Research Compliance Task Force Report

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- Research Advisory Board (RAB) recommended formation of the RCTF.
- RCTF established in April 2014 by VPRI Syrmos.
- Charge: to identify and recommend improvements in research compliance that would reduce the administrative workload on researchers and address long-standing issues with research compliance procedures and processes at UH.
Background Information

- Federal and State laws/regulations are extensive, diverse and complex.
- UH compliance more complex and burdensome to meet federal and state requirements.
- Compliance at UH involves offices with different responsibilities and expertise.
- UH faculty have heavy administrative demands with less time to conduct research.
Work Undertaken

- RCTF Fact-Finding:
  - Reviewed national and state documents; previous UH committee reports.
  - Examined federal and state regulations.
  - Reviewed peer institutions’ online materials and policies, and compared them to UH.

- Interviews: 20 administrators and faculty.

- Survey: 939 respondents across UH campuses.
Recommendation Highlights

- Build an effective research community in compliance with regulations.
- Improve compliance efficiency.
- Reorganize to be more successful and efficient.
Build an Effective Research Community in Compliance with Regulations

- Assist faculty and students to comply with regulations.
- Make information more visible and available.
- Enhance education and training, especially to non-UH Manoa campuses.
Improve Compliance Efficiency

- Increase communication, transparency and accountability.
- Use technology to improve efficiency.
- Coordinate purchase/development of major IT systems.
Reorganize to be More Successful and Efficient

- Place the Office of Research Compliance (ORC) under the OVPRI rather than the UH Manoa OVCR.
- Improve coordination between ORC and other units (eg, ORS, ITS, RCUH).
- Establish Oversight Committee.
THE RESEARCH COMPLIANCE TASK FORCE REPORT 2015

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EXECUTIVE SUMMARY

Researchers at universities nationwide are challenged by administrative tasks necessary to comply with increasing federal, state, and institution-imposed rules and regulations that govern research. In 2014, the National Science Board addressed these challenges in a report highlighting national findings on researchers’ administrative burden and recommendations for reducing unnecessary regulations imposed on researchers and impeding science. Consistent with national trends, the research compliance enterprise at the University of Hawai‘i (UH) has grown significantly during the past decade. This occurred in response to increasing regulatory requirements from external agencies and the need to assist administrators and faculty to comply with the requirements. Despite this assistance, the administrative workload has increased for UH researchers and faculty.

In April 2014, the Research Compliance Task Force (RCTF) was established by the Vice President for Research and Innovation (VPRI), Vassilis L. Syrmos, in response to a request by the UH System Research Advisory Board (RAB) recognizing the need to reduce the administrative burdens associated with inefficiencies in the UH research compliance system. The RCTF was charged to identify and recommend improvements in research compliance that would reduce the administrative workload of researchers and address longstanding issues with research compliance procedures and processes at UH. To implement its charge, the RCTF conducted an extensive yearlong study of research compliance at UH involving multiple sources of data and methods including the following:

**Interviews:** Twenty-one faculty members and administrators who had experience with research compliance in the UH System participated in interview sessions where participants were asked to share their research compliance experiences and recommendations. Faculty members were selected by the RCTF to represent a cross-section of disciplines at UH Mānoa and community colleges.

**Fact-finding:** The RCTF reviewed federal and state regulations and documents; reports prepared by national advisory groups, organizations, and ad hoc committees at UH; and online materials and policies of peer institutions, government websites, and UH’s compliance-related websites. These sources informed the RCTF’s work and yielded information augmenting RCTF interview and survey data.

**Survey:** The RCTF conducted a system-wide web-based survey to assess faculty, staff, and student experience with, and evaluation of, the research compliance structures and processes at the UH. Of the 939 survey participants, 92% were faculty members and 69% were from the UH Mānoa campus. Participants completed rating scales and open-ended questions relating to only those research compliance areas they deemed relevant to their work. These areas included human and animal subjects, biosafety, laboratory safety, chemical safety and radiation safety. Questions pertaining to ethical issues and other compliance areas and practices at UH were answered by all participants.
Regulations Affecting Research and the UH Research Compliance System

United States federal laws, Hawai‘i state laws, and other government regulations governing research activities are extensive, diverse, and complex and have undergone considerable change over time. Almost every federal department has regulations that affect research activities either directly or indirectly. Some laws and regulations affecting research apply to the university as an entity, with “cognizant officials” responsible for compliance. Some apply to the researchers, with penalties that attach directly to these individuals instead of the university.

The University of Hawai‘i has stewardship responsibility to guide and assist its faculty members and principal investigators in maintaining compliance with research regulations, managing the risks of violations, and ensuring the ethical conduct of research. In fulfilling these responsibilities, the UH research compliance systems and structures have evolved in complexity over time, comprised of different administrative authorities whose offices and responsibilities require a wide range of expertise and whose functions may not be harmonized with each other. These offices include those currently reporting directly to UH System administration (e.g. Office of Export Control, OEC; Office of Research Services, ORS) and others reporting directly to UH Mānoa administration (e.g., Office of Research Compliance, ORC; Environmental Health and Safety Office, EHSO).

The RCTF’s in-depth review of government regulations, numerous compliance-related reports prepared by national organizations and UH committees, online materials, websites, and other resources, led to the RCTF finding that a Herculean effort is required to understand the complex web of regulatory requirements and the UH structures, processes, and practices that have gown to maintain compliance.

RCTF Assessment of Research Compliance at the UH

Areas of Progress and Success with Compliance

RCTF survey, interviews, and fact-finding results suggest the UH is progressing well in fulfilling its compliance responsibilities in the following areas.

- The majority of survey respondents did not experience problems understanding compliance requirements and why in the following areas: Ethical Issues (75%), Laboratory Safety/Security (68%), Biosafety (54%), and Institutional Review Board, IRB (52%).

- More than 50% of survey respondents rated the quality of information provided to comply with regulatory requirements “above average to excellent” in the following program areas: IRB, Biosafety, Laboratory Safety/Security, Chemical Safety, and Radiation Safety. Information related to Institutional Animal Care and Use Committee (IACUC) and Ethical Issues were not rated as positively as the other areas.

- More than 50% of survey respondents rated the training received at UH “above average to excellent” in the following program areas: Biosafety, Laboratory Safety/Security, Chemical Safety
and Radiation Safety. Information related to IACUC and Ethical Issues were not rated as positively as the other areas.

- RCTF interviews and fact-finding identified positive developments initiated by the ORC including a new website that consolidates more information about UH research compliance programs, policies and requirements than previously available, and a monthly newsletter, The Good Researcher, focused on best practices for managing “responsible research programs.”

**Areas of Major Concern**

Results of the RCTF survey, interviews, and fact-finding converged on areas of major concern. These areas include IACUC and Biosafety; institutional support and training needs; inadequate communication and collaboration; administrative inefficiencies and need for greater collaboration; and failure to act on compliance-relevant recommendations from prior research reports issued during the past 15 years.

**IACUC and Biosafety**

- While a few survey respondents in each of the compliance areas surveyed reported experiencing some difficulty in meeting regulatory requirements, more than 50% of those whose work involved IACUC and/or Biosafety reported they encountered problems, with severity ranging from “a little” to “very problematic.”
- Major areas of difficulty with regard to IACUC included preparing IACUC protocols and consent forms for initial review (64%), understanding what is required and why (54%), and completing annual IACUC reviews and three-year renewals (51%).
- Regarding Biosafety, slightly more than half of survey respondents (56%) reported experiencing problems with filing applications to comply with state requirements for the use of microorganisms. Survey ratings suggest this is an area of great difficulty for respondents, as 23% rated this task as “very problematic”—twice the proportion of respondents who rated compliance tasks as “very problematic” in any of the other compliance areas surveyed.
- Survey ratings, open-ended responses, and suggestions indicate a need for more appropriate training focused especially on IACUC and Biosafety protocols. Interviewees and survey respondents mentioned the desire for an online flow-chart outlining requirements and how to fulfill them, where researchers could follow a checklist and secure the compliance protocols needed for their specific research project on a timely basis.

**Institutional Support and Training Needs**

- When asked “what would be most important for you in meeting regulatory requirements in teaching and research?” the highest proportion of survey participants selected integrated electronic system for compliance applications, training and communication with faculty and others (62%); assistance for faculty and others on filing compliance applications and documents (57%); and orientation training on compliance requirements, procedures, and assistance for new faculty, staff, and graduate students (56%). However, UH Mānoa and non-UH Mānoa
(i.e., Community Colleges and Maui College) participants differed in their ratings; the largest percent of participants from Community Colleges and UH Maui College rated training on compliance requirements (58%) as most important, while the largest proportion of UH Mānoa respondents rated integrated electronic system (65%) as most important.

- Survey comments, interviews, and fact-finding underscored the disparities in educational outreach and training needs among UH campuses, with UH Mānoa faculty in a more advantageous position than their non-UH Mānoa colleagues. The current research compliance process does not accommodate the needs and interests of instruction. Teaching faculty require compliance training and protocols that are more aligned with their needs whether in the classroom or out in the field. Providing the necessary compliance attention and outreach to instructional faculty will also support undergraduate STEM education and research at UH.

**Inadequate Communication and Transparency**

- The need to improve communication and transparency regarding compliance matters was a consistent theme among interviewees and in the RCTF’s fact-finding. ORC’s new website is an important step toward addressing perceived deficiencies in communication, but much more must be done to help guide faculty, students, and staff through the complexity of internal and external regulatory requirements. Interviews and fact-finding indicated that improved communication and greater transparency would reduce the perceived cloak of secrecy relating to compliance matters, including the assessments of research facilities and programs. Interviewees expressed concerns about ORC’s overly restrictive policy relating to compliance information disclosures, especially when documents now withheld had been previously shared, and questioned why experienced faculty and staff with compliance responsibilities are not enlisted to share their knowledge regarding how UH’s security and safety could be strengthened.

**Administrative Inefficiencies and Need for Collaboration**

- Survey and interviewee comments consistently expressed the need for more timely reviews of compliance protocols and indicated dissatisfaction with bureaucratic demands, reliance on time-consuming paper documents, and the absence of technology to improve efficiency, all of which place excessive demands on faculty’s time.

- Interviewee comments and RCTF fact-finding clearly indicate a need for greater collaboration among the offices and individuals with research compliance responsibilities, including Office of Research Compliance (ORC), Office of Research Services (ORS), Information Technology Services (ITS), Office of Technology Transfer and Economic Development (OTTED), Office of Export Controls (OEC), etc. There was recognition that duplication can be reduced and efficiencies achieved when compliance functions do not operate in administrative silos.
Prior Compliance-Relevant Recommendations

- The UH Research Advisory Board's 2014 evaluation of research reports issued by various committees during the past 15 years, including the recent 2013 Permit Process Review Committee report, shows UH's failure to act on numerous compliance-relevant recommendations. The RCTF survey, interview, and fact-finding clearly indicate that a lack of attention to these recommendations has led to persistent problems, increased faculty frustration, decreased productivity among administrators and faculty who must deal with dysfunctional operations, and the convening of new advisory committees that have identified the same problems.

Areas Requiring Greater Attention

Survey findings indicate that UH faculty are involved in research activities requiring compliance oversight and support in areas that lack institutional presence. The largest numbers of respondents whose work involves compliance regulations for which the RCTF found little or no institutional support were in the areas of the Health Insurance Portability and Accountability Act (HIPAA, n=189); classified/restricted/ sensitive research information (n=180); and locational permits (n=128). UH should develop services for these and other under-served faculty—whose research is often in high-growth areas—and assist them to meet compliance requirements.

Recommendations

To promote and advance the University of Hawai'i's research enterprise, it is critical for UH to develop the most effective, efficient, and collaborative research compliance structures and mechanisms at all levels of functioning. The RCTF's detailed findings from multiple data sources convey a strong need to promote a culture of research compliance that constructively engages administrative leaders, principal investigators, instructional faculty, students, staff, and other stakeholders involved in research activities regulated by applicable laws and policies. The RCTF identified three overarching recommendations and specific steps to achieve UH's research aspirations.

1. Build an Effective Research Community in Compliance With Regulations.
   - Faculty members struggle with inadequate information about regulations affecting research and the training needed to understand and comply with regulatory requirements. UH compliance structures are especially daunting for newer instructional and research faculty. Large organized research units (ORUs) preserve and share knowledge and thus have intrinsic advantages in meeting requirements as compared to individual faculty members in UH academic units. The RCTF strongly encourages UH to improve the culture of research compliance and recommends the following.
   - Improve and streamline web-based information about regulatory requirements, required procedures, and best practices. Regulations and procedures must be clear, organized, up-to-date, and easily accessible. Online communication tools should include flowcharts that guide faculty in meeting compliance responsibilities.

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• Target Biosafety and IACUC for immediate improvements.
• Provide research compliance services to faculty engaged in research activities where there is little or no support including those involving HIPAA privacy rules, classified/restricted/sensitive research information, and locational permits.
• Improve customer service to assist faculty and students. Training in customer relations should be provided to compliance staff, as well as all other UH research support units.
• Enhance research compliance education and training, especially in non-UH Mānoa campuses.
• Provide research compliance training and support specific to STEM undergraduate research and research-related education.
• Appoint a knowledgeable senior faculty member to a Research Compliance Ombudsman position to help solve problems and to guide and promote an effective and compliant community of researchers.

2. **Improve Compliance Efficiency for the UH Research Community.**

To improve the efficiency of research compliance processes, reduce faculty and staff administrative burden, and maximize the effective use of scarce resources, units with research compliance responsibilities must streamline their procedures. UH administration should follow-up on prior recommendations and lessons learned to improve efficiency of research compliance processes.

- Implement “just-in-time” reviews (e.g., IRB, IACUC) of research protocols in grant proposals consistent with the Federal Demonstration Partnership’s (FDP) recommendations (i.e., defer reviews until notification that a proposal is being considered for funding, since many submitted proposals do not make it to that stage).
- Improve communication, transparency, and accountability by disseminating reports widely to the UH community, including site visits, compliance committee memberships, etc. Membership in compliance committees should be determined by nominations of faculty and administrators external to UH compliance programs.
- Request UH research compliance programs and committees to produce annual reports of meetings, activities, budgets, etc.
- Develop an audit system to document issues, identify corrective actions, and monitor outcomes. This will address recurring issues/problems and failure to act on recommendations from various UH committees commissioned during the past decade.
- Streamline business processes and procedures to improve service and use of scarce resources. New procedures and forms should be beta-tested by those who will use them.
- Use technology to improve efficiency of the research compliance process, e.g., using web-based form-fillable applications and tracking approval status.
- Coordinate purchase and development of major IT systems involving relevant UH research compliance units (e.g., ORC, ORS, ITS, etc.). Systems must be interoperable so that information can be transmitted and exchanged across compliance-related systems.
- Create an ad hoc committee to review Facilities Management structures and responsibilities in relation to research compliance needs of other UH units.
3. **Reorganize Compliance Structures to Enable the UH Research Community to be More Successful and Efficient, While Maintaining Compliance With Regulations.**
   
   - Reduce barriers to collaboration and harmonize research compliance units and processes across campuses by having the Office of Research Compliance (ORC) report to the UH Vice President for Research and Innovation (VPRI), who has management and leadership responsibilities over research support and services across all campuses in the UH System.
   
   - Improve coordination between ORC and other units with compliance-related responsibilities, such as the ORS, OEC, OTTED, and ITS. The VPRI should provide leadership and facilitation for collaboration among these units to provide faculty and staff with seamless research compliance services.
   
   - Establish a permanent committee of faculty and administrators to provide oversight of the state of research compliance at the UH, chaired by the faculty Research Compliance Ombudsman. This Research Compliance Oversight Committee should be independent of members of research compliance units and committees and be charged with reviewing annual reports from compliance groups and addressing relevant compliance issues.