'ahu and all community colleges except for Hawai'i Community College.

Contracts & Grants Administration – Hilo Service Center. The Hilo Service Center provides extramural proposal and award administration and support services primarily to the University of Hawai'i at Hilo and Hawai'i Community College.

Financial Compliance Section

The ORS Financial Compliance section coordinates UH's annual Office of Management and Budget Single Audit in accordance with 2 CFR 200, as may be amended from time to time, or any replacement statute (referred to herein as "OMB Single Audit"), sponsor financial audits, site visits and desk reviews, effort certifications; implements policies and procedures to ensure compliance with financial and administrative requirements over extramural funding; administers UH's internal control program over extramural funding; processes subawards; conducts subrecipient monitoring activities and other investigations as requested. Functional responsibilities include:

- Reviewing UH financial management systems and internal controls over extramural funding to ensure compliance with laws, regulations, policies, procedures and award terms and conditions;
- Reviewing departmental records to ensure policies and procedures are adequate to provide reasonable and reliable internal controls over extramural funding; identifying deficiencies, if any, and the corrective actions necessary to improve effectiveness and efficiency;
- Coordinating all functional reviews and audit examinations of sponsored programs conducted by sponsors (i.e., Office of Naval Research, U.S. Department of Health and Human Services, Department of Labor) and independent public accounting firms;
- Reviewing and evaluating audit findings, coordinating the implementation of corrective actions by appropriate units, recommending improvements to established systems and procedures, and coordinating the preparation and submission of audit responses;
- Coordinating internal audits performed by UH to ensure external audit requirements imposed by the federal government are met;
- Ensuring expenditure compliance within funding limitations, and reviewing Effort Certification Salary Transfers;
- Providing counsel and guidance to principal investigators and fiscal administrators on program administrative matters, including the interpretation of extramural award terms and conditions relating to the reprogramming of project funds, allowability and allocability of costs, and subawarding to other entities;

- Ensuring that subrecipient (subaward) monitoring policies and procedures are in compliance with 2 CFR 200, as may be amended from time to time, or any replacement statute;
- Ascertaining the adequacy of the UH's efforts to conform with statutory, regulatory, UH and sponsor policy and procedural requirements; and
- Developing, implementing and making recommendations for update or revision to UH policies and procedures to meet laws, regulations and other requirements, or as otherwise may be necessary.

Projects Fiscal Accounting Section

The ORS Projects Fiscal Accounting section establishes and administers project accounts, ensuring compliance with applicable laws, regulations, policies and award terms and conditions. This section also processes reimbursement requests and maintains UH financial records. The section consists of two (2) teams, each with one (1) team leader who is responsible for day-to-day management, and with accountant team members who are assigned by sponsor. Functional responsibilities include:

- Coordinating post-award accounting, record maintenance and cash management requirements of extramural awards;
- Reviewing and approving requests for establishment of accounts and providing assistance to fiscal administrators in setting up accounting systems and fiscal controls for sponsored project accounts;
- Preparing and processing financial reports, billings and vouchers in accordance with extramural award provisions specified by sponsors;
- Reviewing and calculating final indirect cost charges for extramural awards; initiating adjusting and closing;
- Maintaining accounting records and files for extramural awards, including correspondence and related documents;
- Maintaining and reconciling accounts receivables & advances for sponsors, and preparing fiscal-year end closing and adjusting entries;
- Reviewing, analyzing, and projecting cash requirements for all extramural awards and determining cash drawdown requirements for letter of credit and advance funding agreements;
- Coordinating and processing monthly cash advance requests and reimbursements, including the reconciliation of cash advances with actual expenditures;
- Reviewing and clearing UH financial system suspense transactions on a daily basis;
- Reviewing and clearing RCUH Cash Clearing accounts;
- Reconciling interest due to the federal government on advances and requesting and submitting payments to the federal government as required;
- Reviewing and approving requests for establishment of accounts and account changes for non-ORS USDA Direct Appropriation accounts and Services Cost Center accounts;
- Providing assistance to administer close-out process of extramurally funded research and training contracts and grants;
- Assisting as needed with the OMB Single Audit; and
- Making recommendations for update or revision to UH policies and procedures to meet governmental mandates, or as otherwise may be necessary.

Projects Financial Services Section

The ORS Projects Financial Services section coordinates cash management, account closeout and account collection activities for extramural awards. Functional responsibilities include:

- Coordinating system-wide requirements for each extramurally-funded project to ensure all sponsor requirements are met;

- Monitoring and coordinating the timely closeout of all extramural awards;
- Maintaining and monitoring master files for extramural awards at the closeout stage, and providing closeout assistance to principal investigators and fiscal administrators;
- Coordinating with the ORS Projects Fiscal Accounting section to prepare and process final financial reports, billings and vouchers in accordance with sponsor requirements and extramural award terms and conditions;
- Monitoring and coordinating extramural award closeout to ensure all charges and receivables are reconciled, and all financial and other reports (e.g., management, patent, copyright, property inventory, scientific, technical or other special reports) and required documents are submitted to the sponsor in a timely manner;
- Advising with the adjusting of entries related to project closeout;
- Administering accounting records and files for extramural awards, including correspondence and related documents for closeout;
- Monitoring, reconciling and coordinating the accounts receivable and collection functions for all extramural awards;
- Recording the collection of extramural award projects accounts receivables;
- Developing and implementing effective business processes to collect, manage and reconcile receivables;
- Reconciling accounts receivables and preparing aging management reports;
- Developing policies and procedures for the write-off of uncollectible accounts;
- Developing necessary accounting systems to accommodate financial reporting requirements imposed by the federal government and providing meaningful financial data for the review and evaluation of the financial status of federally sponsored programs;
- Maintaining master files and ensuring the proper coding and deletion of inactive and terminated accounts;
- Reviewing daily reports for distribution and problem resolution;
- Coordinating and assisting the UH financial office with fiscal year beginning and end;
- Developing, modifying, and updating accounting systems that are implemented on a system-wide basis to accommodate research financial reporting requirements imposed by the federal government and auditors;
- Assisting in the design, development, implementation, and maintenance of computer-generated financial management reports;
- Assisting as needed with the OMB Single Audit;
- Making recommendations for update or revision to UH policies and procedures to meet governmental mandates, or as otherwise may be necessary; and
- Monitoring cost sharing data submitted by fiscal administrators.

Cost Studies and Rate Analysis Section

The ORS Cost Studies and Rate Analysis section coordinates and performs analytical studies relating to the computation of F&A and fringe benefit rates in accordance with federal guidelines, and other special studies as required. This section also performs other cost analyses to support UH leadership. Functional responsibilities include:

- Preparing the F&A rate proposal for UH and negotiating UH's F&A rates with the federal government as required;
- Coordinating the audit review process by the U.S. Department of Health and Human Services Cost Allocation Services (referred to herein as "HHS-CAS");
- Ensuring that the rate development process is appropriate, equitable, and in compliance with applicable federal regulations and directives;
- Establishing policies for proper accounting treatment and allocation of costs;

- Monitoring and revising the UH Disclosure Statement as necessary to comply with federal regulations;
- Reconciling and preparing the annual F&A recovery allocation reports for all campuses;
- Interpreting applicable rules and regulations and providing technical support to principal investigators and fiscal administrators on cost sharing;
- Calculating unemployment insurance and terminal vacation pool fringe rates; reviewing third-party computed workers compensation rate calculation; preparing fringe benefit rates schedules; and coordinating the review and negotiation of fringe rates with HHS-CAS, including RCUH fringe rates;
- Assisting as needed with the OMB Single Audit; and
- Making recommendations for update or revision to UH policies and procedures to meet governmental mandates, or as otherwise may be necessary.

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OFFICE OF RESEARCH COMPLIANCE

FUNCTIONAL STATEMENT

INTRODUCTION

The Office of Research Compliance (ORC) at the University of Hawai'i (UH) is responsible for ensuring compliance with federal, state, and local government laws and regulations, and institutional policies and procedures of research endeavors and scholarly work that involves: a) the use of vertebrate animal subjects, b) humans participating as research subjects, c) evaluations of materials of biological origin that have been genetically or synthetically modified, and d) appropriate and controlled use of biological materials that are potentially harmful to UH personnel, the general public and to the environment.

ORC is responsible for providing and/or ensuring that appropriate veterinary care is provided for vertebrate animal species used as research and instructional subjects on UH System campuses and projects in the field. In addition, ORC manages and administratively operates two laboratory animal vivariums that support biomedical and neurosciences research and training on the UH Mānoa campus and at the John A. Burns School of Medicine (JABSOM) at Kaka'ako.

ORC is also responsible for the administration of the compliance program that focuses primarily on matters pertaining to research and scholarly misconduct, including but not limited to whistleblower retaliation, policy development governing institutional procedures and guidance for research activities, and educational activities in support of Responsible Conduct of Research (RCR) requirements.

Human Studies Program

Human Studies Program (HSP) directs and oversees the federally-mandated human research protection program under a Federal Wide Assurance (FWA) agreement executed between UH and the U.S. Department of Health & Human Services' Office for Human Research Protections (OHRP).

The HSP office is responsible for executing these functions to ensure compliance with OHRP's directive:

- Administers three (Biomedical; Social & Behavioral Sciences; Cooperative) Institutional Review Boards (IRB) that serve UH and several partnership research institutions.
- Reviews all exempt research protocols involving human participants.
- Oversees the initial and continuing review of all non-exempt research protocols involving human participants and/or their private identifiable information.
- Provides education, training and consultation and support to UH faculty and others who design and/or conduct human subjects research on behalf of the UH System.
- Provides education and training to UH IRBs that review human participant research across the UH System.
- Develops, updates and implements human research protection policies and procedures to ensure compliance with applicable federal, state and county regulations and UH policies.
- Maintains documentation of protocol review, determinations and oversight.
- Follows up on allegations of non-compliance with applicable regulations and policies.

- Conducts post-approval monitoring of select active UH human participant research.
- Reviews reportable events and modifications to protocol to assess risks to participants.

Animal Welfare and Biosafety Programs (AWBP)

Animal Welfare Program (AWP):

Animal Welfare Program (AWP) administratively supports UH's federally-mandated vertebrate animal care and use program by closely working with the Institutional Animal Care and Use Committee (IACUC) and collaborating with the Animal Veterinary Service (AVS) Program to ensure the protection, humane care and use of animal subjects used for research and instruction under: (1) the Animal Welfare Assurance, an agreement executed between UH and the DHHS Office for Laboratory Animal Welfare (OLAW) to comply with the NIH Public Health Service (PHS) policy; (2) an institutional registration with the U.S. Department of Agriculture (USDA), Animal Plant Health Inspection Service (APHIS) to comply with the Animal Welfare Act (AWA) regulations; and (3) site and activity specific permits to comply with the National Oceanographic and Atmospheric Administration (NOAA), Marine Mammal Protection Act (MMPA) and U.S. Department of Fish and Wildlife Services (USFWS) for field studies and management programs involving the conservation of wildlife and protection of endangered species. The AWP in collaboration with the Animal Veterinary Program (AVP) office executes performance measures to meet mandatory expectations of the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC) to maintain institutional laboratory animal program accreditation.

The AWP office is responsible for executing the following program functions to comply with aforementioned agencies and their directives:

- Administers and provide support to the Institutional Animal Care and Use Committee (IACUC) at UH and other committees that provide additional institutional oversight to animal care and use program (i.e., Fish Advisory Committee).
- Reviews research proposals that may involve vertebrate animal subjects that may be considered exempt.
- Oversees the initial and continuing (*de novo*) review of all non-exempt research and instructional protocols involving vertebrate animal subjects.
- Provides education, training and consultation in support of UH faculty and others who design and/or perform vertebrate animal research and instructional activities in the UH System.
- Provides education and training to IACUC members who review vertebrate animal research.
- Develops, updates and implements policies and procedures to ensure compliance with applicable federal regulations and UH policies.
- Serves as the custodian of records for UH's animal care and use program. Maintains documentation of IACUC protocol review, determinations and committee oversight.
- Investigates and follows up on allegations of non-compliance with applicable regulations and policies.
- Conducts post-approval monitoring (PAM) of active UH vertebrate animal research and instructional protocols in collaboration with the AVS program.
- Works with IACUC, IBC and the Environmental Health and Safety Office (EHSO) specialists to ensure a safe environment for personnel working with vertebrate species.
- Works with the IACUC, IBC and the Office of the Veterinarian to ensure personnel using vertebrate animals are appropriately trained.
- In conjunction with IACUC, oversees and evaluates all aspects of animal care and use, including reviewing animal use protocols to ensure compliance with PHS Policy, AWA and Institutional Assurance -- which entails the

appropriateness of proposed and actual experimental procedures to meet criteria for scientific data gathering.

- Reviews grant proposals to ensure conformity in animal care protocols with IACUC, pre-reviews protocols for federal assurances, scientific and statistical validity, review of literatures searches, and provide rationale and feedback in the drafting of institutional policies.
- Reviews the Program of Humane Care and Use no less than semiannually.
- Inspects and reviews all animal housing facilities and laboratories no less than semi-annually.
- Completes and submit all federally required semi-annual and annual reports.
- Authors the institution's renewal of the Animal Welfare Assurance to the DHHS Office for Laboratory Animal Welfare (OLAW) every four years.
- Completes semi-annual and annual federal reports, and when necessary, provides investigative reports to oversight agencies on behalf of the program's Institutional Official (IO).

Biosafety Program (BP):

Biosafety Program (BP) administratively supports the federally-mandated biosafety program by closely working supporting the efforts of the Institutional Biosafety Committee (IBC) to ensure the protection of UH personnel, public safety and the environment from biological materials associated with research and instructional activities. These may include recombinant genetic material and synthetic nucleic acid molecules, nonpathogenic and pathogenic biological materials, and biologically-derived toxins including those microorganisms classified as Select Agents, and importation and cultivation of transgenic plants, vertebrate and invertebrate animals, and arthropods (insects). In meeting its functional responsibilities, the Biosafety Program and IBC are in compliance with the directives of: (1) DHHS Office for Biotechnology of Activities (OBA), Office of Scientific Policy (OSP); (2) DHHS Centers for Disease Control and Prevention (CDC); and (3) State of Hawai'i's Department of Agriculture (HDOA) and Department of Health (HDOH).

- Administers and provide support to the Institutional Biosafety Committee (IBC) of the UH and other committees that provide additional institutional oversight for institutional biosafety matters (i.e., Dual Use Research of Concern (DURC) Committee).
- Reviews research and instructional activities proposals that may involve the use of biological materials that may be considered exempt.
- Oversees the initial and continuing (*de novo*) review of all non-exempt research and instructional activities protocols involving biological materials that categorically contain recombinant genetic material and/or synthetic molecules.
- Oversees the initial and continuing review of all non-exempt research and instructional activities protocols involving microorganisms considered to be nonpathogenic and pathogenic to humans, animals, plants and the environment, including those microorganisms and biologically-derived toxins classified as Select Agents.
- Provides education, training and consultation in support of UH faculty and others who design and/or perform transgenic biomaterial or conduct research and instructional activities with microorganisms than may or not be biohazardous in UH System.
- Provides education and training to the IBC on the principles of risk assessment and biocontainment using CDC's standard guidance document, *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*.
- Develops, updates and implements policies and procedures to ensure compliance with applicable federal regulations and UH policies
- Maintains documentation of protocol review, determinations and oversight.
- Investigates and follows up on allegations of non-compliance with applicable regulations and policies, including incidents relating to biological materials (e.g. biocontainment breaches, spills, personnel injuries, etc.).

- Conducts post-approval monitoring (PAM) of active UH research and instructional protocols that involve the use of recombinant genetic materials, synthetic nucleic acid molecules and biohazardous biological materials.
- Work with IBC, IACUC and the Environmental Health and Safety Office (EHSO) specialists to ensure a safe working environment for personnel working with vertebrate species.
- Work with the IBC, IACUC and the Office of the Veterinarian to ensure personnel using vertebrate animals are appropriately trained.
- In conjunction with IBC, oversees and evaluates all aspects of research which utilizes recombinant genetic materials, synthetic molecules and biohazardous biological materials. This includes the review of biosafety protocols to ensure compliance with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* -- which entails the appropriateness of proposed and actual experimental procedures to meet criteria for scientific data gathering.
- Reviews grant proposals to ensure conformity in biosafety protocols with IBC, pre-reviews protocols for federal assurances, scientific and statistical validity, review of literatures searches, and provide rationale and feedback in the drafting of institutional policies.
- Inspects and review facilities and laboratories that conduct research using biological materials no less than annually.
- Complete and submit all federally required annual reports.
- Works with Principal Investigators on HDOA applications to secure permits to import, hold, and maintain restricted and non-restricted biomaterials on UH campuses.
- Ensures compliance with HDOH Biological Containment Wastes management requirements.
- Manages the UH Mānoa Sharps Waste Disposal program.
- Completes semiannual and annual federal reports, and when necessary provides investigative reports to oversight agencies on behalf of the program's Responsible Official (RO).

Animal and Veterinary Services Program

Federal law (PL 99-158, PL 89-544 and its amendments) provides the statutory basis for the U.S. Department of Health and Human Services Public Health Service (PHS) Policy and the U.S. Department of Agriculture, Animal Welfare Regulations (AWR). Animal and Veterinary Services Program (AVS) fulfills the requirements set forth by PHS and AWR, and performs its functions in conformance with federal, state, and local laws and requirements, and the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC) standards as set forth by the *Guide for the Care and Use of Laboratory Animals (The Guide)*.

- Provides the services of the UH Veterinarian, *a.k.a.* Attending Veterinarian (AV) who is responsible for the health and well-being of all vertebrate animals used at the UH. The AV shares the primary oversight responsibilities of the Animal Care and Use Program (Program) with the Institutional Official (IO) and the Institutional Animal Care and Use Committee (IACUC). UH is required by law to include the AV as a voting member on its IACUC. (*PHS, AWR*)
- Operates the biomedical and neurobehavioral vivariums at UH Mānoa and at Kaka'ako for the John A. Burns School of Medicine (JABSOM), UH Cancer Center (UHCC) and other researchers.
- Appropriately educates personnel on humane methods of animal maintenance and experimentation. Veterinary staff and vivarium animal care staff provide this education, in conjunction with the IACUC. (*PHS, AWR*)
- Implements and execute the institutional Occupational Health and Safety Program in conjunction with health and safety officials. (*PHS*)

Program and Administrative Functions of the Animal and Veterinary Services Program

Office of the University Veterinarian (AV)

- Conducts semi-annual visits to facilities/sites where vertebrate animals are housed or used by UH to assure conformance with federal, state and local laws and requirements. The following areas are assessed: (*PHS, AWR*)
 - Use of appropriate clinical care and management to prevent, control, diagnose, and treat diseases and injuries. Provision of emergency, weekend and holiday care.
 - Daily observation of all animals to assess their health and well-being (unless otherwise approved by the IACUC) to monitor animal health and well-being (physical and psychological).
 - Establish, review, and oversee medical and animal use records.
 - Husbandry, housing, animal procurement and transportation, preventive medicine (quarantine and stabilization, separation by health status and species, sentinel animal surveillance), clinical disease or health related issues, protocol-associated disease, surgery and perioperative care, pain and distress, anesthesia and analgesia, euthanasia ensure that the Program complies with the Animal Welfare Act and the *Guide for the Care and Use of Laboratory Animals* and the *Guide for the Care and Use of Agricultural Animals in Research and Teaching*.
 - Document demonstration of proficiency for researchers doing surgical procedures and other animal experimental manipulations.
- Receives direct and frequent communication from animal care staff, researchers, and consultant veterinarians associated with the UH program to ensure timely and accurate information on problems of animal health, behavior and well-being is conveyed to the AV. (*PHS, AWR*)
- Provides guidance to investigators and all personnel involved in the care and use of animals during protocol development to ensure appropriate selection of animal models, husbandry, handling, medical treatment, immobilization, sedation, analgesia, anesthesia, euthanasia, and oversight of surgery programs and perioperative care involving animals. (*PHS, AWR*)
- Provides guidance to investigators proposing animal studies involving more than slight or momentary pain or distress. (*AWR*)
- Reviews and vote on IACUC and the Institutional Biosafety Committee (IBC) protocols. (*IACUC: PHS, AWR*)
- Regularly apprizes the Institutional Official and IACUC on the program of veterinary care and issues affecting the health and well-being of vertebrate animals at UH. (*PHS*)
- Participates with investigators on protocol specific animal studies.
- Develops didactic material for educating researchers on humane care and use of animals, including information on zoonosis, and species specific information.
- Provides hands-on education for the care and use of animals, in conjunction with IACUC. Researchers, animal care staff, interns, students and volunteers are educated.
- Develops policies and procedures for the UH IACUC and IBC on issues pertaining to animals used at UH.
- Implements and executes the institutional Occupational Health and Safety Program in conjunction with health and safety officials. (*PHS*)

Vivarium Operations (UH Mānoa and Kakaʻako)

- Provides daily husbandry (including weekends and holidays) for animals used for biomedical and neurobehavioral studies and/or education. Assure that care staff are trained to conform to federal, state, and local laws and requirements, and AAALAC standards. Ensure that AVS staff complete required training to perform their duties.
- Alerts the veterinary staff to animal illness, injury and/or distressful situations. Provides treatment and follow-up on cases as prescribed by the veterinarian.
- Provides research support services to researchers.
- Procures animals and supplies for researchers. Operate a recharge center on a fee for service basis in conjunction with the OVPRI fiscal staff. Coordinate animal transfers within and between institutions.

- Maintains appropriate inventories and staff to operate the vivarium.
- Interfaces with the Granite software for billing, census management and other financial transactions. Alert Principal Investigators when allowable animal numbers are exceeded or when IACUC protocols are nearing expiration in Topaz. Complete internal transfers.
- Gatekeeper for vivarium entry. In conjunction with IACUC, will deny access to researchers with IACUC or IBC protocol deviations. Ensure that researchers and animal care staff receive orientation education and complete the necessary requirements for vivarium entry. At Kaka'ako, manage the Edstrom Watch Dog security access software in fulfilling the gatekeeper function. At UH Mānoa, manage the Biomedical Sciences Tower service elevator security access software.
- Maintains the physical structure and equipment through interfacing with vendors and Facilities Management Offices. Ensure regular repair and maintenance of equipment.
- Reviews IACUC and IBC protocols as the liaison for the AVS staff. Coordinate training for personnel exposed to potential protocol specific hazards.
- Provides training of all personnel engaged in husbandry in the vivarium and in the ABSL3.
- Participates in post approval monitoring of animal studies in the vivarium and in the ABSL3.
- Participates in preparation, event phase, and post recovery of emergencies affecting the vivariums. Participate in drills in the ABSL3 required by federal agencies.
- Chairs the Vivarium Space Committee and coordinate space requests.
- Manages waste stream in accordance with all applicable laws and regulations.
- Performs annual time motion study for determination of per diem rates.
- Interfaces with Facilities Office on renovations and special projects.
- Maintains AAALAC accreditation for JABSOM and UH Cancer Center.
- Develops training materials for vivarium orientations and the Occupational Health and Safety Program. Maintain training records.

Office of Research Integrity

The Office of Research Integrity (ORI) is responsible for responding to allegations of research and scholarly misconduct, including, but not limited to whistleblower retaliation and Conflicts of Interests. The ORI office works closely with the institution's faculty Ethics Committee (EC) to assess, inquire, and, when necessary, investigate alleged research and scholarly misconduct consistent with principles of due process and impartiality as promulgated by: (1) Public Health Service Policies on Research Misconduct, 42 CFR Part 93, Office of Research Integrity (ORI) and (2) EP 12.211, Policy for Responding to Allegations of Research and Scholarly Misconduct. The RIP program also provides informal advice to faculty, staff, and students regarding situations that could be considered research or scholarly misconduct.

In addition to its primary mission, ORI office provides training and education to faculty, staff, and students on Responsible Conduct of Research (RCR).

The ORI office is responsible for executing the following program functions and programs to be in compliance with the Federal Office of Research Integrity's directives and institutional policies and procedures:

- Receive misconduct allegations; assist in information gathering to effectively assess, inquire, and investigate as appropriate.
- Administer and provide staff support to inquiry and investigation panels on all aspects concerning cases of alleged misconduct.
- Monitors the UH Conflicts of Interest and Financial Conflict of Interests policies and procedures to ensure that they are in compliance with statutory, regulatory, A 133 and other sponsor specific agreements.

- Establish and maintain effective communication with key parties including the Complainant, Respondent, Witnesses, EC, the Deciding Official (e.g., Vice President for Research and Innovation) and ORI, as necessary.
- Update or develop research integrity policies and procedures as required by ORI and/or other governing federal regulations.
- Update or develop guidance or policies on RCR topical areas such as data management and authorship.
- Provide educational workshops and training sessions pertaining to misconduct and RCR by:
 - Monitoring CITI on-line or other web-based RCR training component;
 - Prepare and deliver interactive RCR training sessions;
 - Establish and manage a database for RCR training completions;
 - Collaborate and effectively maintain communication with all UH System campuses pertaining to RCR requirements and training; and
 - Update RCR program as required by changes in federal regulation and policy.

Office of Export Controls

The Office of Export Controls (OEC) is responsible for ensuring compliance of research and scholarly work involving: (1) Export Controls; (2) Industrial Security Services; and (3) tasked with administrative processes that are primarily related to restricted research (i.e., export-controlled and/or classified research) and other related business activities of the UH. The OEC serves as the main resource for UH administrators, researchers and other faculty and staff who are involved with research projects and business matters which require the review and execution of certain types of unfunded contractual agreements that may be subject to various U.S. laws and regulations.

Export Controls is responsible for:

1. Assisting UH researchers in complying with complex and ever-changing U.S. export control laws and regulations.
2. Developing and implementing export control policies and procedures to ensure compliance with applicable federal regulations and UH policies and procedures.
3. Providing advice and classification assistance for export controlled technologies and equipment.
4. Preparing and submitting appropriate export control license applications to appropriate federal agencies.
5. Conducting assessments and evaluations as necessary and appropriate.
6. Developing, updating and administering UH policies and procedures relating to export controls.
7. Inspecting labs and specific programs/projects, as necessary and appropriate, and consult and advise on good practices relating to export controls.
8. Investigating allegations of non-compliance with U.S. laws and/or UH policies and procedures relating to export controls.
9. Providing education training, consultation and administrative support to UH researchers and others who perform work with export control matters across the UH System.

Industrial Security Services:

The UH Office of Industrial Security Services (ISS), under the direction of the UH Industrial Security Management Group (ISMG), is responsible for any and all duties

and responsibilities specifically pertaining to the protection of classified information for UH -- including responsibility over all matters necessary to ensure the security of classified information (e.g., the negotiation, execution, administration, and institutional compliance of classified contracts) that are subject to the requirements of the Department of Defense Industrial Security Regulation (ISR) and National Industrial Security Program Operating Manual (NISPOM).

Industrial Security Services is responsible for:

1. Ensuring that UH complies with all policies, regulations and contractual stipulations relative to safeguarding classified information accessed by UH, in accordance with federal requirements (ISR and NISPOM) , and appropriate approvals from the Defense Security Service, when necessary.
2. Assisting researchers in complying with applicable U.S. laws and regulations pertaining to classified research.
3. Developing, updating and administering UH policies and procedures relating to classified research.
4. Investigating allegations of non-compliance with U.S. laws and/or UH policies and procedures relating to classified research.
5. Providing administrative industrial security services support for researchers on a UH System level, including but not limited to the Applied Research Laboratory at UH.
6. Providing education training, consultation and administrative support to UH researchers and others who perform classified work across the UH System.

STATE OF HAWAII
UNIVERSITY OF HAWAII
OFFICE OF THE PRESIDENT
**OFFICE OF THE VICE PRESIDENT FOR RESEARCH AND INNOVATION
OFFICE OF INNOVATION AND COMMERCIALIZATION**

FUNCTIONAL STATEMENT

INTRODUCTION

The University of Hawai'i's Office of Innovation and Commercialization is responsible for the management of intellectual property and technology assets developed at the University of Hawai'i and the transfer of new technology to broader public use through its commercial partners. In addition, it is tasked to develop, coordinate and enhance the innovation and entrepreneurial ecosystem across the University of Hawai'i System.

MAJOR FUNCTIONS

- Manage intellectual property assets developed through research and scholarship at the UH to identify, develop and transfer innovative technologies to broader public use through commercial partners.
- Build strategic relationships with innovators across the UH System, serving as a bridge to connect them with outside constituents in public and private sectors, and support their innovation process in general.
- Foster commercial investment in UH technologies to turn academic research into new products and services to improve public health and welfare.
- Seek closer relationships with entrepreneurs, businesses and investors to expand opportunities for the development and utilization of innovative new technologies.
- Market, promote and license University of Hawai'i-owned intellectual property to generate revenues for the support of the UH's technology transfer and economic development programs.
- Facilitate economic development and innovation through the education, training and research missions of UH.
- Facilitate and encourage technology transfer and economic development activities by the UH on a system-wide basis.
- Promulgate and administer UH policies to assist faculty, students and the community-at-large achieve the goals as described in the functional statements listed above.

Office of Technology Transfer

The Office of Technology Transfer provides for the management of intellectual property assets and the transfer of new technology for the entire UH System. Functional responsibilities include:

- Develop and implement the UH's intellectual property and technology licensing functions, including the day-to-day administration of UH's Patent and Copyright Policy.
- In cooperation with other UH offices, investigate and resolve intellectual property disputes, and develop recommendations for the UH President regarding intellectual property rights.
- Solicit and receive invention disclosures for discoveries and inventions from UH researchers.
- Educate UH administrators, faculty, staff and students in intellectual property issues and provide advice and counsel on intellectual property policies and practices.

- Support related activities that contribute to the efficient operation of the office.
- Actively support the program goals of the office and UH.

UH Ventures

The UH Ventures office is responsible for economic development, education and developing commercial partnerships to drive and stimulate economic growth and opportunities.

Functional responsibilities include:

- Develop and implement business and economic development support programs and activities to stimulate the economic development of the state.
- Work with federal, state and local economic development organizations and the business community to channel UH resources to address the needs of business and collaborate with local, state and federal agencies in various economic development projects and programs.
- Work with federal, state and local economic development organizations and the business community to assist entrepreneurs in the creation of new business enterprises based on the commercial application of UH-licensed intellectual property.
- Develop and implement entrepreneurial education, support programs and activities to foster spin-off of technology businesses from UH research, in an increasing vibrant local ecosystem that can sustain the growth of such UH-related ventures.
- Work with inventors to understand their research innovations, discover commercial applications for their research and identify potential users in both public and private sectors that may be interested in working with UH to develop and commercialize innovative new technologies.
- Analyze the commercial potential, technical risks and market challenges of UH inventions, and selectively focus on technologies where UH has competitive advantages and unique strengths for nurturing and support in further commercialization.
- Seek closer relations with the academic, business, venture and technology communities to assist in the evaluation of commercial feasibility and technical and scientific merit of invention disclosures.
- Develop and implement appropriate and effective patenting, marketing and commercialization strategies.
- Work with researchers to provide additional commercialization pathways.
- Draw upon and expand, the existing network of partners including alumni, industry experts, campus-based entrepreneurship resources, and state agencies and businesses to offer tailored advice for UH-related ventures.
- Support related activities that contribute to the efficient operation of the office.
- Actively support the program goals of the office and UH.

Strategic Grants Development Office

The Strategic Grants Development Office is responsible for assisting and mentoring faculty, students, post-docs, alumni, and the research community at-large in the development and application for research funding and large, multi-investigator grants. Functional responsibilities include:

- Foster entrepreneurship among students, faculty and staff, and in cooperation with other UH and external organizations, provide training in starting and managing a technology business, obtaining needed financing, and protecting and developing intellectual

property.

- Analyze, develop and implement a multitude of strategies to increase research grants funds for UH, with a focus on large multi-disciplinary and/or multi-site opportunities that can enhance UH capabilities in strategic areas.
- Identify potential funding opportunities and collaborations, and is actively involved from the planning to submission stages of major and multi-investigator research and training grants.
- Works with faculty start-ups to identify Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR) funds.

STATE OF HAWAII
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OFFICE OF THE PRESIDENT
OFFICE OF THE VICE PRESIDENT FOR RESEARCH AND INNOVATION
OFFICE OF STRATEGIC INITIATIVES

FUNCTIONAL STATEMENT

INTRODUCTION

The Office of Strategic Initiatives (OSI) at the University of Hawai'i (UH) is responsible for the development, oversight and management of OVPRI's discretionary projects and programs to ensure its continuity and the attainment of, performance metrics, standards, targets, and strategic goals.

STEM Pre-Academy

STEM Pre-Academy is responsible for *amplifying the impact* and *extending the reach* of University of Hawai'i (UH) research and innovation to middle school teachers and students at public and public charter schools statewide.

STEM Pre-Academy performs the following broad functions:

- Fosters inspiration and relevance in Science, Technology, Engineering, and Mathematics through collaborative interaction between middle school teachers, university researchers and subject matter experts. Multidisciplinary interaction takes place in the form of teacher workshops, technical support and tools, and is driven by teacher inquiry and need.
- Provides innovative and collaborative educational experiences for University of Hawai'i research students that promote meaningful collaboration with Hawai'i's teachers and students.
- Develops and grows a broad coalition of UH researchers, graduate and undergraduate students, public middle school teachers and their students, and industry to expand the engagement, capacity, and technical capabilities of Hawai'i's future STEM leaders. STEM Pre-Academy provides these research-based experiences with the aim of introducing and inspiring students to consider future STEM research, educational, and workforce possibilities.

University of Hawai'i Research and Innovation

- Actively supports the strategic goals and focus of the UH System and the Office of the Vice President for Research and Innovation with continued focus in critical areas of interest and strength as outlined in *UH Strategic Directions, 2015-2021*.
- Assists the Office of the Vice President of Research and Innovation with the efficient development of policy that can directly impact larger public school initiatives and student pipelines throughout the state.
- Strategically partners with UH research and outreach programs to facilitate greater effectiveness.
- Fosters relationships between UH research faculty and students with public middle school teachers to bring real-world research into classrooms.
- Develops and refines evaluation measures to ensure that the activities of STEM Pre-Academy contribute to the advancement of science, technology, engineering, and mathematics in middle schools.

- Provides teachers with direct access to the tools, materials, and processes of active research in order for them to incorporate this cutting-edge STEM technology, knowledge, and experience into their classrooms.
- Facilitates technology transfer, economic development activities, and related strategic initiatives by UH System.

Academy for Creative Media

The Academy for Creative Media System (ACM System) supports and coordinates Creative Media programs throughout the UH System to support the diversification of Hawai'i's economy on every island. The ACM System fosters collaboration between and among the campuses and programs of the UH System and encourages a multi-disciplinary approach to education.

Major Functions

Office of the Director

The Office of the Director conceives, directs, and administers the Academy for Creative Media System programs system-wide by articulating a clear and strategic vision for Creative Media education at the University of Hawai'i. Functional responsibilities include:

- Supports creative media programs on all UH System campuses and works with the University of Hawai'i Foundation and public, private, and corporate entities to raise funds for scholarships, equipment, program development, and educational programs.
- Develops and maintains partnerships among UH System campuses and other local educational institutions, including the development of articulation agreements, between and among campuses, promotes student and faculty exchanges, fosters collaboration among campuses by sharing information and best practices, and offering efficiencies in equipment hardware and software purchases among the programs system-wide.
- Represents the ACM System and the University of Hawai'i through public speaking engagements, media coverage, Hawai'i legislative testimony, and participation in educational and media industry events locally and globally.
- Supports workforce development through creative media middle and high school outreach and collaborates with the State of Hawai'i Department of Education, UH STEM Pre-Academy, and related programs and stakeholders.
- Establishes and oversees partnerships with social media platforms, internet distribution platforms, motion picture, television, animation formats, visual effects, and video and mobile game companies to establish student internships, guest lectures by industry professionals, and employment opportunities for graduates.
- Develops an overall fiscal plan for the system-wide ACM program and its initiatives impacting the ten UH campuses; allocates annual funding to campuses for recurring and new programmatic needs.
- Coordinates operational administration and programmatic planning for ACM system-wide initiatives across UH campuses.

- Initiates cross-campus, cross-college, and cross-departmental collaboration to achieve new initiatives in cutting-edge technological programs, practices, and curricula.

Academy for Creative Media Instructional Faculty and Support

The Instructional Faculty and Support provides programmatic and educational support services for the UH System campuses. Working directly with the Office of the Director and the respective campus, the unit coordinates and executes the development and expansion of the ACM system-wide in order to initiate or enhance existing creative media centers on UH campuses by offering a multitude of creative media classes.

University of Hawai'i Research and Innovation

- Actively supports the strategic goals and initiatives of the UH System and the office of the Vice President for Research and Innovation with continued focus in critical areas of interest and strength as outlined in *UH Strategic Directions, 2015-2021*.

STATE OF HAWAI'I
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OFFICE OF THE PRESIDENT
OFFICE OF THE VICE PRESIDENT FOR RESEARCH AND INNOVATION
APPLIED RESEARCH LABORATORY

FUNCTIONAL STATEMENT

INTRODUCTION

Administered by the UH System Offices under the Office of the Vice President for Research and Innovation (OVPRI), the Applied Research Laboratory at the University of Hawai'i (ARL at UH) was established in July of 2008 as a Navy sponsored research laboratory. Its purpose is to serve as a research center of excellence for critical Navy and national defense science, technology and engineering with a focus in naval missions and related areas. ARL at UH conducts strategic research and technical services for the Navy, the Department of Defense (DOD) and other government agencies.

MAJOR FUNCTIONS

The ARL at UH performs the following broad functions:

- Actively support the strategic goals and focus of the UH System and the Office of the Vice President for Research and Innovation with continued focus in critical areas of interest and strength as outlined in UH Strategic Directions (e.g., ocean sciences; astronomy; remote sensing; unmanned and autonomous systems; sensor development; communications; high performance computing, cybersecurity; sustainable energy);
- Organize collaborative activities and promote other linkages between Navy/DOD, academia and industry;
- Assist in the transfer of technology to industry;
- Help build the State's research industry and to create more jobs and opportunities, especially for local and UH students that wish to pursue a career in science, technology, engineering and math (STEM) and in defense related fields.
- Evaluate technology and provide breakthrough software solutions to significantly expand the High Performance Computing Modernization Program (HPCMP).