MEMORANDUM

TO: Virginia S. Hinshaw
   Chancellor

VIA: Gary K. Ostrander
     Vice Chancellor for Research and Graduate Education

FROM: Ching Yuan Hu
      Interim Assistant Vice Chancellor for Research and Graduate Education

SUBJECT: Reorganization Proposal for the Office of the Vice Chancellor for Research and Graduate Education

SPECIFIC ACTION REQUESTED:
We request your approval of the reorganization of the Office of the Vice Chancellor for Research and Graduate Education to create an Office of Research Compliance effective upon your approval.

RECOMMENDED EFFECTIVE DATE:
Upon your approval.

ADDITIONAL COST:
Additional salary cost due to reclassification of a Research Associate position will be covered by the existing budget.

PURPOSE:
The purpose of this reorganization is to realign various functions of existing compliance services and programs to achieve increased efficiency in delivering our programs.

BACKGROUND:
Pursuant to Administrative Procedure A3.101 University of Hawai'i Organizational and Functional Changes dated March 2008, reorganizations that:
   a) do not have an impact on BOR policy and/or laws;
   b) do not create, eliminate, or significantly change responsibilities of programs reporting directly to the Board or President;

September 30, 2011
c) do not incur significant additional expenses; or
d) do not have significant programmatic impact on the University
may be approved under delegated authority by the Chancellor for reorganizations that are
two (2) supervisory levels below (APM A3.101, Section 3b).

This reorganization proposal has been reviewed and discussed with appropriate units and staff members. The details of the reorganization are outlined in the attached Executive Summary and Narrative proposal.

ACTION RECOMMENDED:
It is recommended that you approve the attached reorganization proposal for the Office of the Vice Chancellor for Research and Graduate Education to create an Office of Research Compliance effective upon approval.

Attachments:
1. Executive Summary—Attachment 1
2. Narrative—Attachment 2
3. Allocated and Authorized BJ/BT Positions Impacted by the Reorganization—Attachment 3
4. Current Organizational Charts and Functional Statements—Attachment 4
5. Proposed Organizational Charts and Functional Statements—Attachment 5
6. Copies of letters and responses from campus groups—Attachment 6
7. Copies of letters sent to Union—Attachment 7

APPROVED/ DISAPPROVED:

Virginia S. Hinshaw
Chancellor

JAN 10 2012
Date
Executive Summary

Attachment 1
Executive Summary

Instructions: Complete each section below and clearly indicate "None" or "N/A" where appropriate.

I. Purpose:
Explain the purpose of this reorganization and the anticipated overall impact.

There is presently no formal BOR approved structure for an office of compliance at UH Mānoa. The purpose of this reorganization is to establish a centralized compliance office under the OVCRI. The reorganization calls to realign various functions of four existing compliance services and programs (Committee on Human Studies, Laboratory Animal Service, Animal Welfare and Biosafety, and Research Integrity) to formally report to the Assistant Vice Chancellor for Research and Graduate Education, Position #89119 (AVCRGE) in the new Office of Research Compliance. This new unit will advocate for the University to ensure that the University has the optimal culture for responsible, compliant, and innovative research.

The Assistant Vice Chancellor will continue to lead strategic efforts in the areas of research and regulatory compliance, and the programs will continue to provide oversight for the use of human subjects, the use of vertebrate animals, and the responsible conduct of research. With this program in place, the University will be able to provide optimal support to the University's growing research enterprise.

II. Major Elements of the Proposal:
Explain or list the key changes being proposed in this reorganization relative to purpose and results.

This reorganization proposes to:
A. Create a centralized compliance office called the Office of Research Compliance with the Assistant Vice Chancellor for Research and Graduate Education as the supervisor.
B. Move the reporting line of Committee on Human Studies from the Office of Vice Chancellor for Research and Graduate Education to the Office of Research Compliance.
C. Rename the Committee on Human Studies to Human Studies Program.
D. Create a new unit, Animal Welfare and Biosafety Program, under the Office of Research Compliance.
E. Move the Compliance Officer from Laboratory Animal Services to the Animal Welfare and Biosafety Program.
F. Move the reporting line for the Administrative Officer and two Research Associate positions (to be redescribed) from Laboratory Animal Services to the Office of Research Compliance.
G. Rename the Laboratory Animal Services to Animal and Veterinary Services Program.
H. Create function of Research Integrity to be a direct report to the Office of Research Compliance.

The changes being proposed will build a more effective compliance program, and provide optimal support to the University. The proposal reflects the four regulatory compliance sections reporting to the AVCRGE under one central administrative unit; thus, better utilizing resources by providing the functions required in all compliance sections by one unit. It will also enhance efficiency through coordination and communication within the research communities at the University by becoming the central point of contact. This will better enable the University to promptly address compliance issues with applicable state and federal laws as well as University policies, and to better equip and protect the University from reputational and financial damages caused by compliance breaches.

III. Resource Impact:

Explain the resources impacted as a result of this reorganization? If there is no impact, reflect “None” for each category as appropriate.

A. Budget
1. What is the estimated cost of the reorg? The additional cost will be the possible rebanding of Research Associate #81657 from a PBC to a PBD, estimated at $6,200.
2. Are additional funds needed? No. If so, how will the cost of the reorg be funded? Funding will come from the existing operating budget.
3. Will the reorg result in cost savings or be cost neutral? N/A.

B. Operational
1. What is the overall impact on faculty and staffing responsibilities, if any? The proposed changes reflect the way current operations are actually managed or should have been managed. Rebanding is anticipated to properly reflect work complexity and scope of responsibility.
2. Will additional faculty/support personnel be required? No. If so, what is the plan to obtain the additional faculty/staffing to successfully implement the reorganization? N/A
3. Will there be a reduction in faculty/staff? No. If so, what steps are planned or have been taken to ensure proper consultation? N/A
4. Identify faculty/staff positions impacted by the anticipated changes.
   \[F = \text{Position filled} \quad V = \text{Position vacant}\]
   \- Assistant Vice Chancellor, #89119 (F)  
      Move from Office of Vice Chancellor for Research and Graduate Education to the Office of Research Compliance and will continue to report directly to the Vice Chancellor, #89112 (F).
- No change in reporting structure.
- The position description for #89119 will be updated to reflect the duties and responsibilities of managing this system-wide operation.

- Research Associate, PBD, #80751 (F)
  - Move from Office of Vice Chancellor for Research and Graduate Education to the Office of Research Compliance.
  - Change in supervisor from Vice Chancellor, #89112 to Assistant Vice Chancellor, #89119 (F).
  - No change in position description or responsibilities.

- Research Associate, PBC, #81657 (F)
  - Move from Laboratory Animal Research Support to Office of Research Compliance.
  - Change in supervisor from Director of Laboratory Animal Services, #86262 to Assistant Vice Chancellor, #89119 (F).
  - The position description for #81657 will be updated to reflect the duties and responsibilities of managing this system-wide operation.

- Administrative Officer, PBB, #81901 (F)
  - Move from Laboratory Animal Services to Office of Research Compliance.
  - Change in supervisor from Director of Laboratory Animal Services, #86262 to Assistant Vice Chancellor, #89119 (F).
  - The position description for #81901 will be updated to reflect the duties and responsibilities of supporting this system-wide operation.

- Research Associate, PBA, #80504 (V)
  - Move from Laboratory Animal Services to Office of Research Compliance.
  - Change in supervisor from Director of Laboratory Animal Services, #86262 to Administrative Officer, #81901 (F).
  - The position description for #80504 will be redescribed to reflect the duties and responsibilities of supporting this system-wide operation.

- Research Associate, PBA, #81431 (V)
  - Move from Laboratory Animal Services to Office of Research Compliance.
  - Change in supervisor from Director of Laboratory Animal Services, #86262 to Administrative Officer, #81901 (F).
  - The position description for #81431 will be redescribed to reflect the duties and responsibilities of supporting this system-wide operation.

- Environmental Safety Specialist, PBC, #81109 (F)
  - Move from Office of Vice Chancellor for Research and Graduate Education to the Office of Research Compliance.
  - Change in supervisor from Assistant Vice Chancellor, #89119 to Research Associate, #81657 (F).
  - No change in position description or responsibilities.

- Environmental Safety Specialist, PBA, #80261 (F)
  - Move from Office of Vice Chancellor for Research and Graduate Education to the Office of Research Compliance.
- Change in supervisor from Assistant Vice Chancellor, #89119 to Research Associate, #81657 (F).
- No change in position description or responsibilities.
- Specialist Type Faculty, #86262 (F)
  - No change in position description.
  - No change in reporting structure.
- Research Associate, PBA, #81179 (F)
  - No change in position description.
  - No change in reporting structure.
- Research Associate, PBB, #80369 (V)
  - No change in reporting structure.

C. Space
1. Will additional space outside own resources/allocations be required? No. If so, has the Vice Chancellor for Administration, Finance, and Operations (VCAFO) or designee been consulted? N/A

IV. Consultation:
Explain or list the individuals and groups consulted and the key comments/feedback received.

Extensive consultations with affected units (CHS, LAS, ORS and EHSO) have occurred in the development of this proposal. Additionally, all units reporting to the OVCRGE under this reorganization have taken an active role in updating their roles and responsibilities as proposed in the functional statements. The feedback received by the units under the OVCRGE was positive and supportive of the proposed changes to operate more efficiently while fulfilling the responsibilities of this office.

V. Implementation:
Explain when and how this reorganization will be implemented. Identify anticipated effective date.
The reorganization will be implemented upon approval as it formally realigns and reflects how the functions currently operate. The realignment of these organizational units will result in clearer reporting and operating relationships with improved efficiency.
Narrative
Attachment 2
Reorganization Proposal
Office of the Vice Chancellor for Research and Graduate Education
University of Hawai'i at Mānoa

Narrative

Instructions: Complete each section below and clearly indicate "None" or "N/A" where appropriate.

I. INTRODUCTION:
   A. Provide an overview of the College/School/Department and a snapshot outlining the current situation of the unit(s) involved in the reorganization.

The Office of the Vice Chancellor for Research and Graduate Education (OVCRGE) at University of Hawai'i at Mānoa currently consists of nine research related units (School of Ocean and Earth Science and Technology, Institute for Astronomy, Cancer Research Center, Pacific Biosciences Research Center, Water Resources Research Center, Center on Aging, Waikīkī Aquarium, Lyon Arboretum and Laboratory Animal Service), and three administrative units (Graduate and Professional Education, Environmental Health and Safety Office, and Committee on Human Studies) reporting directly to the Vice Chancellor. Institutional Biosafety Committee (IBC), another federally mandated program, is administered by one of the Assistant Vice Chancellors in the OVCRGE.

Mānoa Committee on Human Studies (MACHS) and Mānoa Laboratory Animal Services (MALAS) are the two units involved in the proposed reorganization. MACHS is designated to function as the federally mandated Institutional Review Board (IRB) for the University of Hawai'i System, and it is responsible for monitoring all research involving human subjects. MALAS has three functions: the University Veterinarian has system-wide responsibilities with direct or delegated authority to execute a program of adequate veterinary care and for the health and well-being of all animals used at the institution, including access to all animals; directs the operations of three vivariums which house and use laboratory animals; provides veterinary care for all animals in the vivariums and for a number of animals housed and used on protocols outside of the vivariums; and provides oversight and direction for the system-wide, federally-mandated Institutional Animal Care and Use Committee (IACUC) for the University of Hawai'i.

Current
Committee on Human Studies
Laboratory Animal Services

Proposed
Office of Research Compliance
- Human Studies Program
- Animal and Veterinary Services Program
- Animal Welfare and Biosafety Program
- Research Integrity Program
B. Specify the objectives/goals of the new/restructured unit(s) involved in the reorganization.

The objective of the proposed reorganization is to consolidate four existing units (CHS, LAS, Animal Welfare and Biosafety, and Research Integrity) responsible for compliance with federal, state and local regulations into one office, a reflection of existing operational workflow. The outcome of the proposed merger will be improved functional efficiency, quality service and accountability.

II. RATIONALE FOR THE REORGANIZATION:
A. Provide background and relevant historical information.

University of Hawai‘i at Mānoa (UHM) is classified by the Carnegie Foundation as a research university with "very high research activity." UHM received nearly $300 million in research award in 2010, with many of these research projects requiring the use of microbiological materials, vertebrate animals, and human subjects. These research activities are governed by federal, state and university laws, regulations and policies. Therefore, compliance is an integral part of the UHM research enterprise, and plays an important role in its continual growth. There is presently no formal BOR approved structure for an office of compliance at UHM. Historically, UHM compliance programs were scattered in various administrative units, such as UH Office of Vice President for Research (OVPR), UH Office of Research Services (ORS), UHM Environmental Health and Safety Office (EHSO), and UHM Office of Vice Chancellor for Research and Graduate Education (OVCRGE). Some realignments were made during past reorganization efforts. However, further adjustments are needed to reflect existing reporting relationships, and to achieve functional efficiency. This proposal addresses the need to consolidate all of the compliance resources into one unit, the Office of Research Compliance under the Assistant Vice Chancellor for Research and Graduate Education (AVCRGE) at UH-Mānoa. This proposed new administrative structure will make our compliance programs stronger with improved communication, and functional efficiency. It will also reduce the risk of compliance breeches at UH, as well as having comprehensive compliance programs located in one defined structure similar to other universities.

B. Provide a detailed explanation of the conditions and/or factors prompting the proposed reorganization and how they will be addressed by the reorganization. Explain why the current organization is inadequate and whether the reorg is consistent with the University's strategic, program, and financial plans.

The proposed reorganization establishes an Office of Research Compliance (ORC), overseeing four units: Animal and Veterinary Services Program, Human Studies Program, Animal Welfare and Biosafety Program, and Research Integrity Program. We propose to change the name of Laboratory Animal Services (LAS) to Animal and Veterinary Services Program. This program is a unit under OVCRGE in the organizational chart; however, LAS Director reports to AVCRGE directly. We propose to change the name of Committee of Human Studies (CHS) to Human Studies...
Program. Currently, the CHS Director reports to the VCRGE, and will be reporting to AVCRGE in the proposed new chart. We propose to move the animal welfare program out from LAS and merge this program with the Biosafety Program, which reports to AVCRGE, into a new unit, Animal Welfare and Biosafety Program. This will avoid any potential for real or perceived conflicts of interest. We propose to add a new unit, Research Integrity Program under ORC. This program was formerly under the Office of Vice President for Research, and transferred to report to AVCRGE. This proposal will formalize the existing organizational structure. Finally, we propose to move the LAS Administrative Officer to report to AVCRGE, and move two Research Associate positions (to be redescribed) to report to the Administrative Officer to better meet the responsibilities of this ORC. Since all the compliance programs are located in the Biomedical Sciences Building, the same location as the LAS, it makes sense to have these positions provide administrative support to all other compliance programs in ORC. Details for each proposal are described below.

Animal and Veterinary Services Program

Laboratory Animal Services (LAS) is the largest unit that AVCRGE oversees. LAS has three functions: ensures that appropriate veterinary care is provided for all animals used at the institution; operates the vivariums; and provides administrative support for the IACUC and Institutional Official concerning animal welfare compliance. LAS is a recharge center and thus it has a fiscal office reporting to the Director. This office provides fiscal and personnel support services in compliance with state and federal laws, and UH and RCUH policies, procedures and rules.

The University Veterinarian (attending veterinarian) has system-wide responsibilities for the health and well-being and clinical care of all vertebrate animals used at the institution. Adequate veterinary care is required by federal agencies and an Attending Veterinarian (AV) must have appropriate authority and resources to execute a program of adequate veterinary care, including access to all animals. LAS assists faculty and staff in guidance in development of their animal research protocols, animal procurement and transportation, preventive medicine, clinical disease or related health issues, protocol-associated disease or other disease, surgery and perioperative care, mitigating pain and distress, providing humane anesthesia and analgesia, proper euthanasia and disposal of animals used on protocol. The AV directs the operations of the vivariums and provides veterinary care for the animal biomedical activities at Mānoa and Kaka'ako, as well as for a number of the protocols that use animals for research and training outside of the vivariums. LAS also fulfills the federal mandate to provide training to personnel involved with care and use of animals so that they are adequately trained, and/or qualified in basic principles of animal care and use to ensure quality research and animal well-being. LAS administers the review of regulations for all system-wide personnel using vertebrate animals for research, training, or other activities.

The AV directs and manages the vivariums involved in biomedical and neuroscience research and training on the UH-Mānoa campus and at the John A. Burns School of Medicine (JABSOM) at Kaka'ako. LAS provides daily husbandry on a fee for service
basis, veterinary care, and maintenance of facilities in accordance with federal, state, and local regulations to support the research effort. LAS has two administrative officers (one fiscal and one personnel), one program assistant, two veterinarians, an operations manager, two facility supervisors, two veterinary technicians, and eight animal care staff (two at half-time); a total of 17 FTE's, plus part-time student workers.

The Institutional Animal Care and Use Committee is required by law, and is responsible for assessment and oversight of the institution's components of animal care and use activities and facilities using animals at UH. It should have sufficient authority and resources to ensure that the program complies with regulations set forth by the United States Department of Agriculture Animal Welfare Act, the National Institutes of Health Public Health Service (PHS) Policy on Humane Care and Use of Animals, as well as other federal, state and local regulations. UH IACUC is supported by a regulatory compliance officer, and one unbudgeted temporary APT staff.

This proposal seeks to move the function of the animal welfare program out from LAS (see Animal Welfare and Biosafety Program), move the Administrative Officer to report to AVCRGE, move two Research Associate positions (to be redescribed) to report to the Administrative Officer and to rename LAS to Animal and Veterinary Services Program. The proposed change will increase functional efficiency, and avoid potential for real or perceived conflicts of interest in meeting compliance requirements.

Animal Welfare and Biosafety Program

The Biological Safety Program is established to meet the requirement mandated by the federal, state, and university's law, rules, and regulations on the use of microbiological material. This program has five major responsibilities: conduct training for faculty, staff, and students; conduct laboratory biosafety inspections; process importing biological material applications; support the Institutional Biosafety Committee (IBC); and biological waste disposal. This program resided in the Environmental Health and Safety Office (EHSO) under the Office of Vice Chancellor for Administration, Finance, and Operations (OVCAFO) until early 2010. When EHSO moved from OVCAFO to OVCAR during last reorganization, the Biological Safety Program, with two biosafety officers, was moved from EHSO to report directly to the Assistant Vice Chancellor for Research and Education. This program has two additional unbudgeted temporary positions.

The function of the animal welfare program is officially housed in LAS under the current organizational structure; the regulatory compliance officer reports to the Director of LAS. This presents a potential conflict of interest. Consequently, the regulatory compliance officer has been reassigned to report to the Assistant Vice Chancellor directly since the early 1990's. This proposal will formalize the existing reporting relationship. In addition, this proposal seeks to merge the biosafety program with the animal welfare program to achieve savings and improve functional efficiency.
Human Studies Program

Research involving human subjects must have their protocols reviewed and approved by the Institutional Review Board (IRB). The Committee on Human Studies (CHS), a unit in the OVCRGE, is tasked to conduct IRB reviews. Director of CHS reports to VCRGE in our current administrative structure. Director is the only G-funded position in this unit, supported by six unbudgeted temporary positions. Since IRB's are committees comprised of faculty and staff, and supported administratively by CHS, the use of Committee in the name of this administrative unit is inappropriate. Since both animal use and care and biosafety compliance programs are reporting to the Assistant Vice Chancellor, it makes sense to include the human compliance program in the same portfolio. This proposal seeks to rename the Committee on Human Studies to Human Studies Program, in line with other research compliance programs, and reassign the Director of this program to report to the Assistant Vice Chancellor.

Research Integrity Program

Research Integrity Program has responsibilities in three areas: Research and Scholarly Misconduct, Responsible Conduct of Research, and Conflicts of Interest.

Executive Policy E5.211, Policy for Responding to Allegations of Research and Scholarly Misconduct, is UH system’s policy on research and scholarly misconduct. It describes what the University defines as research/scholarly misconduct, the process and procedures of how allegations are handled, and the rights and responsibilities of the individuals involved. The policy is modeled after the Public Health Service’s (PHS) policy on research misconduct (42 CFR Part 93), to meet their requirements from institutions that receive PHS funds. It does however include a broader definition, than that defined by the Office of Research Integrity (ORI), of research and scholarly misconduct. This policy applies to the entire University community: faculty, researchers, staff, students, and affiliates.

UH Institutional plans for Responsible Conduct of Research (RCR) were implemented to meet the requirements of the National Science Foundation and National Institutes of Health to provide appropriate education, training and oversight in the responsible and ethical conduct of research. Certain individuals supported by such Federal funds are required to obtain RCR training, however, all members of our research community who are responsible for the design, conduct or reporting of research are encouraged to participate in this training.

Executive Policy E5.214, Conflicts of Interests, addresses concerns regarding conflicts of interest, namely financial conflicts of interest (FCOI), and conflicts of commitment on the part of University employees. It is founded on National Science Foundation (NSF) and Public Health Service (PHS) regulations (42 CFR Part 50 Subpart F and 45 CFR Part 94), but also includes broader requirements and disclosure standards specific to this University. This policy conveys the University’s intent in promoting integrity and
objectivity in instruction, research, public service, and administrative decision-making through disclosure and management.

All these three functions of the UH Research Integrity Program are carried out by the Assistant Vice Chancellor with one full-time temporary APT staff and three part-time temporary faculty members. This program plays a critical role in the overall university compliance responsibility, and currently is not reflected in the university organizational chart. Therefore, this proposal seeks to remedy this omission in the organizational chart.

C. Explain other alternatives explored.

N/A.

D. Explain how the proposed changes will affect current relationships and workflows, including impact on services and relations with other University segments.

The proposed changes will facilitate communication, collaboration, and accountability within the research compliance programs. These proposed changes also reflect mostly the way current operations are actually managed. The focus and increase interactions between the units will enable the research compliance programs to serve research faculty members more efficiently and effectively, protecting the university from potential federal or state sanctions and any negative impacts to the UH.

E. List the groups that will be impacted by the reorganization and indicate whether they have been informed/consulted.

The reorganization has been discussed and agreed to by the responsible head of each unit reporting to the Assistant Vice Chancellor and the following campus groups:

- Office of Vice Chancellor for Research and Graduate Education
- UH Office of Research Services
- UHM Human Resources
- Committee on Human Studies
- Environmental Health and Safety Office
- Laboratory Animal Services

F. Outline the benefits that will be achieved by the reorganization, including efficiencies and service improvements. Explain whether the supervisor/subordinate reporting relationships are properly identified and whether the reorganization will minimize confusion over authority, roles, and responsibilities.

This reorganization of the OVCRGE unit will provide the campus community with the following benefits:

- Improved efficiency in providing support for faculty
- Clear accountability for each program
The supervisor/subordinate reporting relationships are properly identified in the proposed organizational charts by clear functions, minimizing confusion over authority, roles, and responsibilities.

III. IMPACT ON RESOURCES AND THE UNIVERSITY

Provide a detailed description of the resource requirements and the programmatic impacts of the reorganization on the University.

A. Impact on budget resources:
   1. What is the estimated cost of the reorg? Possibly, $6,200. The additional cost will be the rebanding of Research Associate #81657 from a PBC to a PBD.
   2. Are additional funds needed? No; funds will come from existing operating budget.
      If so, how will the cost of the reorg be funded? The possible rebanding will come from the existing operating budget.
   3. Will the reorg result in cost savings or be cost neutral? N/A.

B. Impact on operational resources:
   1. What is the overall impact on faculty and staffing responsibilities, if any? Explain reasons for the anticipated changes/relocation/reassignment/etc.

      The proposed changes reflect the way current operations are actually managed. Rebanding is anticipated to properly reflect work complexity and scope of responsibility.

   2. Will additional faculty/support personnel be required? No.
      If so, what is the plan to obtain the additional faculty/staffing to successfully implement the reorganization? What is the impact of the increase? N/A.

   3. Will there be a reduction in faculty/staff? No.
      If so, what steps are planned or have been taken to ensure proper consultation? What is the impact of the reduction? N/A.

   4. Identify the positions impacted by position number, classification title, and anticipated changes.
      F = Position filled        V = Position vacant
      • Assistant Vice Chancellor, #89119 (F)
         - Move from Office of Vice Chancellor for Research and Graduate Education to the Office of Research Compliance and will continue to report directly to the Vice Chancellor, #89112 (F).
         - No change in reporting structure.
         - The position description for #89119 will be updated to reflect the duties and responsibilities of managing this system-wide operation.
• Research Associate, PBD, #80751 (F)
  - Move from Office of Vice Chancellor for Research and Graduate Education to the Office of Research Compliance.
  - Change in supervisor from Vice Chancellor, #89112 to Assistant Vice Chancellor, #89119 (F).
  - No change in position description or responsibilities.

• Research Associate, PBC, #81657 (F)
  - Move from Laboratory Animal Research Support to Office of Research Compliance.
  - Change in supervisor from Director of Laboratory Animal Services, #86262 to Assistant Vice Chancellor, #89119 (F).
  - The position description for #81657 will be updated to reflect the duties and responsibilities of managing this system-wide operation.

• Administrative Officer, PBB, #81901 (F)
  - Move from Laboratory Animal Services to Office of Research Compliance.
  - Change in supervisor from Director of Laboratory Animal Services, #86262 to Assistant Vice Chancellor, #89119 (F).
  - The position description for #81901 will be updated to reflect the duties and responsibilities of supporting this system-wide operation.

• Research Associate, PBA, #80504 (V)
  - Move from Laboratory Animal Services to Office of Research Compliance.
  - Change in supervisor from Director of Laboratory Animal Services, #86262 to Administrative Officer, #81901 (F).
  - The position description for #80504 will be redescribed to reflect the duties and responsibilities of supporting this system-wide operation.

• Research Associate, PBA, #81431 (V)
  - Move from Laboratory Animal Services to Office of Research Compliance.
  - Change in supervisor from Director of Laboratory Animal Services, #86262 to Administrative Officer, #81901 (F).
  - The position description for #81431 will be redescribed to reflect the duties and responsibilities of supporting this system-wide operation.

• Environmental Safety Specialist, PBC, #81109 (F)
  - Move from Office of Vice Chancellor for Research and Graduate Education to the Office of Research Compliance.
  - Change in supervisor from Assistant Vice Chancellor, #89119 to Research Associate, #81657 (F).
  - No change in position description or responsibilities.

• Environmental Safety Specialist, PBA, #80261 (F)
  - Move from Office of Vice Chancellor for Research and Graduate Education to the Office of Research Compliance.
  - Change in supervisor from Assistant Vice Chancellor, #89119 to Research Associate, #81657 (F).
  - No change in position description or responsibilities.
• Specialist Type Faculty, #86262 (F)
  - No change in position description.
  - No change in reporting structure.
• Research Associate, PBA, #81179 (F)
  - No change in position description.
  - No change in reporting structure.
• Research Associate, PBB, #80369 (V)
  - No change in reporting structure.

5. Will there be changes to supervisory/subordinate relationships? Yes. If so, identify the impact. Will the changes streamline operations, reduce supervisory span of control, etc.?

The regulatory compliance officer supports the activities of the IACUC which is responsible for monitoring the proper care and use of vertebrate animals in the UH System; while the Attending Veterinarian, who also directs Laboratory Animal Services is responsible for the health and well-being of all laboratory animals used at the institution. The present organization of LAS represents an inherent conflict of interest in their working relationship. Therefore, in practice, the regulatory compliance officer has been reporting to the Assistant Vice Chancellor for Research and Graduate Education since the early 1990’s. In this proposed reorganization we seek to formalize this reporting relationship. In addition, there are functional overlaps in the animal compliance program and biosafety compliance program, it makes sense to merge these two programs into one since the AVCRGE also serves as the responsible Institutional Official for both committees which these programs support. This relationship allows cross-training of existing staff to deliver required work more efficiently.

Based on the proposed reorganization, position descriptions for impacted positions will be submitted for update to reflect the appropriate new supervisors and duties and responsibilities. The proposed change will result in improved efficiency in providing required compliance.

C. Impact on space resources:
  1. Will additional space outside own resources/allocations be required? No. If so, has the Vice Chancellor for Administration, Finance, and Operations (VCAFO) or designee been consulted? N/A.
Allocated and Authorized BJ/BT Positions Impacted by the Reorganization

Attachment 3
### Program Title:
Office of the Vice Chancellor for Research and Graduate Education (OVCRGE)

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Chart No.(s)</th>
<th>Affected Position No.(s)</th>
<th>Classification/Organizational/Functional Change</th>
<th>Basis for Change/Impact on Position</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>III</td>
<td>89119 (F)</td>
<td>Office of the Vice Chancellor for Research and Graduate Education</td>
<td>Office of Research Compliance (Chart III-A)</td>
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<td>III</td>
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<td>Office of Research Compliance - Animal Welfare and Biosafety Program (Chart III-A)</td>
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<td>81901 (F)</td>
<td>Laboratory Animal Service Fiscal Office</td>
<td>Office of Research Compliance (Chart III-A)</td>
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<td>Animal Welfare and Biosafety Program</td>
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<td>Office of the Director</td>
<td>Animal and Veterinary Services Program</td>
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<td>61179 (F)</td>
<td>Laboratory Animal Research Support</td>
<td>Animal and Veterinary Services Program (Chart III-A)</td>
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<td>I</td>
<td>60737 (F)</td>
<td>Laboratory Animal Research Support</td>
<td>Office of Research Compliance (Chart III-A)</td>
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<tr>
<td>8</td>
<td>I</td>
<td>61431 (V)</td>
<td>Laboratory Animal Research Support</td>
<td>Office of Research Compliance (Chart III-A)</td>
</tr>
<tr>
<td>9</td>
<td>I</td>
<td>60369 (V)</td>
<td>Laboratory Animal Research Support</td>
<td>Animal and Veterinary Services Program (Chart III-A)</td>
</tr>
<tr>
<td>10</td>
<td>III</td>
<td>80751 (F)</td>
<td>Committee on Human Studies</td>
<td>Office of Research Compliance, Human Studies Program (Chart III-A)</td>
</tr>
<tr>
<td>11</td>
<td>I</td>
<td></td>
<td>Move unit and function of Human Studies Program to be a direct report to the AVCRGE (Chart III-A)</td>
<td></td>
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<tr>
<td>12</td>
<td>I</td>
<td></td>
<td>Create function of Research Integrity to be a direct report to AVCRGE (Chart III-A)</td>
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<tr>
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<td>Change in OVCRGE functional statement. Moved and renamed Committee on Human Studies and Laboratory Animal Services. Created Office of Research Compliance functional statement.</td>
<td></td>
</tr>
</tbody>
</table>

**Administrator's Signature, Name and Title**
Karen Okamura, Administrative Officer

**Date** 9/30/11
**Telephone Number** 956-8179

**Review**
HR Review
CFA Review
Current
Organizational Charts and
Functional Statements

Attachment 4
STATE OF HAWAII
UNIVERSITY OF HAWAI'I
UNIVERSITY OF HAWAI'I AT MĀNOA
OFFICE OF THE VICE CHANCELLOR
FOR RESEARCH AND GRADUATE EDUCATION
POSITION ORGANIZATION CHART III

General Funds: 12.00 FTE

Footnotes:
+ Academic matters within the School of Ocean and Earth Science and Technology will be administered in coordination with the Vice Chancellor for Academic Affairs
* Position number and count to be requested
OFFICE OF THE VICE CHANCELLOR FOR RESEARCH AND GRADUATE EDUCATION (OVCRGE) – Org Code: MAVCRG

Overview of Office:
In support of the deans and directors and in collaboration with the Office of the Vice Chancellor for Academic Affairs, this Office has leadership responsibility for the planning, direction, initiation, development and coordination of research and graduate programs of the University of Hawaii at Manoa. The Vice Chancellor for Research and Graduate Education (VCRGE) serves as the chief policy advisor to the Chancellor in these areas and the chief operating officer for University of Hawaii at Manoa research programs.

Authority:
The office of the VCRGE has the authority to develop new research programs within the applicable campus executive and Board of Regents policies, to allocate or reallocate budgets of the Research and Training Revolving Funds in support of the research enterprise, to develop and promulgate policies for compliance of the research faculty and staff with Federal and State regulations, and to take actions to improve the research climate at the University of Hawaii at Manoa. Leadership, direction and oversight is provided to select organized research units (ORUs), and the School of Ocean and Earth Science and Technology.

Interactions with other UHM Vice Chancellors
The VCRGE works with the Vice Chancellor for Academic Affairs to ensure that the research and graduate programs of the academic units are provided with the best possible support; with the VC for Administration, Finance and Operations to ensure responsible allocation and expenditure of financial resources, to ensure that the research enterprise is well-represented in the media, to ensure that researchers have access to the best information technology available at the University, and to ensure that personnel actions taken are reasonable and compliant; to ensure that physical facilities are adequate for research needs; and with the VC for Students to ensure optimal involvement of students in the research activities of the University of Hawaii at Manoa.

Major Functions of the Office
In support of and under the direction of the Chancellor, the Office directs the University of Hawaii at Manoa’s research and graduate programs through the development of governing policies, the conduct of program planning and assessment, the determination of directions, the setting of priorities in response to new research opportunities, the formulation of goals and objectives, and the allocation of resources.

The Office is actively involved in encouraging and developing new research initiatives, in providing an environment conducive to research, in establishing approved new research programs, and in restructuring existing programs within policy. The Office facilitates and encourages technology transfer and economic development activities by the University of Hawaii at Manoa.

The responsibilities of this Office also include the following:
• Initiates and develops long-range planning studies for research at the University of Hawaii at Manoa.
• Administers a policy of continuing qualitative evaluation of each of the major efforts relative to the development and maintenance of an international standard of excellence.
• Coordinates the activities of the research units and programs through the respective academic deans and directors.
• Selects/appoints University of Hawaii at Manoa representatives to various external and internal boards and committees associated with University research programs.
• Serves as the Chancellor's representative for research with a variety of individuals, groups and agencies, both inside and outside the University of Hawaii at Manoa, such as Federal and State agencies, other research institutes and universities, legislators, and the general public, which have the potential to take appropriate actions to enhance the University of Hawaii at Manoa's research programs and capabilities.
• Serves as the University of Hawai'i at Manoa source of expertise on the subject of research programs and activities.
• Manages strategic initiatives, research program development, research information systems, business operations of the Office of the VCRGE, and interacts with the Office of Research Services; oversees research and technology transfer, research commercialization and industrial support.
• Oversees matters having to do with vertebrate animal care and use, including oversight of the Institutional Animal Care and Use Committee and supervision of the Laboratory Animal Service.
• Finds means by which the research environment can be improved and made more conducive to research and educating faculty concerning research funding opportunities and proposal preparation.
• Identifies opportunities for Federal funding of research and helping researchers obtain the Federal financial support they need.
• Manages the Research and Training Revolving Funds, the fiscal management of campus wide research initiative headed by the office of the VCRGE, the management of internal resource allocations within the office of the VCRGE and the interaction with the Research Corporation of the University of Hawai'i in fiscal matters.
• Interacts with the Office of Research Services to provide appropriate procedures to foster research and training activities at the University of Hawai'i at Manoa.
• Provides general oversight of the appointment, compensation, and service conditions of post-doctoral fellows.
• Serves as the Chancellor's representative and advisor on interactions with the Research Corporation of the University of Hawai'i.
• Provides advice, assistance, financial support, and administrative guidance for new research centers and institutions during the formative or start-up phases.
• Supports the Chancellor in other matters as directed.

The following units report to the Vice Chancellor:
• School of Ocean and Earth Science Technology – Org Code: MADOEST
• Pacific Biosciences Research Center – Org Code: MAPBRC
• Cancer Research Center – Org Code: MACRCH
• Waikīkī Aquarium – Org Code: MAWA
• Lyon Arboretum – Org Code: MALYON
• Institute for Astronomy – Org Code: MAIFA
• Water Resources Research Center – Org Code: MAWRRC
• Graduate and Professional Education – Org Code: MAGRAD
• Committee on Human Studies – Org Code: MACHS
  o Designated to function as the federally mandated Institutional Review Board (IRB) for the University of Hawai'i System.
  o Responsible for monitoring all research involving human subjects.
• Environmental Health and Safety Office – Org Code: MAEHSO
• Laboratory Animal Services – Org Code: MALAS
• Center on Aging – Org Code: MACOA
  o The University of Hawai'i Center on Aging offers graduate and undergraduate 15-credit certificates in gerontology, with student taking courses from professors across campus in the fields of family resources, law, medicine, nursing, public health, psychology, social work, sociology, etc.
  o Support the UH chapter of Sigma Phi Omega (gerontological honor society), provide service to the community, and conduct research on aging.
Current research focuses in three areas: Asian and Pacific Islander aging, end-of-life issues, and developing/testing health education and training materials. Mānoa faculty affiliated with the Center on Aging also conduct research, provide service, and consult on many aspects of aging, including program development and evaluation.
OFFICE OF THE DIRECTOR – Org Code: MALAS

The Office of the Director, i.e., the University Veterinarian, has System-wide responsibilities for administering the Program of Humane Care and Use of all vertebrate animals used for research, training, testing and other activities by the University of Hawaii. The Office of the Director, i.e., the University Veterinarian, also directs and manages the animal facilities involved in biomedical and neuroscience research and training on the UH Manoa campus and at the John A. Burns School of Medicine (JABSOM) at Kaka’ako. The Office provides 24/7 veterinary care for the animal biomedical activities at Manoa and Kaka’ako, as well as to a number of the System-wide protocols that use animals for research and training. The Office provides training of investigators and their staff on animal handling procedures, as well as provides review of regulations for all System-wide vertebrate animal personnel. The Program is required by law to comply with regulations set forth by the United States Department of Agriculture Animal Welfare Act, the National Institutes of Health Public Health Service (PHS) Policy on Humane Care and Use of Animals, as well as other Federal, State and local regulations.

FISCAL OFFICE – Org Code: MAFSLA

The Fiscal Office provides fiscal and personnel support services in compliance with state and federal laws, and UH and RCUH policies, procedures and rules. Responsibilities include fiscal accountability, budget development and execution, rate setting and analysis, contracts and grants management, Memorandum of Agreements with private biotech companies and external organizations, and documentation of procurement and acquisition initiated against G, S-Tuition, S-Revenue, extramural and RTRF. Provides systems administration support for system-wide animal census and protocol information system Topaz/Granite. Perform billing, collections, recordation and reporting of income derived from services provided by the Program. Responsible for all phases of UH and RCUH personnel transactions (i.e., recruitment, hiring, termination, W/C, TDI, and payroll).

LABORATORY ANIMAL RESEARCH SUPPORT – Org Code: MARSLA

Laboratory Animal Research Support provides oversight and direction for the System-wide, federally-mandated Institutional Animal Care and Use Committee (IACUC) for the University of Hawaii. The Research Division is comprised of the Regulatory Compliance Office (RCO) which oversees the vertebrate animal use activities on all campuses and community colleges that are authorized and sanctioned by the UH’s Program of Care and Use for Vertebrate Animals. The responsibilities of the RCO exclude all veterinary care and animal husbandry oversight. The UH Program of Care and Use for Vertebrate Animals encompasses all biomedical and non-biomedical aquatic, terrestrial, and avian vertebrate animal use activities. The RCO professional staff interacts daily with its constituency, directs and coordinates all IACUC activities including, but not limited to the review of animal use protocol applications; conducts scheduled semi-annual inspections of the System-wide animal facilities and laboratories; conducts investigations when necessary; provides general and specific advisement or consultation as needed or requested to personnel of research and teaching administrative units and programs, faculty, students, and non-affiliated community members on matters governing the use of animals for research, training/teaching, wildlife and conservation management activities; provides interactive training on the use of the web-based protocol management software.
system TOPAZ; provides critical reviews of grant applications to determine congruency and compliance with vertebrate animal use applications; maintains extensive electronic database inventory of personnel training records, etc. Guidance is provided to Principal Investigators and Research Staff, to comply with all Federal, State, and local regulations pertaining to the described Program underlying the expectations of ethical and moral use of vertebrate animal subjects when used in research, teaching/training, and management-related activities. The Division also provides supervisory personnel for the facilities on the Manoa campus and at JABSOM at Kaka'ako involved with animal biomedical and neuroscience research and teaching. Animal care is provided in accordance with all Federal, State, and local regulations and using industry standards.
Proposed Organizational Charts and Functional Statements

Attachment 5
Footnotes:
+ Academic matters within the School of Ocean and Earth Science and Technology will be administered in coordination with the Vice Chancellor for Academic Affairs
*Position number and count to be requested
FUNCTIONAL STATEMENT

OFFICE OF THE VICE CHANCELLOR FOR RESEARCH AND GRADUATE EDUCATION (OVCRGE) – Org Code: MAVCRG

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Authority:
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• Administers a policy of continuing qualitative evaluation of each of the major efforts relative to the development and maintenance of an international standard of excellence.
• Coordinates the activities of the research units and programs through the respective academic deans and directors.
• Selects/appoints University of Hawai‘i at Mānoa representatives to various external and internal boards and committees associated with University research programs.
• Serves as the Chancellor’s representative for research with a variety of individuals, groups and agencies, both inside and outside the University of Hawai‘i at Mānoa, such as Federal and State agencies, other research institutes and universities, legislators, and the general public, which have the potential to take appropriate actions to enhance the University of Hawai‘i at Mānoa’s research programs and capabilities.
• Serves as the University of Hawai‘i at Mānoa source of expertise on the subject of research programs and activities.
• Manages strategic initiatives, research program development, research information systems, business operations of the Office of the VCRGE, and interacts with the Office of Research Services; oversees research and technology transfer, research commercialization and industrial support.
• Finds means by which the research environment can be improved and made more conducive to research and educating faculty concerning research funding opportunities and proposal preparation.
• Identifies opportunities for Federal funding of research and helping researchers obtain the Federal financial support they need.
• Manages of the Research and Training Revolving Funds, the fiscal management of campus wide research initiative headed by the office of the VCRGE, the management of internal resource allocations within the office of the VCRGE and the interaction with the Research Corporation of the University of Hawaii in fiscal matters.
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• Provides general oversight of the appointment, compensation, and service conditions of post-doctoral fellows.
• Serves as the Chancellor′s representative and advisor on interactions with the Research Corporation of the University of Hawai′i.
• Provides advice, assistance, financial support, and administrative guidance for new research centers and institutions during the formative or start-up phases.
• Supports the Chancellor in other matters as directed.

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• School of Ocean and Earth Science Technology – Org Code: MAOEST
• Pacific Biosciences Research Center – Org Code: MAPBRC
• Cancer Research Center – Org Code: MACRCH
• Waikīkī Aquarium – Org Code: MAWA
• Lyon Arboretum – Org Code: MALYON
• Institute for Astronomy – Org Code: MAIFA
• Water Resources Research Center – Org Code: MAWRRC
• Graduate and Professional Education – Org Code: MAGRAD
• Environmental Health and Safety Office – Org Code: MAEHSO
• Center on Aging – Org Code: MACOA
  o The University of Hawai′i Center on Aging offers graduate and undergraduate 15-credit certificates in gerontology, with student taking courses from professors across campus in the fields of family resources, law, medicine, nursing, public health, psychology, social work, sociology, etc.
  o Support the UH chapter of Sigma Phi Omega (gerontological honor society), provide service to the community, and conduct research on aging.
  o Conducts program development and evaluation.
• Office of Research Compliance – Org Code: XXXXXX
  o Human Studies Program – Org Code: XXXXXX
    o Oversees and directs the federally-mandated human research protection program.
    o Designed to function as the federally mandated Institutional Review Board (IRB) for the University of Hawai′i System.
    o Responsible for monitoring all research involving human subjects.
  o Animal Welfare and Biosafety Program – Org Code: XXXXXX
    o Oversees and directs the federally mandated Institutional Animal Care and Use Committee (IACUC), and Institutional Biosafety Committee (IBC) for the University of Hawai′i System.
  o Animal and Veterinary Services Program – Org Code: XXXXXX
    o Responsible for administering the Program of Humane Care and Use of all vertebrate animals for the University of Hawai′i System.
○ Research Integrity Program – Org Code: XXXXXX
○ Responsible for administering compliance in the areas of Research and Scholarly Misconduct, Responsible Conduct of Research (RCR), and Conflicts of Interest (COI) for the University of Hawai‘i System.

APPROVED:

[Signature]

Virginia S. Hinshaw, Chancellor

JAN 1 0 2012

Date
OFFICE OF RESEARCH COMPLIANCE
Org Code:

- Assistant Vice Chancellor, #89119 1.00
- Administrative Officer, PBB, #81901 1.00 (B)
- Research Associate, PBA, #80504* 1.00 (B)
- Research Associate, PBA, #81431* 1.00 (B)

ANIMAL WELFARE AND BIOSAFETY PROGRAM
Org Code:

- Research Associate, PBB, #81657* 1.00
- Environmental Sfty Sp, PBB, #81109 1.00
- Environmental Sfty Sp, PBA, #80261 1.00

ANIMAL AND VETERINARY SERVICES PROGRAM
Org Code:

- Specialist Type Faculty, #86262 1.00
- Research Associate, PBB, #80369 1.00 (B)
- Research Associate, PBB, #81179 1.00 (B)

RESEARCH INTEGRITY PROGRAM
Org Code:

"Non Appropriated"

General Funds: 6.00 FTE
(B) Special Funds: 5.00 FTE

APPROVED:

Virginia S. Hinshaw
Chancellor

Date: JAN 10 2012
OFFICE OF RESEARCH COMPLIANCE (ORC) – Org Code:

Major Functions of the Office:

In support of and under the direction of the Vice Chancellor for Research and Graduate Education, the Office is responsible for ensuring compliance of research and scholarly work involving the use of vertebrate animals, human subjects, microbiological materials, and issues related to the research and scholarly misconduct, responsible conduct of research, and conflicts of interest. This office is also responsible for appropriate veterinary care, and for the health and well-being for all animals used at the institution, and for managing and operating university animal facilities involved in biomedical and neuroscience research and training on the UH Manoa campus and at the John A. Burns School of Medicine at Kaka'ako.

Human Studies Program – Org Code:

Human Studies Program directs and oversees the federally-mandated human research protection program under a Federal wide Assurance (FWA), an agreement executed between the University of Hawai‘i and the DHHS Office for Human Research Protections (OHRP).

The Human Studies Program staff conducts the following tasks:

1. Administers three Institutional Review Boards (IRB) that serve the University of Hawai‘i and several partnership institutions;
2. Oversees the initial and continuing review of all non-exempt research protocols involving human subjects or their private identifiable information;
3. Provides education, training, consultation and support to UH faculty and others who perform human subjects research across the University of Hawai‘i system;
4. Develops and implements policies and procedures to ensure compliance with applicable federal regulations and University policies;
5. Maintains documentation of protocol review, approval and oversight; and
6. Follows up on allegations of non-compliance with applicable regulations and policies.
Animal Welfare and Biosafety Program – Org Code:

Animal Welfare and Biosafety Program provides oversight and direction for the system-wide, federally-mandated Institutional Animal Care and Use Committee (IACUC) and Institutional Biosafety Committee (IBC) for the University of Hawaii.

Animal Welfare Program staff conducts the following tasks:
1. Review and approve animal use protocols
2. Inspect animal facilities and specific programs
3. Investigate alleged and confirmed non-compliant adverse events
4. Consult and advise on appropriateness of proposed and actual experimental procedures to meet criteria for scientific data gathering
5. Review and confirm extramural award information conformity with actual animal use protocol design
6. Provide administrative support for IACUC

Biosafety Program staff conducts the following tasks:
1. Conduct trainings for faculty, staff, and students
   a. General Biological Safety
   b. Transportation of Biological Commodities
   c. Blood Borne Pathogen Standards and Sharps Hazard Prevention
   d. Select Agents
   e. Biosafety Cabinet Use
2. Conduct laboratory biosafety inspections
   a. Annual Review
   b. Unannounced
   c. Permitting and IBC Protocols
3. Process biological material importation applications
4. Dispose biological waste
5. Provide administrative support for IBC

Animal and Veterinary Services Program – Org Code:

Animal and Veterinary Services Program directed by the University Veterinarian (Attending Veterinarian) has system-wide responsibilities with direct or delegated authority to execute a program of adequate veterinary care and for the health and well-being of all vertebrate animals used at the institution, including access to all animals. Adequate veterinary care is required by federal agencies which oversees the Program. The AV also directs the operations of the vivariums which house and use laboratory animals, and provides veterinary care for all animal biomedical activities at Manoa and Kaka’ako, as well as for a number of protocols that use animals for research and training outside of the vivariums. The AV also provides training to investigators and their staff on animal procedures, as well as reviews of regulations for all system-wide personnel using vertebrate animals.
Research Integrity Program - Org Code:

Research Integrity Program has responsibilities in the areas of Research and Scholarly Misconduct, Responsible Conduct of Research, and Conflicts of Interest.

Research Program staff conducts the following tasks:

Research and Scholarly Misconduct:
1. Receive misconduct allegations, assist in gathering information and completing the assessment
2. Provide staff support for misconduct cases and Ethics Committee (EC)
3. Communicate with key parties: complainant, respondent, EC, Office of Research Integrity (ORI), and witnesses
4. Manage case records
5. Transcribe interviews
6. Update misconduct policy/program as federal regulations require
7. Provide training sessions or workshops related to misconduct

Responsible Conduct of Research (RCR):
1. Monitor and maintain online RCR training (CITI) component
2. Organize and prepare content for interactive RCR training sessions
3. Manage database on RCR training completions
4. Maintain communication with other campuses for collaboration
5. Update RCR plan/program as federal regulations require

Conflicts of Interest (COI):
1. Review and update E5.214, COI disclosure forms, and COI management plan
2. Collect and review upper administration COI disclosures and COI summaries for Manoa
3. Update COI policy/program as federal regulations require
4. Provide staff support for the COI committee
5. Review COI disclosure forms for potential unresolved conflicts
6. Review Departmental/unit COI procedures for proactive compliance
7. Provide training sessions for all campuses and Deans/Directors

APPROVED:

[Signature]
JAN 10 2012
Virginia S. Hinshaw
Chancellor
Copies of letters and responses from campus groups

Attachment 6
March 4, 2011

Ching Yuan Hu, Ph.D.
Interim Assistant Vice Chancellor
Office of the Vice Chancellor for Research and Graduate Education
University of Hawaii at Manoa
1960 East-West Road, Biomed T-110
Honolulu, Hawaii 96822

Dear C.Y.:

The establishment of the Office of Research Complaince (ORC) to oversee four research compliance sections will enhance coordination and communication within the research communities at the University of Hawaii (UH). It is critically important for the institution to respond promptly to any inquiries received from federal agencies. It has been a challenge in the past to coordinate consent responses and keep all parties informed when the Office of Research Services (ORS) receives a new research compliance mandate from a federal agency. The proposed plan will provide ORS with a central point of contact which will significantly enhance efficiency.

The reorganization will also provide a clear chain of command for these research compliance programs and the ORC will be able to establish or change research compliance policies and procedures with input from each section without much delay. It will also facilitate ORS/UH's efforts to be in compliance with federal funding agencies' mandates in a timely manner.

Thank you for sharing the proposed changes with me. Please let me know if you need anything else.

Very truly yours,

Yaa-Yin Fong
Director
From: Nancy King <nrking@hawai.ledu>
Date: Mon, 07 Mar 2011 09:27:13 -1000
To: "C.Y. Hu" <hucy@ctahr.hawai.ledu>
Subject: Functional Statement -- Suggested Change

CY,

See attached. I tried to keep this in the same format as before.

In the Narrative section, I don’t know how much feedback you want.

I don’t have any substantive changes to the section on Human Subjects – except, we do not have a single IRB as implied here. We currently have 3 IRBs.

I think it would be useful to describe the importance of a centralized compliance program, the expectations of the federal government to provide all of the required elements and functions of a compliance program, and the consequences to the institution of non-compliance. You could also state that this the direction that most Universities have been moving over the past decade (and longer). But, this is up to you. As written, the justification for change is a little weak.

I think one of the stronger arguments for consolidation is to build a more effective compliance program while promoting a more efficient use of University resources. I believe that, by establishing a central unit that can provide the functions required in all compliance programs, the University will be better protected from the reputational and financial damage caused by compliance breaches.

Under section II, I believe that $300m (for 2010) underestimates the size of the UH research program. I thought it was higher than this (over $400m in 2010).

Finally, I find the right justified margins to make the document more difficult to read – and I consider it to be an outdated style. But this is a matter of personal preference.

I hope this is helpful.

Nancy

------ End of Forwarded Message
Suggested HSP section for the Functional Statement

Human Studies Program

Human Studies Program directs and oversees the federally-mandated human research protection program under a Federalwide Assurance (FWA), an agreement executed between the University of Hawaii and the DHHS Office for Human Research Protections (OHRP).

The Human Studies Program staff conducts the following tasks:

1. Administers three Institutional Review Boards (IRB) that serve the University of Hawaii and several partnership institutions;
2. Oversees the initial and continuing review of all non-exempt research protocols involving human subjects or their private Identifiable Information;
3. Provides education, training, consultation and support to UH faculty and others who perform human subjects research across the University of Hawaii system;
4. Develops and implements policies and procedures to ensure compliance with applicable federal regulations and University policies;
5. Maintains documentation of protocol review, approval and oversight; and
6. Follows up on allegations of non-compliance with applicable regulations and policies.
FW: Reorganization Proposal
1 message

From: Roy Takekawa <takekawa@hawaii.edu>
Date: Fri, 4 Mar 2011 10:21:11 -1000
To: "C.Y. Hu" <hucy@ctahr.hawaii.edu>
Subject: Reorganization Proposal

C.Y.:

Thank you for the opportunity to review and comment on the proposed reorganization. The consolidation of the four programs into one office should enhance efficiency and certainly, from our perspective, clarifies and improves the operational structure of the affected units.

We endorse its approval and look forward to working together in the future.

Aloha,

Roy Takekawa, Director
Environmental Health and Safety Office

----- End of Forwarded Message
MEMORANDUM

TO: Ching Yuan Hu
FROM: Sylvia Kondo
SUBJECT: Summary of comments regarding proposed Reorganization Plans

A. Names of Programs:

I would recommend re-naming LAS to Veterinary and Animal Services Program. The chief responsibility of the veterinarian is to provide for the health and welfare of all animals used at the institution, therefore, clear provisions should be made to give the veterinarian appropriate direct or delegated authority to execute a program of adequate veterinary care, including access to all animals. This system wide function is not conveyed in the current proposed title.


Concurrently, I would recommend re-naming Animal Welfare and Biosafety Program to IACUC and Biosafety Compliance Program. Assuring animal welfare is a partnership among Institutional Official (IO), the IACUC, the veterinarian, and the investigator (see Attachment 1). "The chief role of the IACUC staff is to provide administrative support to the IACUC and IO. It is important however, that neither the IO nor the IACUC Chair overinvest authority or responsibility in the IACUC staff."


B. Interaction between the Programs:

The Attending Veterinarian must have legal authority for the animal care and use Program; hence the compliance component within LAS (Veterinary and Animal Services Program) must not be lost in the reorganization. There must be a balance between these two Programs working in tandem with one another to achieve compliance.

C. Administrative Support:

Several concerns arise in my mind with this re-organization. First, the administrative support is a critical leg of LAS, and currently charged with many critical tasks to allow LAS to service the PIs and to remain in compliance. Unlike the other compliance units, LAS is a recharge center. Most vivariums are
organized with a business office reporting to the Director. LAS really only has one Administrative Officer who serves as the Fiscal Officer for all of the biomedical research program, including, but not limited to: dealing with large numbers of purchasing (animals and supplies), billing and receiving payment, bill collections, dealing with multiple vendors, budget reports, reconciling transactions, dealing with discrepancies with orders, writing contracts such as MOUs, sole sourcing, setting per rates, and interacting on a daily basis with researchers, as well as LAS staff, to answer questions about animal and supply orders, and billing. These tasks take up 80% of the incumbent’s time, plus 20% for special projects and dealing with unexpected needs of the Program. In addition, the LAS Facilities and Program Assistant provides some clerical support to the AO. The Fiscal Officer is burdened by his current duties, and the difficulty to keep up with the rising demands of the position was brought to the Director’s attention at least two years ago. LAS management staff interacts throughout the day with the administrative staff with needs that require immediate attention, worsened by the fact that we are geographically isolated from the mainland and must ship things into the State.

The other AO is used mainly for personnel and some IACUC fiscal support. We have a regular turn over of care staff that needs to be filled quickly to meet the demands of the vivarium operations.

Hence any slowing down of administrative support would greatly curtail LAS’s ability to meet these demands on a timely basis, and may jeopardize the research effort, and could result in fines, citations, suspension or loss of funds to do animal research, and negative publicity to the institution. The Jacobs’ report indicated the business office was functioning well, and may even need an additional position to support growth in Cancer Research and Tropical Medicine.

Therefore, the following questions and concerns are critical to be resolved before the re-organization of the Administrative Support staff is finalized:

1. What are the expectations of the other units who will share the Administrative staff? Will they use be used for more than just fiscal, personnel, and IT? If so, what kind of load will be placed on the existing staff?
2. When will the IT position be recruited for in order to take the burden off the existing administrative support staff? Especially as they will now be support three other programs.
3. Will LAS no longer be an Organized Research Unit or Department?
4. How will support staff’s duties be prioritized so that there is not a further slowing of output for LAS?
5. Who will supervise the staff?
   a. Having multiple supervisors is ambiguous and a clear chain of command is difficult to achieve. We have experienced this first hand when we have tried to assign dual functions with dual supervisors to a position. This type of arrangement usually results in frustration on part of the part of the employee and the supervisors managing the employee.
Ching Yuan Hu
March 7, 2011

b. It is difficult to motivate an employee to fulfill expectations assigned by one supervisor, when the employee is evaluated by other supervisors.

c. Who will have signing authority for day to day transactions?

d. If the AVCRGE is managing the administrative staff, what will be the procedure for LAS to use the services of the administrative staff?

6. How will the Administrative Staff be paid? In FY12, 90% of the fiscal officer, 100% of the program assistant, and a 50% of the personnel officer’s salaries are being funded through S-revenue per diem collected from PIs using animals in the vivarium. It would not be correct to use these positions for the other units, without a mechanism to reimburse the per diem fund for use of their time.

I would strongly recommend we retain a business office with at least one Administrative Officer to support the biomedical program exclusively to run the day to day program as described above. Other institutions have their own business office, with higher level fiscal functions handled centrally.

Reference: Jacobs’ draft report (February 2011). Organizational Summary of Animal Care and Use Program at Other Institutions (February 28, 2011).

D. Comment regarding statement “No funds are necessary for the reorganization”:

LAS is currently stretched to its limit and has been asking for positions such as another veterinarian, Standard Operating Procedures Trainer and others for a few years. The Jacobs’ report indicated that an additional fiscal position may be needed to support the growth of the biomedical program. In addition, funds would also be needed for the IT position to alleviate the burden on the administrative officers. If administrative positions are shifted, it appears to me to be taking from Peter to pay Paul. I am concerned that LAS and its clientele will suffer from this reorganization. I cannot keep up with the current demands, let alone the additional load of the cage wash project and the growth of the System-wide animal care and use Program. To have all of the administrative support shifted to assist the rest of the units without some way of compensating for the loss to LAS, and without a clear plan of how the administrative staff will be used and funded should be researched more thoroughly before finalizing plans to reorganize this component.
Hi Robert – The internal review on the reorganization proposal for OVCRGE has been completed and is now posted on the Organizational Charts website for SEC review.

http://www.manoa.hawaii.edu/ovca/docs/ovc_chartsindex.html

In this proposal, OVCRGE is establishing an Office of Research Compliance as a functional unit in their organization. Please review and submit comments to Tracie Nakagawa at tracen@hawaii.edu no later than November 26, 2011.

If additional time is needed, please work with Tracie on a mutually agreeable extension.

Thank you.

Ann A. Sakuma

OVCA/RO

Hawai‘i Hall 307

Tel: 956-5658
COPIES OF LETTERS SENT TO UNION
Dear Mr. Musto:

The University of Hawai‘i is proposing a reorganization of Office of the Vice Chancellor for Research and Graduate Education at the University of Hawai‘i at Mānoa (UHM) and is requesting your input and comments relative to the proposal as part of the formal consultation process.

As part of the University’s sustainability efforts, we have loaded the proposal and documents onto the UHM website at: http://www.manoa.hawaii.edu/ovcafo/neworg_charts/index.html

Your comments on the proposal would be appreciated no later than December 3, 2011. If we do not hear from you by this date, we will assume there are no comments on the reorganization proposal.

Should you have any questions, please contact me at 956-9585 or chinghu@hawaii.edu.

Sincerely,

Ching Yuan Hu
Interim Assistant Vice Chancellor for Research and Graduate Education

c: Tracie Nakagawa, OVCRGE Administrative Officer
Karen Okamura, LAS, Administrative Officer
Randy Perreira, Executive Director  
Hawai’i Government Employees Association  
888 Mililani Street, Suite 601  
Honolulu, Hawai’i 96813-2991

Dear Mr. Perreira:

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Sincerely,

Ching Yuan Hu  
Interim Assistant Vice Chancellor  
for Research and Graduate Education

c: Tracie Nakagawa, OVCRGE Administrative Officer  
Karen Okamura, LAS, Administrative Officer