

# RESEARCH COMPLIANCE TASK FORCE REPORT

October 2015



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of HAWAII®  
SYSTEM



# 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.

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## 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 grown 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.

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- 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

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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,

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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.
- 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.

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- 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.

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### **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.

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## I. THE UNIVERSITY OF HAWAI‘I RESEARCH COMPLIANCE TASK FORCE

Numerous federal and state laws regulate the conduct of research at the University of Hawai‘i (UH). Complying with these regulations is complex and demanding for researchers in terms of attention, time, and resources. Over the years, these regulations have become more numerous, complex, and extensive. Additionally, new research areas and methods have come to overlap existing regulatory regimes in ways that were not anticipated.

Some laws and regulations affecting research apply to UH as an entity, with “cognizant officials” responsible for compliance. Some apply to the researchers, with penalties that attach directly to the researchers instead of UH. The University of Hawai‘i, in any case, has an important stake in preserving its abilities and resources to conduct research by avoiding compliance failures and inefficiencies.

In order to meet new and changing statutory requirements, UH has evolved mechanisms to minimize possible compliance infractions. It has developed other mechanisms to assist researchers in their efforts to comply with regulations governing research.

The Research Compliance Task Force (RCTF) was established by Vice President for Research and Innovation (VPRI) Vassilis Syrmos in April 2014 in consultation with the UH System Research Advisory Board (RAB). As part of its initial tasks, the RAB was asked in January 2014 to review all relevant committee reports concerning research at the UH and to assess the degree to which their recommendations had been implemented. The difficulty in implementing each outstanding recommendation was also categorized. This “report card” was delivered, but the RAB and VPRI recognized that a number of previous recommendations concerning research compliance matters at UH were difficult to assess, especially considering regulatory changes and the substantial range of expertise involved.

The RCTF’s charge was to identify and recommend improvements in research compliance that would reduce the administrative workload of researchers and address longstanding problems with research compliance procedures and processes at the University of Hawai‘i.

The RCTF conducted extensive interviews with researchers in different research settings, and these conversations provided important input to this report. It reviewed federal and state documents and regulations, as well as the online materials and policies of peer institutions, and compared them with those of UH, and conducted other fact-finding activities. A web-based survey about research compliance was also developed to provide broader opportunities for input by UH researchers to the RCTF study. Both the quantitative and the qualitative data generated by the survey assisted the RCTF greatly in providing a more comprehensive basis for developing recommendations around specific topics and suggested some topics that had not been previously considered.

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The initial intent of the RCTF was to develop a rather brief report of its findings and recommendations. However, it became apparent that historical and current information regarding compliance and its various facets at UH—the offices responsible for enforcing regulations and providing compliance services, the compliance issues germane to researchers as reported by faculty themselves, and the interplay among compliance functions—was scattered and difficult to find and needed to be brought together in one document. This compilation had never been done before and provides a contextual understanding of research compliance at UH, which will contribute to informed decision-making in the future. The reader is invited to read this comprehensive report in its entirety or to concentrate only on the sections of interest.

The remainder of this report includes the (a) Background on Regulations Affecting Research, (b) Compliance Dimensions and Structures at UH, (c) Current Assessment of Research Compliance at UH, and (d) Summary Findings and Recommendations. The Appendices provide documentation of the resources and data gathered by the RCTF.

The RCTF would like to thank the administrators, faculty, and staff who made themselves available to the committee, as well as the 939 survey respondents for their numerous comments and suggestions. The members of the RCTF are grateful to Michelle Isa-Atta, Darrell Leong, Kevin Hanaoka, Tracie Nakagawa, Adriene Yafuso, and Craig Hirasaki for supporting our research efforts and report development.

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## II. BACKGROUND ON REGULATIONS AFFECTING RESEARCH

The global community of researchers continues to push the topics of research broadly into every aspect of nature, including human beings and their interactions with the environment and each other. At the same time, the assemblage of laws that govern research (and other) activities continues to grow, becoming more comprehensive and complex. United States federal laws, Hawai'i Revised Statutes, and agency regulations deriving from these laws require special attention from the UH research community in order to maintain compliance and manage the risks of violations. At the same time, the costs of research compliance, including the diversion of faculty time away from generating and conducting research programs, must be controlled.

Research regulations and compliance requirements have largely arisen from governmental efforts to protect people, animals, and the natural environment from a broad spectrum of human activities, including the actions undertaken by researchers themselves. Almost every federal department has regulations that affect research activities either directly (e.g., Department of Health and Human Services) or indirectly (e.g., Department of Transportation). Interestingly, many of these regulations themselves are based on advanced understanding derived from research activities, and some laws require ongoing research focused on supporting improved regulation, implementation, and enforcement.

Here, the RCTF addresses the laws with which UH and its administration, faculty members/principal investigators, and staff must comply. It will become apparent from this section that the legal systems governing research activities are not only numerous and diverse but that they also have undergone considerable change over time. The following section of this report discusses the organizational structure that UH has developed to achieve compliance in its research activities.

While the scope of this report is broad, it was not possible to fully address some topics that are integral to research compliance, as this would have required more time and investigation than could be undertaken by the RCTF. For example, Conflict of Interest (COI) policies are fundamental to research and the development of intellectual property at UH. Ascertaining, reporting, and tabulating conflicts of interest is a complex, involved, and often an arduous process for researchers (<https://manoa.hawaii.edu/researchcompliance/conflict-interest-policies>). While all faculty, staff, and even graduate students are required to complete annual COI forms, few understand where the requirements derive from and why this time, effort, and resource-intensive process cannot be made more efficient. Moreover, current regulations regarding the provenance of intellectual property hinder, rather than foster, the commercialization of basic and applied research. Specific actions need to be developed to address these and other system-wide COI issues, including the economic and public benefits derived from the conduct of research at UH.

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## A. Federal Law

### 1. Human Subjects

Early concerns about the unethical use of human subjects in scientific research led to a number of laws at the federal and state levels. The 1974 National Research Act established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research within the Department of Health, Education and Welfare (now the Department of Health and Human Services, DHHS), which issued the well-known “Belmont Report” (1979) that described ethical principles and guidelines for research involving human subjects (<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>). This report and the National Commission’s work led to revisions of regulations and the evolution of the current version of federal regulations for the protection of human subjects in research supported by DHHS (45 CFR 46).

The Health Information Portability and Accountability Act (HIPAA, 1996), administered by the DHHS, *“includes the HIPAA Privacy Rule, which protects the privacy of individually identifiable health information; the HIPAA Security Rule, which sets national standards for the security of electronic protected health information; the HIPAA Breach Notification Rule, which requires covered entities and business associates to provide notification following a breach of unsecured protected health information; and the confidentiality provisions of the Patient Safety Rule, which protect identifiable information being used to analyze patient safety events and improve patient safety”* (DHHS, <http://www.hhs.gov/ocr/privacy/index.html>). The intersection with research includes clinical trials and statistical studies of health information, such as the ground-breaking Framingham Heart Study.

National Institutes of Health (NIH) current guidelines for recombinant DNA research are available at [http://osp.od.nih.gov/sites/default/files/NIH\\_Guidelines\\_0.pdf](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines_0.pdf), a document of 137 pages, over 100 of which are appendices. In the discussion of scope, the guidelines note that work funded either by NIH or by an institution that is receiving other funding from NIH must comply with the guidelines. Thus, the guidelines have force of law for any research institution receiving any form of NIH funding. The guidelines are comprehensive; they define conditions and limitations placed on the study material; the fitness of the experimental staff; security obligations of the institution; protective gear; and occupational roles, including those of the Biologic Safety Officer and the Institutional Biosafety Committee.

Human stem cell research is similarly regulated by the NIH. The Executive Order revising and delimiting restrictions on human stem cell research, originally published March 9, 2009, and amended by several subsequent notices, set the stage for the National Institutes of Health Guidelines on Human Stem Cell Research, published on July 9, 2009, and available at <http://stemcells.nih>.

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[gov/policy/pages/2009guidelines.aspx](http://www.nih.gov/policy/pages/2009guidelines.aspx). These guidelines were upheld by federal court in 2011 and remain in force. None of the foregoing bears on the status of such research if conducted without NIH support or in an NIH-independent institution.

## 2. Animal Subjects

The Animal Welfare Act (AWA; 1966), administered by the U.S. Department of Agriculture (USDA), regulates the transport, sale and handling of dogs, cats, guinea pigs, nonhuman primates, hamsters, and rabbits intended for research or other purposes. Exclusions are described in Wikipedia ([http://en.wikipedia.org/wiki/Animal\\_Welfare\\_Act\\_of\\_1966](http://en.wikipedia.org/wiki/Animal_Welfare_Act_of_1966)):

*There is much debate as to the actual definition of an animal, but for the purpose of AWA, birds, rats, mice, horses, and other farm animals were excluded from its protection as initially legislated in 1966. The most commonly used animals in laboratories are rats and mice, and therefore they were not regulated in the original law. Purpose-bred rats of the genus Rattus and mice of the genus Mus are not covered by the Animal Welfare Act, but are regulated under PHS policy which applies only to research receiving federal funding from certain federal agencies, including the NIH. These are not federal laws but conditions of funding.*

The 1985 Health Research Extension Act mandated that the NIH oversee research by grantee institutions to ensure proper care of laboratory animals. The NIH Revitalization Act of 1993 included development of a Plan for Use of Animals in Research. This plan can be accessed at <http://altweb.jhsph.edu/regulations/nih-plan.html>.

The definitive federal agency documents are at [www.aphis.usda.gov/animal\\_welfare/downloads/Animal%20Care%20Blue%20Book%20-%202013%20-%20FINAL.pdf](http://www.aphis.usda.gov/animal_welfare/downloads/Animal%20Care%20Blue%20Book%20-%202013%20-%20FINAL.pdf)  
<http://grants.nih.gov/grants/OLAW/pl103-43.pdf>

A useful website of resources can be found at <http://www.neavs.org/research/laws>. More can be found at <http://awic.nal.usda.gov/government-and-professional-resources/legislation-regulations-and-guidelines-subject/laboratory>

## 3. Workplace Safety

The Occupational Safety and Health Act was enacted by Congress in 1970 to “make sure employers provide their workers a place of employment free from recognized hazards to safety and health, such as exposure to toxic chemicals, excessive noise levels, mechanical dangers, heat or cold stress, or unsanitary conditions.” The Act also created the National Institute for Occupational Safety and Health as the research institution for the Occupational Safety and Health Administration (OSHA) within the U.S. Department of Labor. Research laboratories and field activities—indeed, universities in general—are subject to broad and specific OSHA regulations.

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#### 4. Environmental Protection

An era of environmental activism led to the establishment of the Environmental Protection Agency (EPA) by Executive Order in 1970 and enactment of several U.S. federal laws governing research, including the National Environmental Policy Act (1969), the Clean Air Act (1970), the Clean Water Act (1972), the Endangered Species Act (1973), and the Toxic Substances Control Act (TSCA; 1976).

Some EPA responsibilities were reassigned from other agencies (<http://www2.epa.gov/aboutepa/epas-origins-duties-transferred-epa-other-federal-agencies>). In particular, the Atomic Energy Act of 1946 (AEA) authorized the Atomic Energy Commission (AEC), but the AEC's authority to issue environmental radiation standards was transferred to the EPA when it was established. The EPA's website explains, *"EPA also received the Federal Radiation Council's authority under the AEA to develop guidance for federal and state agencies containing recommendations for their use in developing radiation protection requirements, and to work with states to establish and execute radiation protection programs."*

Responsibility for enforcing the Endangered Species Act is shared between the U.S. Fish and Wildlife Service of the Department of the Interior and the National Oceanic and Atmospheric Administration (NOAA) in the Department of Commerce.

The TSCA addresses the production, importation, use, and disposal of specific chemicals (more than 83,000 are on the list at this time; see <http://www.epa.gov/opptintr/existingchemicals/pubs/tscainventory>). EPA administers these laws and the regulations that implement them (<http://www2.epa.gov/laws-regulations/laws-and-executive-orders>). Some EPA responsibilities are shared with other agencies; for example, the OSHA Occupational Chemical Database (<https://www.osha.gov/chemicaldata/>) was developed and is maintained in collaboration with EPA.

Over time, some laws have been amended, and most regulations have been made much more specific. For example, agency implementation of the National Environmental Policy Act (<http://www2.epa.gov/nepa>) now requires research site- and project-specific permitting in U.S. waters within the U.S. Exclusive Economic Zone (the outer edge defined as 200 nautical miles from U.S. coasts).

#### 5. International Traffic in Arms Regulations (ITAR) and Export Controls

The 1976 Arms Export Control Act authorizes the U.S. president to control the import and export of defense articles and defense services. This authority was delegated by Executive Order 11958 to the Secretary of State (control of exports of defense articles and services) and to the Secretary of the Treasury (to control imports of defense articles and services). The Department of State controls the export of defense articles and services on its U.S. Munitions List (USML), including military items, weapons, and space-related items such as satellites. In contrast, the Department of Justice

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controls the import of these items, pursuant to the U.S. Munitions Import List (USMIL) administered by the Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF). It is worth noting that software and algorithms are also included on the USMIL. In 2013, a new Executive Order implemented important changes to export controls: <https://www.whitehouse.gov/the-press-office/2013/03/08/fact-sheet-implementation-export-control-reform>

This site tracks subsequent rule-making and implementation changes: <http://www.export.gov/ecr/>

The U.S. Departments in charge of implementing and enforcing other export regulations are the Department of Commerce and the Department of the Treasury; the Departments may also share jurisdiction over some items. The Department of Commerce administers, through the Export Administration Regulations (EAR), the export of “dual-use” items, those that have both civilian and potential military applications. Examples of these include mapping software and centrifuges. The EAR also prohibits U.S. businesses and individuals from engaging in any boycotts not sanctioned by the U.S.

The U.S. Department of the Treasury enforces all U.S. embargoes and sanctions through the Office of Foreign Assets Control. Interactions with embargoed or sanctioned countries may be subject to strict licensing requirements, or licenses may not be obtainable.

If export controls are not complied with, severe fines up to \$1 million may be levied against the non-complying individual or the University. Other possible penalties include prison sentences of up to 20 years, the potential loss of all federal funding, and the loss of export privileges for the university.

## **6. Research Integrity and the Responsible Conduct of Research**

The history of the Department of Health and Human Services Office of Research Integrity is provided here: <http://ori.hhs.gov/historical-background>. Briefly, several cases of research misconduct at major research centers in 1980 and earlier received prominent media attention, leading to congressional hearings. The Health Research Extension Act (1985) Section 493 of the Public Health Service Act required institutions receiving federal funds to specify procedures for investigating alleged scientific fraud.

Section 7009 of the America COMPETES Act (ACA; 2007) is titled “The Responsible Conduct of Research.” It states that the Director of the National Science Foundation *“shall require that each institution that applies for financial assistance from the Foundation for science and engineering research or education describe in its grant proposal a plan to provide appropriate training and oversight in the responsible and ethical conduct of research to undergraduate students, graduate students, and postdoctoral researchers participating in the proposed research project.”*

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The ACA was reauthorized in 2010, and it is currently undergoing the process of reauthorization again (<http://science.house.gov/markup/hr-1806-america-competes-reauthorization-act-2015>). The current House version contains sections on Misrepresentation of Research Results (SEC. 116) and on Research Reproducibility and Replication (SEC. 117).

## **7. Public Health Service Law Regarding Financial Conflicts of Interest**

The U.S. Public Health Service (PHS) financial conflict of interest (FCOI) code requires institutions applying for or receiving PHS research funding by means of a grant or cooperative agreement or contract to be in compliance with the regulations titled “Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors,” 42 CFR Part 50, Subpart F and 45 CFR Part 94. These are commonly referred to as the “FCOI Regulations.” The purpose of the FCOI Regulations is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research performed under PHS grants, cooperative agreements, or contracts will be free from bias resulting from investigators’ financial conflicts of interest.

The most recent versions are effective August 24, 2012; they are roughly subdivided into the regulations themselves and a discussion of the roles in compliance for the responsible contractors; they are available at <http://grants.nih.gov/grants/policy/coi/>. Agencies that are held to the PHS FCOI Regulations include but are not limited to the

- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Disease Control and Prevention (CDC)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- National Institutes of Health (NIH) Centers and Institutes
- Office of the Inspector General (OIG)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

In discussing accountability, the FCOI Regulations employ the term “Investigator” throughout. PHS defines “Investigator” as the project director or Principal Investigator as well as any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research. Thus, this term may be applied to consultants and graduate assistants who are engaged in the project.

## **B. State of Hawai‘i Law**

There are multiple state agencies that issue regulations with which researchers may have to be in compliance for their research activities. Below is a brief background on some of the major state compliance regulations (see also Appendices G and H).

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## 1. State Ethics Code

The UH Conflict of Interest (COI) policy is currently interpreted from the State Ethics Code. However, concerns have been raised that efficient and effective technology transfer may be hampered by an overly broad interpretation of the general conflict of interest, fair treatment, and employment restrictions contained in the State Ethics Code (see HB975 HD1 and SB1144 SD2 HD1).

The conflict of interest statute for the State of Hawai'i restricts its scope to employees and is available at <http://ethics.hawaii.gov/wp-content/uploads/2013/08/Chapter-84.pdf>.

## 2. Department of Agriculture (DOA)

Faculty and staff who work with plants, microorganisms, parasites, pesticides, and a variety of animals must comply with Hawai'i DOA Hawai'i Administrative Rules (HAR) relating to plants and non-domestic animals (see <http://hdoa.hawaii.gov/pi/pq/import-program/pq-non-domestic-animal-and-microorganism-lists/>). The HAR were developed by the DOA to implement the requirements of Hawai'i Revised Statutes, Chapter 150A ([http://www.capitol.hawaii.gov/hrscurrent/Vol03\\_Ch0121-0200D/HRS0150A/HRS\\_0150A-.htm](http://www.capitol.hawaii.gov/hrscurrent/Vol03_Ch0121-0200D/HRS0150A/HRS_0150A-.htm)), which were adopted to safeguard Hawai'i's agriculture, environment, and public health. Researchers and instructors who are subject to the HAR must file an application, remit payment, and receive DOA approval before they are permitted to conduct work on their projects. The permitting process requires several levels of review and may require years before approval is granted. This complicated and arduous process has long been a problem for researchers, as it jeopardizes the timely completion of research, funding of grants by agencies, initiation of teaching modules, and the training of the next generation of students for future STEM positions.

## 3. Department of Land and Natural Resources (DLNR)

Within the DLNR, there are several compliance areas for researchers. It is currently the sole responsibility of researchers to ensure that all applicable permits are held prior to the commencement of regulated activities. Currently, requests for permits must be submitted a minimum of 90 days prior to the expected start of fieldwork, which has impacted both research and STEM education. The following three areas within DLNR are regularly encountered by researchers and educators from the UH System:

***Division of Aquatic Resources (DAR)*** (<http://dlnr.hawaii.gov/dar/licenses-permits/>). Any individual associated with any research, educational, or management institution who wishes to collect aquatic life or use certain fishing gear or methods that are prohibited or restricted by regulations is required to obtain a special activity permit.

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***Division of Forestry and Wildlife (DOFAW)*** (<http://dlnr.hawaii.gov/dofaw/permits/>).

Regulated activities include those involving native wildlife, introduced wild birds, and game animals (Wildlife Permit Guidelines); rare, threatened, or endangered plants (Plant Permit Guidelines); the collection or exportation of injurious wildlife (Wildlife Permit Guidelines); or native invertebrates. Also regulated are activities within a Natural Area Reserve (NARS Permit Guideline) or activities requiring access to DOFAW-managed land (Forest Reserve System guidelines). Researchers who wish to perform work that may affect any endangered, threatened, candidate, or proposed species (terrestrial or marine bird, animal, or plant) must also contact the Conservation Initiatives Coordinator.

***Research on State Lands.*** Multiple agencies handle research on state lands, including State Parks, Land Division, Office of Conservation and Coastal Lands, and the Historic Preservation Division.

#### **4. Department of Labor and Industrial Relations (DLIR)**

***Occupational Safety and Health (HIOSH)*** (<http://labor.hawaii.gov/hiosh/>). General safety health requirements state, *“Every employer shall comply with the state laws, standards and rules regarding a safe place of employment and safe practices, and shall do everything reasonable and necessary to protect the life, safety, and health of the employees”* (<http://labor.hawaii.gov/hiosh/files/2012/12/12-60-General-Safety-Health-Requirements.pdf>). HIOSH (and OSHA) requirements inform the practice of research protocols, equipment use, and personnel workloads.

#### **5. Department of Health (DOH)**

There appear to be few instances of DOH’s particular interest in research that are not already addressed in federal rules and regulations. The DOH mandates reporting of communicable diseases by any practitioner or agency to whom such illnesses are disclosed, including laboratories. The operative law is HRS 325-0325: [http://www.capitol.hawaii.gov/hrscurrent/Vol06\\_Ch0321-0344/HRS0325/HRS\\_0325-0002.htm](http://www.capitol.hawaii.gov/hrscurrent/Vol06_Ch0321-0344/HRS0325/HRS_0325-0002.htm). HRS 622-57 addresses privacy and disclosure of patient records independent of Federal regulations (such as Title 42 CFR and HIPAA), and is accessible at [http://www.capitol.hawaii.gov/hrscurrent/Vol13\\_Ch0601-0676/HRS0622/HRS\\_0622-0057.htm](http://www.capitol.hawaii.gov/hrscurrent/Vol13_Ch0601-0676/HRS0622/HRS_0622-0057.htm). This would have interest for investigators pursuing retrospective record reviews.

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## C. Institutionally Self-Imposed Requirements

The University of Hawai'i self-imposes certain requirements and regulations that are intended to exempt UH from more onerous federal and state legislation on occupational health and safety. For example, the Diving Safety Control Program exempts UH research diving activities from Commercial Diving Regulations under OSHA and the Hawai'i Revised Statutes. Unlike other regulatory areas under the jurisdiction of the Office of Research Compliance, the UH Diving Safety Program is responsible for the authorization of UH scientific divers, evaluation and approval of dive plans, training and program support for UH-authorized divers, coordination of diver medical exam scheduling, and investigation of SCUBA diving accidents.

Other examples of self-imposed research compliance are concerned with the ways institutions handle intellectual property (IP) that is created through research. The UH has specific policies concerning patenting and licensing of IP created by its faculty and staff: Board of Regents Policy 12.205 Patent and Copyright Policy and Hawai'i Administrative Rule Title 20, Chapter 3, University of Hawai'i Patent and Copyright Policy (<http://hawaii.edu/offices/bor/adminrules/chapter03.pdf>).

## D. Required Research Compliance Activities

Institutions that conduct research activities are responsible for (a) compliance monitoring/reporting and (b) assisting their personnel in conducting research in compliance with regulations. As suggested by the above review, regulatory requirements and policies governing research are often complex and daunting, with regulations varying for different types of research. The following is a list of compliance requirements that the UH research community of faculty, staff, and students may encounter during the course of a typical research project. UH offices and programs responsible for assisting the research community to meet regulatory requirements are detailed in Section 3, Compliance Dimensions and Structures at UH. The following list of required research compliance activities is not exhaustive, as different types of research may be subject to unique regulations. Also, the report does not address issues involving personnel and fiscal compliance.

### 1. Pre-research, pre-proposal, and post-award continuing requirements for activities involving

- Human subjects: Human Subjects Program (HSP)/Institutional Review Board (IRB) protocol approval: <https://manoa.hawaii.edu/researchcompliance/institutional-review-board-irb-0>
- Hawai'i Department of Education (HIDOE school or office): HIDOE Data Governance and Analysis Branch research and data request approval: <http://www.hawaiipublicschools.org/VisionForSuccess/SchoolDataAndReports/HawaiiEdData/Pages/Data-Requests.aspx>
- Vertebrate animals: Institutional Animal Care and Use Committee (IACUC) protocol approval: <https://manoa.hawaii.edu/researchcompliance/iacuc>

- Recombinant DNA, select agents, biological commodities: Institutional Biosafety Committee (IBC) protocol registration/approval: <https://manoa.hawaii.edu/researchcompliance/ibc>
- Export-controlled technology or data: UH Office of Export Controls: <http://www.hawaii.edu/research/export-controls/>
- Creation of patentable or licensable invention: UH Office of Technology Transfer and Economic Development (OTTED): <http://www.hawaii.edu/research/otted/>
- Compressed-gas diving or radioactive material: UH Environmental Health and Safety Office (EHSO) protocol/application approval: <http://www.hawaii.edu/ehso/InfoNewPI.htm>
- Hazardous working conditions (e.g., use of watercraft): Insurance documents: [http://www.hawaii.edu/riskmanagement/insurance/minimum\\_requirements.html](http://www.hawaii.edu/riskmanagement/insurance/minimum_requirements.html)
- Responsible Conduct of Research (RCR), if required by grant sponsor: UH Office of Research Services (ORS) Federal Conflict of Interest form: <http://www.ors.hawaii.edu/index.php/fcoi-information>

## 2. Training and certification

- Human subjects research: <https://manoa.hawaii.edu/researchcompliance/get-training-0>
- Animal subjects: <https://manoa.hawaii.edu/researchcompliance/new-animal-user>
- Responsible conduct of research: <https://manoa.hawaii.edu/researchcompliance/uh-rcr-education>
- Health Insurance Portability and Accountability Act (HIPAA): <http://manoa.hawaii.edu/jabsom/admin/hips/curriculum/login.php> (available to all UH faculty, staff, and students) and <http://www.hhs.gov/ocr/privacy/hipaa/understanding/training/index.html> (provides comprehensive background and enforcement discussions)
- Biological safety: <https://manoa.hawaii.edu/researchcompliance/biosafety-education>
- Laboratory/chemical safety: <http://www.hawaii.edu/ehso/lab/>
- Diving safety: <http://www.hawaii.edu/ehso/diving/>
- Radiation safety: <http://www.hawaii.edu/ehso/radiation/>
- Hazardous materials management: <http://www.hawaii.edu/ehso/hazmat/>
- Laser safety: <http://www.hawaii.edu/ehso/radiation/Laser%20Safety%20Manual.pdf>

## 3. Permit, licenses, approvals

- U.S. Department of Commerce, Export Administration Regulations (EAR): <http://www.bis.doc.gov/index.php/regulations/export-administration-regulations-ear>
- U.S. Department of State, International Traffic in Arms Regulations (ITAR): [http://www.pmdtdc.state.gov/regulations\\_laws/itar.html](http://www.pmdtdc.state.gov/regulations_laws/itar.html)
- U.S. Department of Treasury, Office of Foreign Assets Control (OFAC): <http://www.treasury.gov/resource-center/sanctions/Pages/default.aspx>
- U.S. Department of Defense (DOD), Certificate of Environmental Compliance: [http://www.usamraa.army.mil/pages/baa\\_paa/BAA\\_13\\_1/Attachment\\_3-Certificate\\_of\\_Environmental\\_Compliance.pdf](http://www.usamraa.army.mil/pages/baa_paa/BAA_13_1/Attachment_3-Certificate_of_Environmental_Compliance.pdf)

- U.S. Drug Enforcement Administration (DEA); controlled substances registration: <http://www.deadiversion.usdoj.gov/>
- U.S. Nuclear Regulatory Commission (NRC); radioactive materials: <http://www.nrc.gov/about-nrc/regulatory/licensing.html>
- U.S. Fish and Wildlife Service (USFWS), Division of Management Authority and the National Oceanographic and Atmospheric Administration (NOAA) Office of Protected Resources; marine mammals: [http://www.nmfs.noaa.gov/pr/permits/faq\\_mmpermits.htm](http://www.nmfs.noaa.gov/pr/permits/faq_mmpermits.htm)
- U.S. Department of Interior, National Park Service: [http://www.nps.gov/cue/research/research\\_application\\_faq.pdf](http://www.nps.gov/cue/research/research_application_faq.pdf)
- USDA Animal and Plant Health Inspection Service (APHIS): <http://www.aphis.usda.gov/wps/portal/aphis/resources/permits>
- U.S. Environmental Protection Agency (EPA); National Environmental Policy Act (NEPA): <http://www2.epa.gov/nepa>
- U.S. Army Corps of Engineers: <http://www.usace.army.mil/Missions/CivilWorks/RegulatoryProgramandPermits/NationwidePermits.aspx>
- U.S. Coast Guard: <http://www.uscg.mil/d14/cmd/dp/dpw/>
- U.S. Department of Health and Human Services (DHHS), Centers for Disease Control and Prevention (CDC) Import Permit Program (IPP): <http://www.cdc.gov/od/eaipp/importApplication/agents.htm>
- Hawai'i Department of Agriculture (HDOA; Plant and Non-Domestic Animal Quarantine Branch), importing microorganisms: <http://hdoa.hawaii.gov/pi/pq/import-program/>
- Hawai'i Department of Land and Natural Resources (DLNR); endangered species, fresh water or marine species, state parks, conservation districts, historical sites: <http://dlnr.hawaii.gov/dofaw/permits/>
- UH Biological Materials: <https://manoa.hawaii.edu/researchcompliance/get-permit>

#### 4. Inspection (internal and external agencies)

- CDC Division of Select Agents and Toxins; USDA APHIS Agriculture Select Agent Services: [http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalhealth/sa\\_import\\_into\\_us/sa\\_ag\\_select\\_agent/](http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalhealth/sa_import_into_us/sa_ag_select_agent/)
- UH biosafety inspection: <https://manoa.hawaii.edu/researchcompliance/inspection-checklists>
- UH lab safety inspection: <http://www.hawaii.edu/ehso/lab/>
- UH radiation inspection: <http://www.hawaii.edu/ehso/radiation/>

#### 5. Reporting requirements

- Conflict of interest
- Research misconduct (plagiarism, falsification, fabrication)
- Unanticipated problem and protocol violation, UH Human Studies Program
- OSHA violations
- EPA violations

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## E. Emerging Compliance Requirements

Since the PATRIOT Act (2001), matters of national security have been brought to the forefront, affecting purchase, shipment, and use of research equipment and instruments; research with chemical and biological agents; and research with or producing “sensitive” information. Increasingly specific regulations have been issued. For example, the “deemed export” of restricted technology or information occurs at the moment that a foreign national can access it within the United States.

The FREEDOM Act (2015) addresses many matters of the PATRIOT Act, which expired, but the differences are not yet clear in terms of compliance.

It appears that university compliance offices are increasingly concerned with restricting sensitive compliance information.

### 1. Dual use research of concern

The United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern was issued on September 24, 2014, and compliance is required within one year. The term “dual use” refers to the possibility that new results of research may be put to both good and bad uses. The “research of concern” currently refers to the federal list of “select agents,” which are generally biological pathogens or toxins.

<http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf>

New UH executive policies and administrative procedures have been proposed (March 2015) to comply with impending federal requirements regarding “dual use research of concern (DURC)” in the life sciences. A UH DURC policy was drafted in 2013, but it was not shared with the UH community until March 2015, with an implementation deadline of September 24, 2015. <https://manoa.hawaii.edu/researchcompliance/uh-durc-policies-procedures>

### 2. Nanotechnology

Because the physical, chemical, and biological behavior of materials on very small scales is not well understood, nanotechnology is being considered as posing potential new hazards to human and environmental health:

<http://www.wilsoncenter.org/publication-series/project-emerging-nanotechnologies>

<http://www.wilsoncenter.org/publication/pen-9-epa-and-nanotechnology-oversight-for-the-21st-century>

### 3. Research compliance itself as a growing topic of research

National Research Council. International Animal Research Regulations: Impact on Neuroscience Research: Workshop Summary. Washington, DC: The National Academies Press, 2012.

<http://www.ncbi.nlm.nih.gov/books/NBK100123/>

[https://www.fbo.gov/index?s=opportunity&mode=form&tab=core&id=dd4be3c98f213c-2470debb7c775035a4&\\_cvview=1](https://www.fbo.gov/index?s=opportunity&mode=form&tab=core&id=dd4be3c98f213c-2470debb7c775035a4&_cvview=1)

<https://pharm.ucsf.edu/cersi>

[http://en.wikipedia.org/wiki/Regulatory\\_science](http://en.wikipedia.org/wiki/Regulatory_science)

### 4. Reducing regulatory burdens

The body of federal legislation affecting research activities continues to grow, and with it the burden of compliance on institutions and researchers. The visibility of the related issues has risen from funding agencies to the National Science Board to the White House, and back again to Congress.

The Federal Demonstration Project is a consortium of federal agencies and grantee institutions that has been working since 1986 to find ways to reduce the compliance and reporting burdens and to make requirements consistent across federal agencies where possible.

[http://sites.nationalacademies.org/PGA/fdp/PGA\\_054588](http://sites.nationalacademies.org/PGA/fdp/PGA_054588)

On March 11, 2011, a memorandum on the “Principles for Regulation and Oversight of Emerging Technologies” was issued to the heads of executive departments and agencies by the Director of the Office of Science and Technology Policy (Assistant to the President for Science and Technology), the Administrator of the Office of Information and Regulatory Affairs (Office of Management and Budget), and the Chief Agricultural Negotiator (United States Trade Representative).

The memo addresses

*“...innovation with respect to emerging technologies—such as nanotechnology, synthetic biology, and genetic engineering, among others—[which] requires not only coordinated research and development but also appropriate and balanced oversight. The White House Emerging Technologies Interagency Policy Coordination Committee (ETIPC) has developed the following broad principles, consistent with Executive Order 13563, to guide the development and implementation of policies for oversight of emerging technologies at the agency level.*

*We share a fundamental desire for regulation and oversight that ensure the fulfillment of legitimate objectives such as the protection of safety, health, and the environment. Regulation and oversight should avoid unjustifiably inhibiting innovation, stigmatizing new technologies, or creating trade barriers.”*

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The America COMPETES Reauthorization Act of 2015 (H.R. 1806) is in the legislative process of reauthorization, and the current House version directs the Office of Science and Technology Policy to improve regulatory efficiency by establishing *“a working group under the authority of the National Science and Technology Council, to include the Office of Management and Budget. The working group shall be responsible for reviewing federal regulations affecting research and research universities and making recommendations on how to—(1) harmonize, streamline, and eliminate duplicative Federal regulations and reporting requirements; (2) minimize the regulatory burden on United States institutions of higher education performing federally funded research while maintaining accountability for Federal tax dollars; and (3) identify and update specific regulations to refocus on performance-based goals rather than on process while still meeting the desired outcome.”* (SEC. 302. REGULATORY EFFICIENCY: <https://www.congress.gov/bill/114th-congress/house-bill/1806/text>). If enacted, this review will likely have profound impacts on research and research compliance at institutions of higher education.

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### III. COMPLIANCE DIMENSIONS AND STRUCTURES AT UH

This report appears to be the first attempt to summarize the compliance of UH’s research enterprise. It is almost certainly incomplete, as the RCTF found no single source for such material, Internet resources were scattered and incomplete, and there was no consistency in presentation or content across compliance offices. Many offices failed to explain the authority under which they operated, and some did not even spell out the rules Principal Investigators are expected to follow. Researchers appear to be expected to know a priori what compliance obligations they face and why. This expectation places a significant burden on new investigators and their graduate students and represents a significant liability in terms of both compliance and the reporting of non-compliance. The review below of compliance dimensions and structure at UH excludes financial and human resource compliance.

#### A. Introduction to Compliance History at UH

Compliance issues have grown with the UH research enterprise, which has expanded from around \$200M/year in FY2001 (UH ORS 2000-2001 Annual Report) to almost \$500M/year in FY2011 (UH ORS 2010-2011 Annual Report). To an even greater extent, these issues have grown in response to the ever-increasing complexity of federal and state laws, rules, and regulations that often overlap across compliance entities, forcing duplication of effort by researchers trying to stay in compliance.

Triggers for the expansion of compliance at universities and colleges include the public concern or outrage at national or international levels over particular incidents, such as the Tuskegee Project, the abduction and death of a Dalmatian named Pepper, the Gore Hearings in 1981 on scientific misconduct, the 9-11 terrorist attack concerns over research on dangerous diseases, and more recently genetically modified organisms.

Nationally the result has been a “culture of overregulation” that “has resulted in wasted federal research dollars” (National Science Board, 2014). Even in this atmosphere, UH compliance appears to be exceptionally zealous. A former chancellor estimated that researchers now spend 60% of their time at UH dealing with compliance and other administrative tasks, in comparison to the national average of 40% (T. Apple pers. comm.; National Science Board 2014).

Over the years there have been several efforts to reform the compliance establishment at UH, paralleling efforts at the federal level (National Science Board, 2014), but these efforts appear to have had limited success and follow-through.

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In 2001, at the request of the UH Association of Research Investigators (UHARI), then-President Evan Dobelle established the Task Force on Restructuring the Administration of Research, which produced what has come to be known as the Raleigh Report, named after its chair Barry Raleigh, former SOEST dean. The report noted that research administration seemed designed more to protect the university than to facilitate research and that this problem was greatest when services were most centralized. It recommended the creation of a Vice President for Research position; that UH, rather than RCUH, be responsible for research administration; that authority for decisions be placed “as far down the hierarchical structure as is consistent with accountability”; that administration become paperless; and that support staff be better rewarded for performance. In terms of compliance, the report called for faster reviews by the human subject and animal support services, with better funding, incentives for faculty to serve on compliance committees, and online training. The report also recommended the creation of an oversight committee to review and document improvements in research administration. Only two of these recommendations were implemented: creation of the Vice President for Research position and some online training.

In 2002, a consultant named Robert Forrester visited UH to “begin the collaborative development of a research strategic plan” through consultation with researchers, administrators and the Chancellor’s Research Task Force. The resulting Forrester Report (2003) summarized the research enterprise and opportunities and identified amongst the weaknesses and threats to the enterprise a “lack of a research culture,” “acknowledged weaknesses in the research support structure,” and an “indecisive bureaucracy.”

In 2004, Andrew Hashimoto, then-dean of the College of Tropical Agriculture and Human Resources, examined how excess bureaucracy might be reduced in the UH System. The RCTF has only been able to find the PowerPoint presentation of the report. Hashimoto identified an inefficient management structure, requirements for monitoring low-value items, and ineffective and rigid processes and controls as issues. He suggested that bureaucracy should support research but provide only “adequate” operational control, taking into account the cost/benefit ratio of such controls, reducing the number of signatures needed, reducing paper, and moving to simple, “post audit” reviews, not 100% preaudits.

In 2012, UHARI, at the request of then President M.R.C. Greenwood, developed a proposal for a committee to review hindrances to further growth of the research enterprise. The president did not act on the proposal.

Nationally, in 2014, the National Science Board (NSB) produced the latest in a series of documents on how to reduce administrative load on researchers. The NSB report contained a series of concrete steps that universities and agencies can take, many of them reflecting that universities have been more

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restrictive than agency rules require. Some of these steps may have been implemented by UH but not reported to the research community. The report recommends that universities review their human subject and animal use processes.

## **B. Compliance at UH**

The boundaries between research compliance and other regulatory concerns are often unclear and dynamic, so this list may be incomplete, but the following subjects represent the main areas of compliance concern.

### **1. Human Subjects**

As noted in the previous section, Background on Regulations Affecting Research, at the national level the 1979 Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects set in motion increased attention on human subjects in biomedical and behavioral research and the creation of Institutional Review Boards (IRB) at universities to evaluate the ethics of experiments on humans. Coverage then expanded from medicine to include research activities and methodologies in the social and life sciences (e.g., surveys, focus groups, etc.). UH now has three IRBs: Biomedical, Social and Behavioral Sciences, and Cooperative for projects undertaken jointly with other institutions.

### **2. Animal Welfare**

Animal care was ad hoc and local until 1963, when veterinarians produced the first Guide for the Care and Use of Laboratory Animals. Following a series of scandals, Congress passed the Animal Welfare Act in 1966 to regulate animal facilities. The act was expanded in 1971 to allow institutional compliance through accreditation or an animal care and use committee. At UH, this led to the creation of the Institutional Animal Care and Use Committee (IACUC).

### **3. Export Controls**

While there have been decades of concern about industrial espionage and tensions over granting visas to foreign nationals, the events of September 11, 2001, led to the Agricultural Bioterrorism Act (2002), the Public Health Security and Bioterrorism Preparedness and Response Act (2002), the Homeland Security Act (2002), the Arms Export Control Act (1976, amended), the Export Administration Act of 1979 (amended 2002), and changes in visa and immigration policies that affect collaboration among scholars. These placed restrictions on use, movement, and export of dangerous or dual-use biological (select) materials and technology and of currency that might facilitate attacks on the U.S. The acts also made it more difficult for certain foreign nationals to visit or participate in research. The operations of the UH Institutional Biosafety Committee, the Office of Export Controls, and the Faculty and Scholar Immigration Services expanded in scope and complexity as a result.

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#### 4. Scientific Misconduct/Ethics

Congressional concerns in the 1980s over reports of scientific misconduct and the apparent failure of federal agencies and research institutions to respond appropriately led to the Health Research Extension Act (1985) and subsequent guidelines that required institutions receiving federal funds to investigate and report scientific fraud. In response, UH created the Office of Research Integrity and the Ethics Committee to address these types of issues.

#### 5. Laboratory and Radiation Safety

Following laboratory accidents involving radiation, chemical explosions, release of toxins or disease organisms, and as a result of increasing knowledge of the dangers of chemicals and practices formerly regarded as innocuous, the federal Occupational Safety and Health Agency and its state counterpart, HIOSH, have continually generated and updated training requirements and regulations.

At UH, two major incidents shaped compliance in this area. In 1997, the Environmental Protection Agency found that UH had improperly stored and disposed of hazardous chemicals. The agency imposed a \$500,000 fine and required UH to spend \$1,200,000 to conduct an audit of chemicals throughout the system, implement pollution controls, and develop methods to reduce use of such chemicals. <http://yosemite.epa.gov/opa/admpress.nsf/8b75cea4165024c685257359003f022e/06324df96f33462f852570d8005e140c!OpenDocument>

In 2004–2005, federal concerns about the security of a research irradiator at the Food Technology Building led to its deactivation and the removal of UH’s radiation safety officer.

UH’s response to these incidents and related concerns led to expansion of the Environmental Health & Safety Office and the Institutional Biosafety Committee (<https://manoa.hawaii.edu/researchcompliance/ibc>).

### C. Current UH Research Compliance Offices

This section summarizes the research compliance infrastructure at UH. It is essentially divided into an Office of Research Compliance (ORC), which deals with many of the most significant federal and state compliance issues, and a series of other offices and programs that affect compliance for some research projects. This is because compliance responsibilities are delegated to various UH offices, a system that often results in independently operating functions that are not well integrated with one another. However, research thrives when there is coordination among all compliance offices to reduce duplication, create efficiencies, and interact with faculty users with “one voice.” The descriptions below are based on web material, some of which is in the process of being updated. Organization

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charts and functional statements relating to the offices presented below can be found in Appendix A, Office of the VPRI; Appendix B, the UH Mānoa Office of the Vice Chancellor for Research; and Appendix C, the UH Mānoa ORC.

### **Office of Research Compliance**

Formed in 2010 as an amalgamation of research compliance programs, the ORC has responsibility for five main areas: Biological Safety, Animal Welfare, Research Integrity, Human Studies, and Animal and Veterinary Services, assuring that “research at UH is performed responsibly.” Its mission is “to enhance the research reputation of the University” (UH ORC draft Annual Report 2013, Vol. 1). The ORC reports to the UH Mānoa Vice Chancellor for Research. In FY 2012, the ORC had a budget of \$1,565,797; in FY 2013, the budget was \$1,937,951, with a staff of 41.5 FTE in both years (UH ORC draft Annual Report 2013, Vol. 1).

The **Biological Safety Program** oversees “all research, teaching, and testing activities involving infectious agents and recombinant materials” to reduce risk to investigators, students, and the community. It does so through education and laboratory inspections. A separate Institutional Biosafety Committee covers recombinant materials and infectious agents.

<https://manoa.hawaii.edu/researchcompliance/biological-safety>

The **Animal Welfare Program** oversees the well-being of vertebrate animals used in teaching and research and investigates reported violations of protocols. The Institutional Animal Care and Use Committee (IACUC) reviews research protocols and teaching activities that fall under this program to ensure animals are used ethically.

<https://manoa.hawaii.edu/researchcompliance/animal-welfare>

The **Research Integrity Program** administers UH Executive Policy E5.211 and federal regulations concerning scientific and scholarly misconduct through a sequential process of assessment, inquiry and investigation. Review panels made up of staff and faculty assess the results and recommend appropriate measures to the Vice President for Research and Innovation, the institutional “Deciding Official” or Research Integrity Officer who makes the final determinations.

<https://manoa.hawaii.edu/researchcompliance/research-integrity>

The **Human Studies Program** protects “the health, welfare, rights, and dignity of people” who participate as subjects in research and scholarly activity. This program administers three Institutional Review Boards (IRBs: Biomedical, Social and Behavioral Sciences, and Cooperative, involving other institutions) that evaluate research protocols involving human participants.

<https://manoa.hawaii.edu/researchcompliance/human-studies>

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The ***Animal and Veterinary Services Program*** “1) provides veterinary care, 2) operates two vivaria, and 3) educates personnel on animal related activities.”  
<https://manoa.hawaii.edu/researchcompliance/university-veterinary-services>

### **Offices With Compliance-Related Responsibilities**

Beyond the Office of Research Compliance, there are several other programs that can play a significant role in the regulation of research, both directly and indirectly. This list is indicative of the range of such programs; it is not intended to be exhaustive. It does not include fiscal management of sponsored research or the Research Corporation of the University of Hawai‘i.

#### **1. Office of the Vice President for Research and Innovation (VPRI)**

The ***Office of Technology Transfer and Economic Development (OTTED)*** works with the UH community to commercialize intellectual property and reports to the UH System VPRI. For faculty, the University of Hawai‘i Professional Assembly agreement (Article XI, C.) spells out the management of intellectual property rights (<http://www.uhpa.org/contracts/2015-2017-ta-pdf/article-xi-intellectual-property-patents-and-copyrights/>).  
<http://www.hawaii.edu/research/otted/>

The ***Office of Research Services (ORS)*** deals with the pre-award process and financial compliance (not dealt with further in this report), checks that proposals have addressed compliance issues before submission, deals with potential pre-submission conflicts of interest, and handles post-award accounting and reports to sponsors. The ORS reports to the UH System VPRI.  
<http://www.ors.hawaii.edu/>

The ***Office of Export Controls (OEC)*** assists researchers through education and consultation on the “complex and ever-changing U.S. laws and regulations which regulate certain strategic information, technology, and services.” It reports to the UH System VPRI.  
<http://www.hawaii.edu/research/export-controls/>

#### **2. Office of the Vice President for Academic Affairs (VPAA)**

The ***Institutional Data Governance*** office “provides oversight for the management of Institutional Data across the UH System” regarding data security and use.  
<http://www.hawaii.edu/uhdtagov/>

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### 3. Office of the Vice President for Information Technology (VPIT) and Chief Information Officer

The **Information Security Team** protects university online resources from cyber-attacks and ensures compliance with UH policies. The team is not part of the Information Technology Services (ITS) but works closely with them.

<http://www.hawaii.edu/infosec/>

### 4. Office of the Vice President for Administration (VPA)

This office provides “*systemwide executive leadership in planning, organizing, managing and administering the university’s programs relating to capital improvements, human resources, procurement and real property management, risk management, and university/community relations.*” In the event of hazardous and emergency events—such as floods, biological threats, hazardous materials incidents, and tsunamis—the VPA provides guidelines regarding preparation for, response to, and recovery after emergencies that may disrupt and damage research facilities.

<http://www.hawaii.edu/offices/?office=admin>

### 5. Office of the UH Mānoa Vice Chancellor for Research (VCR)

The **Environmental Health & Safety Office (EHSO)** deals with safety concerns across campus, including a number that are essential for research and teaching. These include the Diving Safety Office; Radiation, Fire, and Laboratory safety programs; Hazardous Waste Management; Environmental Compliance; and Occupational Health and Safety. Some of these appear to overlap in parts with other programs, such as Biosafety and Laboratory safety. The EHSO reports to the UH Mānoa Vice Chancellor for Research.

<http://www.hawaii.edu/ehso/>

### 6. Office of the UH Mānoa Vice Chancellor for Academic Affairs (VCAA)

The **Faculty and Scholar Immigration Services** office provides immigration and visa assistance to UH employees, but not to employees hired by UH PIs via RCUH.

<http://www.hawaii.edu/fsis>

### 7. Office of the UH Mānoa Vice Chancellor for Administration, Finance and Operations (VCAFO)

The **Office of Planning and Facilities** includes the procurement of repair and maintenance supplies and equipment among its range of administrative support services. If these services are not provided in a timely manner, research investigations can be greatly delayed.

<http://manoa.hawaii.edu/opf/>

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## D. UH Faculty Involvement in Research Compliance (Formal and Informal)

The following is a partial list of compliance-related committees on which faculty serve. Details of terms of service, selection method, and qualifications are not always presented. Other committees may exist but do not necessarily have an Internet presence.

### 1. President

The **Research Task Force—2015**, an ad hoc task force appointed by the president, was charged to review research support division between the UH campuses and UH System and develop a plan to optimize and streamline research processes.

### 2. Vice President for Research and Innovation

The **Research Advisory Board (RAB)** reports to the VPRI as an official advisory arm to advance the UH research agenda. The chair is appointed by the VPRI. The other six members are appointed through consultation between the chair, the president, and the vice president, aiming for a balance of three research faculty and three research administrators. The board has spawned two ad hoc working groups: the Research Compliance Task Force (RCTF, the present committee) and the Cancer Center Review Committee, which was charged to review the center's mission, performance, and resources with a view as to how best to ensure its future success.

Membership of the **Office of Research Services Faculty Advisory Committee** includes the UH Mānoa Vice Chancellor for Research; representatives from UH Information Technology Services (ITS), UH Hilo, and UH West O'ahu; and various researchers from academic and research units at UH Mānoa. This committee meets quarterly with the ORS director and staff to discuss new issues and regulations.

### 3. UH Mānoa Vice Chancellor for Research

The **Mānoa Research Advisory Council (RAC)** is a standing committee that advises the Vice Chancellor for Research on research issues such as building human capital (faculty, staff, postdocs, and students); improving shared-use instrumentation and facilities; promoting research development; communicating research impacts; and other issues. The council meets monthly and serves as the task force for planning goals and implementing the research aspects of UH Mānoa's new Strategic Plan in alignment with system strategic initiatives. Members are appointed by the VCR and include UH Mānoa faculty representing academic units, deans/directors, and representatives from the Graduate Student Organization (GSO) and the Associated Students of the UH (ASUH).

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### **Office of Research Compliance**

See Appendix D for the complete list of ORC Advisory Committees and below for brief descriptions of some of them.

The **Institutional Biosafety Committee (IBC)** provides system-wide compliance oversight for research on recombinant DNA, select agents, and dual-use research. The committee membership specified by National Institutes of Health (NIH) Guidelines includes both faculty and members of the community. In 2013, 7 of 16 committee members were UH faculty, and the committee reviewed 137 applications at 12 meetings (UH ORC draft Annual Report 2013, Vol. 1). Members are appointed by the Vice President for Research and Innovation and serve three-year terms.

<https://manoa.hawaii.edu/researchcompliance/ibc>

The **Institutional Animal Care & Use Committee (IACUC)** is responsible for the system-wide oversight and evaluation of research protocols and animal care and use. UH Hilo is charged a fee for semi-annual site visits. In 2013, the committee reviewed 315 protocols, 59 of which were new, at 13 meetings. Including 3 alternates, 13 of 22 members were UH faculty (UH ORC draft Annual Report 2013, Vol. 1).

The members are appointed to represent both scientists and community members. Members are anonymous and no term of service is given. The “Designated Institutional Official” appoints them. The Institutional Agreement with DHHS that is the legal basis for IACUC’s existence is not transparent and faculty outside IACUC are not involved as authors or reviewers.

<https://manoa.hawaii.edu/researchcompliance/iacuc>

The **Ethics Committee** has 16 faculty members who may be called upon as needed, in addition to subject experts, to form review panels to evaluate evidence and make formal recommendations related to determinations of misconduct across all campuses. No information on membership, term of service, or appointment procedures is made available to the public.

[http://www.ors.hawaii.edu/files/UH\\_Guidelines\\_Mngmt%20Plan.pdf](http://www.ors.hawaii.edu/files/UH_Guidelines_Mngmt%20Plan.pdf) <https://manoa.hawaii.edu/researchcompliance/print/219>

Three **Institutional Review Boards (IRBs)** are responsible for reviewing research involving human subjects. They reviewed 1,389 proposals in calendar year 2013, of which 43% were exempt from further review under federal guidelines. For the Biomedical IRB, 14 of 18 members were UH “scientists”; for the Social and Behavioral Sciences, 14 of 18 members were UH “scientists”; for the Cooperative IRB, only 5 of 14 were UH “scientists” (UH ORC Draft Annual Report 2013, Vol. 1). For projects with industry sponsors, there is a \$2,500 initial fee and a \$1,000 fee for reviews (UH ORC Draft Annual Report 2013, Vol. 1).

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In addition to the UH IRBs, there are at least two other external IRBs that may approve UH projects, one at Queen’s Medical Center and the other is Western IRB, a commercial firm in Washington State that is used by institutions to outsource compliance. Concerns have been expressed about liability, lack of local knowledge, the ways local and external IRBs work together, and researchers’ reduced interest in complying with a “distant bureaucracy.” <http://jnci.oxfordjournals.org/content/99/7/502.long>

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## IV. CURRENT ASSESSMENT OF RESEARCH COMPLIANCE AT UH

### A. Methods and Sources of Information

#### 1. Interviews

Interviews were conducted with administrators and faculty who had experience with research compliance at UH. These face-to-face sessions were held with former directors, as well as the current director of the Office of Research Compliance, administrators of units with responsibilities related to compliance, researchers across disciplines at UH Mānoa, faculty representing the community colleges, members of advisory and oversight committees, and mentors to newly appointed faculty. A total of 21 individuals participated in the interviews (one person declined to meet with the RCTF; see Appendix E for list of participants). The interviews were typically completed in an hour and generally consisted of interviewees sharing their research compliance experiences and recommendations, followed by questions from the RCTF.

#### 2. RCTF Fact-Finding

The RCTF conducted various fact-finding activities to gather data relevant to its charge, augmenting information from the interviews and research compliance survey described below. It reviewed federal and state documents, as well as reports from independent policy advisory groups such as the National Science Board (see Appendix F for list of references). These references were used to inform the RCTF's work and for guidance on best practices. Reviews were also conducted on reports issued by previously appointed UH committees with compliance responsibilities to determine whether their recommendations had been implemented. The RCTF also requested from the ORC and EHSO a list of federal and state regulations that impact UH (see Appendices G and H) and a list of standing committees (see Appendix D) that advise the ORC on compliance issues. In addition, the RCTF reviewed the websites, online materials, and policies of peer institutions and compared them to those of UH. RCTF's review of UH's website showed what was being publicly disseminated and what faculty and others undergo when seeking information regarding compliance requirements, applications, training, assistance, and other matters.

#### 3. Survey

##### *Design and Procedures*

A web-based survey was developed to assess faculty, staff, and student experience and evaluation of the compliance structure and process at UH (see Appendix I for survey instrument and Appendix J for survey results). The survey was comprised of 10 sections: Background; Human Subjects (IRB); Institutional Animal Care and Use Committee (IACUC); Biosafety; Laboratory Safety/Security; Chemical Safety; Radiation Safety; Ethical Issues; Additional Compliance Areas; and Institutional

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Practices. The response formats included both closed-ended ratings and open-ended text entry. Respondents answered questions related to only those compliance areas relevant to their work (e.g., IRB, IACUC, etc.). All respondents, however, were asked to complete questions pertaining to Ethical Issues, their involvement or familiarity with additional compliance areas (e.g., classified/restricted/sensitive research information; Health Insurance Portability and Accountability Act; etc.), and the importance of various practices that may assist faculty and staff meet compliance requirements at UH.

Questions pertaining to each compliance area were adapted from items contained in the 2012 Federal Demonstration Project (FDP) Faculty Workload Survey (Schneider, Ness, Rockwell, Shaver, & Brutkiewicz, 2014). Respondents were asked to rate their experiences with various tasks related to each compliance area using the following response options: “not a problem,” “a little problematic,” “somewhat problematic,” “quite problematic,” “very problematic,” and “not applicable/no experience.” Each rating scale was followed by an optional text box for respondents to provide a narrative description of the issue and suggestions they might have for fixing the problem. All compliance areas of the survey also contained a question about the quality of (a) information provided that enabled the respondent to comply with regulatory requirements and (b) training at UH on the specific compliance area involved in the respondents’ research and/or teaching. An optional text box was provided at the end of each compliance section for respondents to provide suggestions that might help them better meet compliance requirements in their research and/or teaching.

Survey length varied depending on which compliance area(s) respondents identified as relevant to their own research or teaching. Based on pilot-testing of the survey, estimated length of time to complete the survey ranged from 10 to 20 minutes. Survey participation was voluntary, and respondents’ identities remained anonymous.

On January 16, 2015, the OVPRI emailed a letter from VPRI Vassilis Syrmos to 3,678 UH faculty system-wide inviting them to participate in the survey via an anonymous survey link. Faculty were also asked to forward the survey to staff and graduate students engaged in research and/or teaching involving human subjects or the use of animals, biological materials, chemicals, radiation, endangered species, or other regulated subjects. Follow-up emails reminding faculty about the survey were sent on January 28 and February 4, 2015. At the request of faculty, the original survey deadline of February 6 was extended to February 20, 2015.

### Participants

Survey participants consisted of 939 UH faculty, staff, graduate students, or other personnel. Respondent characteristics are presented in Table 1. As shown in the table, 92% of survey respondents were tenured (59%) and untenured faculty (33%). Among all respondents, the average length of time at UH was 14.2 years (range = less than 1 year to 47 years; standard deviation = 10.6 years). The majority of respondents were at UH Mānoa (69%) and UH Community Colleges/Maui College (24%). As shown in Table 1, respondents' principal fields of study were diverse. The majority of respondents were in the fields of humanities/arts/architecture (17%), social and behavioral sciences (16%), biological/biomedical sciences (15%), education (10%), and clinical sciences/medicine (8%).

**Table 1**  
**Demographic Characteristics of Survey Respondents**

CHARACTERISTIC	NUMBER	PERCENT
<b>Classification:</b> <ul style="list-style-type: none"> <li>· Tenured faculty</li> <li>· Untenured faculty</li> <li>· Staff member (UH or RCUH)</li> <li>· Graduate student</li> <li>· Other</li> <li>· Total</li> </ul> (4 missing responses)	548 311 33 29 14 935	59 33 4 3 1 100
<b>Campus:</b> <ul style="list-style-type: none"> <li>· UH Mānoa</li> <li>· UH West O'ahu</li> <li>· UH Hilo</li> <li>· UH Community Colleges/Maui College</li> <li>· Total</li> </ul> (16 missing responses)	640 19 43 221 923	69 2 5 24 100
<b>Principal field of study:</b> <ul style="list-style-type: none"> <li>· Agricultural Sciences</li> <li>· Biological; Biomedical Sciences</li> <li>· Business; Law</li> <li>· Clinical Sciences; Medicine</li> <li>· Education</li> <li>· Engineering; Computer Sciences</li> <li>· Environmental Sciences</li> <li>· Humanities/Arts; Architecture</li> <li>· Physical Sciences; Mathematics</li> <li>· Social and Behavioral Sciences</li> <li>· Other</li> <li>· Total</li> </ul> (19 missing responses)	43 134 37 76 96 51 57 157 71 145 53 920	5 15 4 8 10 5 6 17 8 16 6 100

## B. Results

### 1. Areas of Progress and Success with Compliance

#### *Results from Survey*

Documents reviewed by the RCTF clearly indicate that academic institutions nationwide are challenged to effectively implement the increasing and ever-changing federal and state regulatory mandates. In spite of these regulatory challenges, results of the survey suggest that, in some areas, UH is progressing well in fulfilling its compliance responsibilities. For example, while responses of survey participants varied across compliance areas, when asked to rate their *understanding of what was required and why*, the majority of respondents (> 50%) in the following compliance areas indicated that understanding requirements is not a problem: Ethical Issues (75%), Laboratory Safety/Security (68%), Biosafety (54%), and Institutional Review Board (IRB; 52%). The lone exception was IACUC, where the majority (54%) of respondents indicated they experience problems understanding requirements.

Also, more than half of the respondents rated the *quality of information provided to comply with regulatory requirements* “excellent to above average” in 5 of 7 program areas—IRB, Biosafety, Laboratory Safety/Security, Chemical Safety, and Radiation Safety (see Table 2). More than half of the respondents who answered questions related to IACUC and Ethical Issues, however, did not rate the quality of information as positively as for other compliance program areas.

**Table 2**  
**Respondents’ Ratings of the Quality of Information Provided to Comply With Regulatory Requirements**

PROGRAM AREA	RATING		
	Above Average-Excellent %	Average %	Poor-Below Average %
Institutional Review Board (IRB): n=337	58	33	9
Institutional Animal Care and Use Committee (IACUC): n=100	48	38	14
Biosafety: n=216	52	29	19
Laboratory Safety/Security: n= 271	54	33	13
Chemical Safety: n=237	57	36	6
Radiation Safety: n=48	58	33	8
Ethical Issues: n=736	43	42	15

Similarly, more than half of the respondents rated the *training received* at UH “above average to excellent” in 4 of 7 program areas—Biosafety, Laboratory Safety/Security, Chemical Safety, and Radiation Safety (see Table 3); however, respondents did not assign such positive ratings to the training provided by IACUC and Ethical Issues.

**Table 3**  
**Respondents’ Ratings of the Training Received at UH**

PROGRAM AREA	RATING		
	Above Average-Excellent %	Average %	Poor-Below Average %
Institutional Review Board (IRB): n=311	48	39	13
Institutional Animal Care and Use Committee (IACUC): n=96	37	45	18
Biosafety: n=216	54	31	15
Laboratory Safety/Security: n=266	54	32	14
Chemical Safety: n=233	57	34	9
Radiation Safety: n=46	56	35	9
Ethical Issues: n=695	40	42	18

*“I like the Review Category Flowchart on the Human Studies Website to help determine what type of application form to submit—very helpful.”*

*“I actually have not had any training but the materials online were quite self explanatory in my opinion.”*

*“The Rad Safety staff have been very helpful and informative in helping our program to maintain compliance with DOH.”*

**Results From Interviews and RCTF Fact-Finding**

The Office of Research Compliance developed a new website that presents more information on research compliance in one location than previously available. For example, the website provides links to all of the ORC’s programs, other compliance-related offices at UH, compliance policies, resources at other institutions, and news and events. Although it does not contain critical information that would assist faculty in navigating UH’s compliance system, the website is attractive and has links to a wealth of resources.

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*The Good Researcher*, a monthly newsletter, was launched in April 2015 by the ORC and is accessible via its website. The aim of the newsletter is to “generate discussion about the skills necessary to be successful in establishing and running a research program.” Articles may be submitted to ORC, and readers can comment and view the comments from others.

The above initiatives are positive tools that enable the ORC to share information more effectively with its geographically dispersed clientele.

## 2. Areas of Major Concern

### **Results From Survey**

Complying with rules and regulations is greatly dependent on knowing what is required and how to abide by these requirements. Education and training were identified by many survey respondents as areas where improvements can and should be made at UH in order to prevent problems.

As shown in Tables 2 and 3, although many were pleased with the quality of information and training received, a cluster of respondents were not. When asked to rate the *quality of the information provided to comply with regulatory requirements*, 13% or more of the survey respondents selected “poor to below average” in Laboratory Safety/Security (13%), IACUC (14%), Ethical Issues (15%), and Biosafety (19%). Also, 13% or more of the respondents in these program areas, as well as in IRB, rated the training received at UH as “poor to below average” as follows: IRB (13%), Laboratory Safety/Security (14%), Biosafety (15%), IACUC (18%), and Ethical Issues (18%).

▶ *“What are the guidelines and where can we find them?”*

*“Training modules offer no real training but are done just to fulfill federal requirements.” (IACUC)*

*“I have not yet been informed of ethical training that I should take at UH. I am applying principles that I have learned at previous institutions.” (Ethical Issues)*

*“The requirements are onerous and there isn’t a simple way to get at the information needed. It took me talking to many people and making many phone calls before I understood minimally what was required.” (Biosafety)*

*“There is an urgent need to assist young investigators in obtaining permits in a timely fashion. UH could focus more on facilitating compliance to reasonable, well-documented regulations, rather than arbitrary rules and ‘one size fits all’ regulations. Over-regulation particularly in the microbial acquisition and use area is a serious problem. Permits are not provided in a timely fashion and the review system is cumbersome, designed to fail. The reporting system is particularly cumbersome. When young researchers cannot obtain permits to do reasonable research in a timely fashion, the entire University of Hawaii suffers. Some give up, others leave. UH does NOT have a good national reputation in this regard, and such impediments foster discontent and difficulty in recruiting new faculty.”*

Although there were respondents in each of the compliance area surveyed who 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” (see Table 4 below). Within IACUC, the major areas of difficulty were 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%). In Biosafety, 56% of the respondents reported varying degrees of 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 whose work involves biosafety, as 23% rated this task as “very problematic.” This percentage is twice the proportion of respondents who rated compliance tasks as “very problematic” in any of the other areas surveyed.

*“Filing the application is a major hurdle, but it is nothing compared to the long, long wait for approval. It’s like throwing the application in a deep, dark hole because there’s no feedback, and it could take years.” (Biosafety)*

*“Very cumbersome and takes a lot of time. It really hinders getting funded work done in a timely fashion. It actually deters me from ordering positive controls I need for my research.” (Biosafety)*

**Table 4**  
**Program Areas Where a Majority of Respondents**  
**Indicated They Encountered Problems**

PROGRAM AREA	NOT A PROBLEM %	A LITTLE PROBLEMATIC %	SOMEWHAT PROBLEMATIC %	QUITE PROBLEMATIC %	VERY PROBLEMATIC %
Institutional Animal Care and Use Committee (IACUC)					
· Understanding what is required and why: n=105	46	24	13	9	8
· Preparing IACUC protocols and consent forms for initial review: n=98	36	24	22	11	7
· Completing annual IACUC reviews and three-year renewals: n=95	49	20	22	7	1
Biosafety					
· Filing applications to comply with state requirements for the use of micro-organisms: n=154	43	13	14	7	23

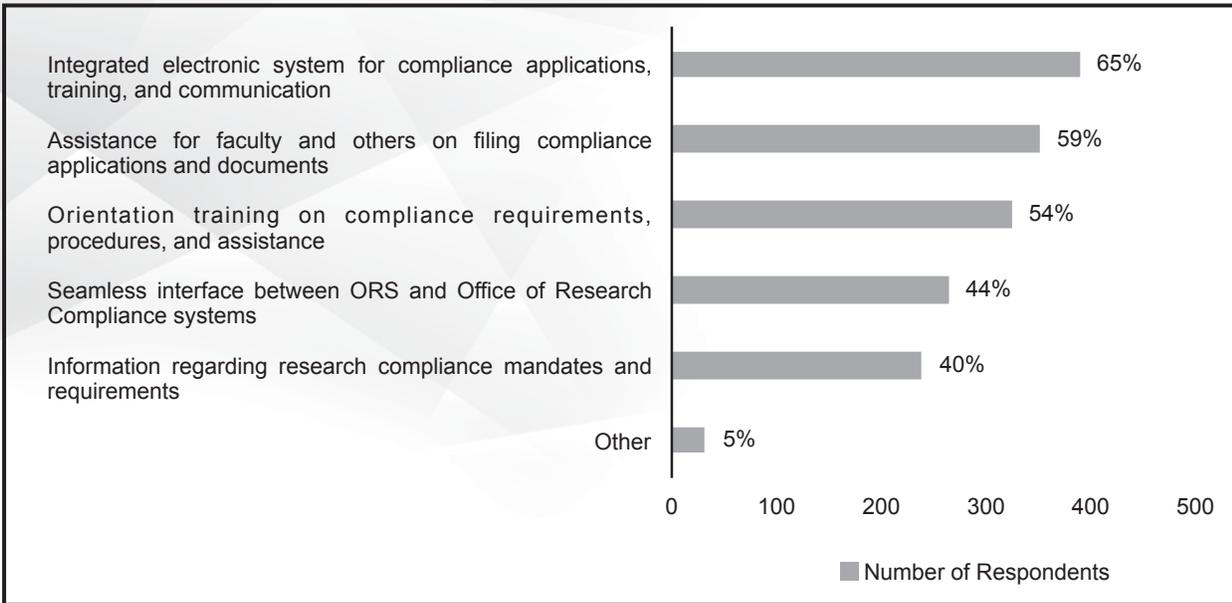
Results from the survey indicate educational outreach and training are particularly needed on non-UH Mānoa campuses. When asked “*what would be most important for you in meeting regulatory requirements in teaching and research?*” the top choice for community college and UH Maui College respondents was orientation training on compliance requirements, procedures, and assistance for new faculty, staff, and graduate students (58%), whereas UHM respondents selected an integrated electronic system for compliance applications, training, and communication with faculty and others (65%) (see Figures 1 and 2 below). In response to the aforementioned question, the highest ratings among respondents from all campuses combined were 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%).

*“Training is a real issue at UH.”*

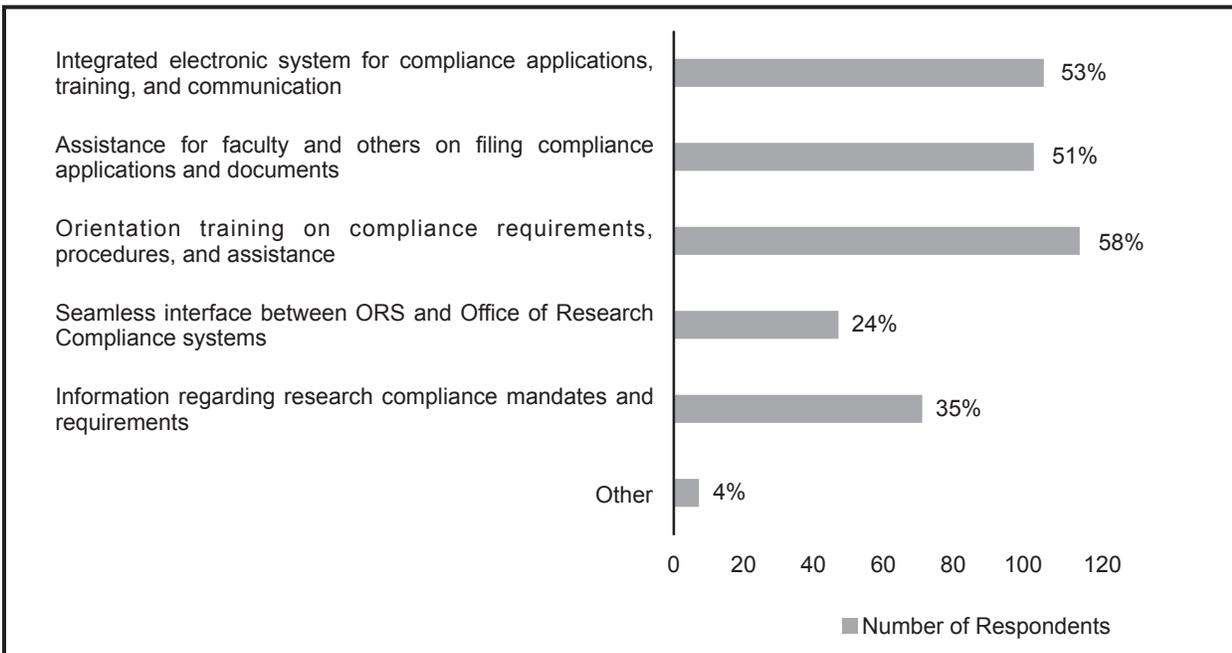
*“An integrated electronics system for compiling applications and training information would be very helpful for storing relevant documents.”*

*“Instead of producing a plethora of documents for researchers and teachers to follow, please provide support by hiring professional and experienced staff to train and enable research at UH instead of hampering and disabling research at UH.”*

**Figure 1**  
**Responses to What's Most Important for You in Meeting Regulatory Requirements**  
**UHM, 598 Responses**



**Figure 2**  
**Responses to What's Most Important for You in Meeting Regulatory Requirements**  
**Community Colleges/Maui College, 195 Responses**



More comprehensive training on compliance procedures would alleviate some of the issues related to information and outreach. Both IACUC and Biosafety deal with complex compliance issues, and it is clear from respondents' ratings and open-ended responses that more training especially focused

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on the protocols for these two areas would be helpful. Several interviewees and survey respondents mentioned the desire for a flow-chart outlining the requirements and how to fulfill them, with yes/no options, where researchers could follow a checklist and secure the compliance protocols needed for their specific research project.

The variance between survey respondents from UH Mānoa, the Community Colleges, and UH Hilo suggests there are differences in the training needs of those who primarily teach and those who conduct research. There is a perception that the current compliance process does not accommodate the interests and needs of classroom instruction or undergraduate STEM research. Several of the survey comments suggested that a separate compliance track for instructional and undergraduate STEM research would ease the compliance process, as would the assignment of ORC personnel specific to education. The UH teaching institutions and faculty require compliance training and protocols that are more aligned with their needs and supportive of undergraduate STEM education.

### ***Results From Interviews and RCTF Fact-Finding***

The interviews and fact-finding underscored the disparities in educational outreach and training among UH campuses, with UH Mānoa faculty in a more advantageous position than their non-UH Mānoa colleagues. Moreover, faculty whose teaching and/or student projects involved humans, animals, or microorganisms found compliance particularly troublesome, as the compliance information and procedures were geared toward research and not instruction. This concern was noted as an especially important issue for new faculty and instructional faculty and staff. Interviewees mentioned that innovative research and undergraduate STEM research are often interdisciplinary, making it more difficult to navigate the current UH compliance system. Moreover, training was offered less often than needed, was conducted at inconvenient times, was not easily accessible for those not on the UH Mānoa campus, did not contain the information required by regulatory agencies, and was sometimes taught by staff who did not possess the requisite knowledge. For all these reasons, some interviewees suspected there might be faculty, staff, and students who are engaged in work that is not in compliance with mandated regulations.

The need to improve communication regarding compliance matters was a consistent theme among those interviewed and in the RCTF's fact-finding. ORC's new website is a major and positive step toward addressing this problem, but much more must be done to help guide the research community through the complexity of internal and external regulatory requirements. Effective adherence to compliance regulations requires an environment in which administrators, faculty, staff, and students are supportive of one another as they work toward common goals. Frustration and non-compliance increase when there is lack of understanding of the regulations, who must comply, and how to successfully navigate the approval process. Interviewees echoed the survey respondents' comments that the present situation should be replaced by a culture of service and mutual support.

There was dissatisfaction with bureaucratic demands, the reliance on time-consuming paper documents, and the absence of technology to improve efficiency, all of which placed excessive demands on researchers' time. To illustrate, in response to the question of how many copies of each application are required, the answer from IACUC was "fourteen (14) copies and the signed original application must be submitted" (<http://manoa.hawaii.edu/researchcompliance/iacuc-fags>).

Concern was expressed that some of the most knowledgeable and helpful ORC staff members had been released from their positions and their responsibilities assigned to less- knowledgeable individuals. There were fears of the possible negative consequences if gaps left by these employees were not filled, such as the absence of needed information and assistance with compliance requirements by helpful and courteous employees, longer delays for permit approvals by the DOA, and mounting frustration with the UH compliance system.

*"Work on building the infrastructure for a 'community of researchers' at UH who can work together to conduct research and resolve practical and ethical issues that they are facing in their work."*

*"The system needs to push everyone on the service side to be mindful of their service being not just lawful, but to make the system run efficiently, particularly being timely and helpful to the research tasks, and hence to the larger issues of success for UH research endeavors."*

*"There seems to be a 'police' attitude rather than a facilitating attitude, this should change. Many of the infractions that probably occur in compliance are through ignorance, not intention."*

The 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 programs and facilities. Although there are times when information cannot and should not be widely disseminated, in most situations information can be judiciously shared, particularly with faculty and staff who are responsible for resolving problems and making improvements. Administrators and faculty are perplexed by ORC's overly restrictive policy relating to compliance information, especially when documents now withheld had been previously shared, and 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. Standard operating procedures should be followed and, if not available, should be developed for informing the UH community about internal and external reviews as well as committee reports. Standard procedures for contracting consultants are also needed and at the very least should include the requirement for written reports.

Interviewees, including administrators of compliance-related units, called for greater collaboration among the offices and individuals with research compliance responsibilities. There was recognition that duplication can be reduced and efficiencies achieved when compliance functions do not operate in silos. To illustrate, when major IT systems are purchased by a program without consultation with others, the administrative burden often increases for faculty who must learn and use yet another system that inevitably is not integrated with existing IT systems. Many interviewees thought greater coordination would occur if the ORC were administratively placed under the VPRI rather than UH Mānoa VCR. In addition, research activities are increasing on non-UH Mānoa campuses, all of which are overseen by the VPRI and whose needs have received scant attention in the past.

**Recommendations From Prior Reports**

The Research Advisory Board’s 2014 evaluation of UH research reports issued during the past two decades indicated most of the compliance-relevant recommendations had not been implemented. Of the 23 recommendations outlined in four reports, 10 were determined to be straightforward, 5 were complex, none presented major challenges, and the remainder were not categorized (see Table 5). The two recommendations that might be considered “done” were to (1) fully fund the Environmental Health and Safety Office (EHSO) and the Laboratory Animal Services (LAS) and (2) make CHS training and certifications available online. Some progress was made on the recommendation to restructure the Office of Planning and Facilities to provide responsive service to labs and make outsourcing of services available to improve efficiency and response time.

**Table 5  
Research Advisory Board’s Evaluation of Recommendations from UH Reports  
During the Past Two Decades**

REPORT	RECOMMENDATION	STATUS			
		“Done”	Straight-forward	Complex	Major Challenge
Forrester	Provide open accounting, annually or regularly, of how funds invested in research are allocated.		X		
Raleigh	Reduce response time for review processes by CHS and LAS		X		
	UH should provide better risk management and insurance coverage for employees and committee members of regulatory support organizations.			X	
	Adequately compensate faculty members who serve on CHSs.		X		
	Combine multiple CHS reviews when possible to fast-track established projects that have already done extensive review.		X		

Table 5 (continued)

REPORT	RECOMMENDATION	STATUS	TYPE OF RECOMMENDATION		
		“Done”	Straight-forward	Complex	Major Challenge
Raleigh	LAS admin should respond to PI requests without delay.		X		
	Provide incentives for faculty participation on IRBs		X		
Hashimoto	Provide liability insurance for UH and RCUH.		X		
Raleigh	Recruit additional IT staff to develop and maintain software information systems and interfaces; collaborate with other institutions w/ ERA in place.		X		
	Stress a flat or distributed, rather than centralized or hierarchical, structure for admin research services.		X		
	Decentralize the processes and accountability.		X		
	Support timely and online training for service providers and customers (research regulatory support services).			X	
	Fund research regulatory support and increase with demands for services.			X	
	Reduce response time for review processes by IRB and LAS.			X	
	Fully fund Office of Environment Health and Safety and LAS.	X			
	University should form 2 CHSs that meet every 2 weeks.				
	Make CHS training and certifications for PIs, staff, and students available online.	X			
	CHS should implement Applicable Service Standards to provide timely responses to PIs.				
	Ensure timely CHS reviews.				
	Restructure PFMO to provide responsive service to labs and make outsourcing of services available to improve efficiency and response time.	Some Progress			
	Move from a control-oriented to a service-oriented environment.			X	
	Ensure that research management includes all steps.				
Establish data warehouse.					

Recommendations for distributed services (and accountability) for administration and support of research are understood as requiring greater and more timely support to faculty, staff, and students in

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labs and in the field. While legal accountability for research compliance matters rests primarily with upper-level administration (ITAR and Export Controls are exceptions), faculty and staff may also be legally liable. Three recommendations concern the need for UH to manage risks by providing legal support and liability insurance for UH and RCUH employees in regard to compliance and regulatory matters. These recommendations might help to ensure a balance between avoiding risks and taking some risks that are essential to conducting research, and they are consistent with another recommendation that research administration move from a control-oriented to a service-oriented environment. The subject of liability insurance has not been taken up by the RCTF.

The recommendations in the reports also include expanding research regulatory support as demands increase and providing open accounting of such research investments. Additional IT support was recommended to provide improved information systems in collaboration with other institutions (e.g., the Kualii Foundation). Data “warehousing” was recommended to minimize time spent on manual data entry, to allow interchange of data across software platforms, and to provide information for improved reporting.

Institutional review committees—such as those related to human subjects (IRB) and animal subjects (IACUC)—were the subject of the bulk of the recommendations from prior reports. These included making the review process more timely and responsive to the needs of PIs and providing incentives for faculty participation in these critical committees. The requirement for timely and efficient laboratory renovation and maintenance led to a recommendation for restructuring facilities management services. Although some of the recommendations conflict with current trends towards cost-saving, it is assumed that they will result in greater overall efficiency for the research enterprise.

In addition to these reports, the Permit Process Review Committee, a group convened by the Department of Agriculture (DOA) in partnership with UH to determine how the permit process for importation of microorganisms could be streamlined and improved, developed recommendations that have not been addressed. The work was undertaken to address longstanding problems with the permitting process that impeded the productivity of researchers, jeopardized grant-funding, and negatively affected the education of students and the STEM workforce. The Committee’s report was released in 2013 and, despite participation in the development of the report and commitment to follow through on the recommendations for UH, few of the recommendations were completed by the ORC.

The failure to act on recommendations often results in persistent problems, increasing faculty frustration, decreasing productivity among administrators and faculty who must continually deal with dysfunctional operations, and leading to the convening of new advisory committees which often identify the same existing problems. For example, although the Permit Process Review Committee focused on only one facet of research compliance, some of its recommendations parallel the actions called for in prior reports evaluated by the RAB, such as these:

- Develop a pre-application process within the UH to assist researchers to efficiently file permit applications with a high probability of securing approval. The process should be transparent and widely shared within the University community.
- Develop, in collaboration with the DOA, an IT-based application process which will improve accountability and efficiency. User feedback, pilot testing, and training are necessary components in the development and implementation of the new electronic system.

These and other themes identified in previous reports also appear in the RCTF’s survey, interviews, and fact-finding. There is currently no identified process for administrators to communicate to faculty what actions were taken, if any, on the recommendations from officially convened committees, task forces, and consultants.

Lastly, even administrators of related units called for greater collaboration among the offices and individuals with research compliance responsibilities. There was recognition that duplication can be reduced and efficiencies achieved when compliance functions did not operate in silos.

### 3. Areas Requiring Greater Attention

There are UH research activities that require compliance oversight, but for which there is little or no institutional support. To assess this situation, the RCTF survey asked respondents to select the statement that best describes your involvement or familiarity with the following additional compliance areas, and offered three choices: (a) relevant to your work; (b) familiar with, but not relevant to your work; and (c) not applicable. Table 6 presents the number of respondents who indicated that the area was relevant to their work.

**Table 6**  
**Number of Respondents Whose Work Entails Regulatory Areas**  
**for Which the RCTF Found Little or No Institutional Support**

AREA OF WORK	NO. OF RESPONDENTS
Classified/restricted/sensitive research information	180
Currency movement between countries	35
Endangered Species Act	62
Federal Cave Protection Act	8
Health Insurance Portability and Accountability Act (HIPAA)	189
International Traffic in Arms Regulations (ITAR)/Export Controls	33
Locational permits	128
National Environmental Policy Act (NEPA)	68
Native American Graves Protection and Repatriation Act (NAGPRA)	14
Unmanned Aerial Vehicles (UAV) and/or Drones	31
Unmanned Underwater Vehicles (UUV) and/or Deploying Moorings	37

Note. 43 respondents indicated that diving safety was relevant to their work. There is institutional support for this program (see Section II, C. Institutionally Self-Imposed Requirements of this report).

As shown in Table 6, there are a considerable number of survey respondents who are involved in activities that require regulatory oversight but for which there is little or no institutional support. For example, there are many faculty whose research require locational permits from federal (e.g., Federal Aviation Administration, U.S. Coast Guard) or state (e.g., Department of Land and Natural Resources) agencies and departments but, to the RCTF's knowledge, no information, training, or assistance is provided by the UH to assist in meeting these requirements. 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=182); classified/restricted/sensitive research information (n=175); and locational permits (n=124). However challenging it may be, the 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.

*“Where environmental documents are required, there is no assistance in getting those done or in submission. At one point, I had a VP Administration refuse to sign an EA that I had prepared for a project. And the same VP refused to sign a required air emissions permit (for Hawaii DOH) for a project. Unhelpful to say the least. The biggest problem I have had is in non-responsiveness of Office of General Counsel. I have to obtain Rights of Entry to conduct field surveys and it can take months to get a response and, in one case, it's been 18 months waiting for a determination and no likelihood that I will get a response. The funds for that work are long since expended on other field research sites.”*

#### 4. Best Practices

The National Science Board's Task Force's report on Administrative Workload for Federally Funded Research (2014) articulated the need to streamline and modify regulatory requirements “interfering with the conduct of science.” To meet this need, the NSB Task Force recommended

*“...that Federal agencies collaborate with research institutions, and organizations representing investigators and institutions, to identify and disseminate model programs and best practices... that could be adapted for use at other institutions.”*

During the search and review of compliance-relevant reports, online materials, and websites, the RCTF identified rich resources that should in future efforts inform “best practices” and strategies for assisting the UH research community in navigating the compliance regulatory landscape. Example resources include the following:

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- National Council of University Research Administrators (NCURA 2010). *Sponsored Research Administration: A Guide to Effective Strategies and Recommended Practices; Chapter 15 Research Compliance*. [http://www.utexas.edu/research/osp/resources/ncura\\_documents/research\\_compliance\\_chapter\\_1500.pdf](http://www.utexas.edu/research/osp/resources/ncura_documents/research_compliance_chapter_1500.pdf)
  - National Council of University Research Administrators (NCURA 2014). *Regulation and Compliance: 2014*. <http://www.ncura.edu/PublicationsStore/ProductInfo.aspx?productcd=40675-037>
  - University of Minnesota. *Research Education & Oversight: Guide to Research Compliance*. [http://research.umn.edu/reo/oversight/guide.html#VWPHUU\\_BzRY](http://research.umn.edu/reo/oversight/guide.html#VWPHUU_BzRY)
  - University of California, Merced. Research Compliance and Integrity: Handbook. <http://research.ucmerced.edu/departments/research-compliance/handbook>
  - Stanford University. Research Policy Handbook. <https://doresearch.stanford.edu/policies/research-policy-handbook>
  - University at Albany, Division for Research. <http://www.albany.edu/orrc/>
  - University of California, Irvine, Office of Research. <http://www.research.uci.edu/compliance/index.html>
  - Columbia University, Research Compliance and Training. [http://www.columbia.edu/cu/compliance/docs/training/Certification\\_Program/index.html](http://www.columbia.edu/cu/compliance/docs/training/Certification_Program/index.html)
  - Harvard T.H. Chan School of Public Health, Office of Regulatory Affairs and Research Compliance. <http://www.hsph.harvard.edu/regulatory-affairs-and-research-compliance/>
  - North Carolina State University, Sponsored Programs and Regulatory Compliance. <http://research.ncsu.edu/sparcs/compliance/>
  - Boston University, Research Compliance. <http://www.bu.edu/orc/>
  - Massachusetts Institute of Technology, Office of Sponsored Programs. <http://osp.mit.edu/compliance>

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## V. SUMMARY OF FINDINGS AND RECOMMENDATIONS

The detailed findings of the RCTF's assessment of the state of research compliance at the University of Hawai'i (Section IV) can be brought together in many different ways. Here, the RCTF chose to organize them by a broader view of the characteristics of the desired outcomes, and the implementation pathways to achieve them. The RCTF's three overarching recommendations are presented below. Within each recommendation, summary findings of the assessment and specific steps that should be taken to achieve the desired outcomes are delineated.

The University of Hawai'i must further develop its research compliance structures and mechanisms to promote more effective and efficient relationships among all stakeholders. It is important that the culture of research compliance at UH be dramatically improved. This will require significant efforts, including adopting the best practices of Research I universities throughout the U.S. wherever possible.

### 1. Build an Effective Research Community in Compliance With Statutes and Regulations

As suggested in Section IV, Current Assessment of Research Compliance at UH, faculty have largely succeeded in their projects because they are passionate about their research and have been willing to devote extra hours to overcome burgeoning compliance constraints. These extra hours include struggling with inadequate and inefficient presentation of information about regulations affecting research and the training needed to understand and cope with restrictions. Large research groups preserve and share knowledge, and thus have intrinsic advantages compared to the many individual or small-group investigations. University compliance structures are especially daunting for newer faculty and for faculty whose primary responsibility is teaching, and the growing focus on interdisciplinary research and STEM education demands a higher degree of coordination and cooperation from research compliance structures. Violations of regulations occur generally because of ignorance of the regulations or lack of knowledge about standard mitigation procedures.

The University of Hawai'i must focus on building its research community that includes faculty, students, staff, and administrators who are involved in the research enterprise and in educational activities that intersect research compliance requirements. This community needs to pull together in the same direction. Research compliance activities must improve compliance support to all proposed and approved UH faculty research endeavors. The barriers to effective research and research education must be lowered while maintaining compliance with regulations that are becoming increasingly complex.

*"It has been my experience that while staff are very concerned about compliance, it is not always a priority for PIs and/or the leadership. It would be great to know and to reassure staff that while we get the brunt of the push back on compliance, there might be a position/place higher up where we can voice our compliance concerns without fear of retribution. Staff underneath PIs are constantly in an awkward position to enforce compliance."*

The Office of Research Compliance does not have the mandate to address all research compliance matters. As examples, data security regulations are the purview of ITS, while laboratory safety responsibility is within EHSO, whose focus is primarily UH Mānoa. Compliance communications are random, dispersed, and disorganized. Most such communications are not consistently and effectively announced nor available to the UH community. Often faculty, staff, and students must rely on the "coconut wireless" or search UH websites for new information that is important but unknown to them. Knowledge, including regulatory requirements, best practices, and required procedures, must be clear, organized, up to date, online, and easily accessible. This is critical especially because regulations affecting research are rapidly growing and sometimes inconsistent. All UH compliance rules and procedures (and draft modifications) should be accessible from a single web page that should serve as the definitive source. They should also include links to compliance agreements with the government, links to the laws or rules that affect compliance, and links to useful compliance resource sites. The pages should have flowcharts and decision trees that guide PIs through the processes and methods of determining and meeting their compliance responsibilities. Initially these might be schematics of existing procedures, but they can also be used to streamline the work of the compliance groups. Biosafety and IACUC should be the first targets for immediate improvement, as faculty rate these areas highest in problems encountered.

Online tools for faculty and administrators to share knowledge efficiently and widely are required. Establishment of a moderated research compliance bulletin board with topical forums is essential. Questions can be easily posted and shared with the community, with previous discussion threads available to those who might need them. These can be secured from public view as required.

Faculty and students require training about research compliance issues, as many do not know the procedures or even that they are subject to the regulations. Adherence to regulatory requirements increases when users understand what is required and when compliance procedures are not onerous. Individuals serving on research compliance committees should also receive orientation and training. Training in customer relations should be provided to compliance staff. Training resources need to be made available online to the extent possible so that they are available when needed, either for orientation or for refreshing individual knowledge. Online certification should be used to the maximum extent possible, with in-class or in-laboratory training provided as requested/needed.

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The growth of research in undergraduate STEM education requires enhanced attention to the compliance needs of instructional faculty and staff, including those conducting research at the UH Community Colleges, UH Maui College, UH Hilo, and UH West O‘ahu. Many undergraduate research projects have shorter time-scale needs and are highly interdisciplinary. Facilitating the expansion of research in STEM education should be a continuing goal, especially considering that teaching faculty have less time available to navigate complex compliance issues. Compliance-related training and support specific to STEM undergraduate research and research-related education, both in and out of the classroom, is needed, particularly at non-UH Mānoa campuses.

The RCTF recommends the appointment of a knowledgeable senior faculty member to the position of research compliance ombudsman with a 0.5 FTE position to help solve problems, help guide the development of a shared knowledge base and access methods, and promote the shared partnerships that are required to build an effective and compliant community of researchers. This person should chair the Oversight Committee discussed below.

## **2. Improve Compliance Efficiency for the UH Research Community That Balances Risks, Costs, and Benefits**

The University of Hawai‘i is a member of the Federal Demonstration Partnership (FDP), which is a coalition of universities and federal agencies. The FDP mission is to streamline interactions between these groups, including in matters of research compliance. According to the report of the National Science Board Task Force on Administrative Burdens (NSB, 2014),

*“[T]he 2005 Federal Demonstration Partnership (FDP) survey of investigators found that principal investigators (PIs) of federally sponsored research projects spend, on average, 42 percent of their time on associated administrative tasks. Seven years later, and despite collective Federal reform efforts, a 2012 FDP survey found the average remained at 42 percent.”*

During Phase V of the FDP, the Research Compliance Standing Committee and several subcommittees ([http://sites.nationalacademies.org/PGA/fdp/PGA\\_054588](http://sites.nationalacademies.org/PGA/fdp/PGA_054588)) were established. The Research Compliance Committee “reviews existing and new administrative requirements imposed by federal regulations and program officers related to but not limited to the human research participant protections, animal use and care, conflicts of interest (individual and institutional), objectivity in research, and export controls.” Its focus is on “harmonization of requirements across federal agencies, reduction of redundancies and identifying good practices.”

One outcome is that the FDP Human Subjects Protections Subcommittee issued the “Practical Guide for Reducing Regulatory Burden” ([http://sites.nationalacademies.org/PGA/fdp/PGA\\_061067](http://sites.nationalacademies.org/PGA/fdp/PGA_061067)). The introduction to the guide states:

*“In an effort to understand the factors associated with the increased administrative burden in human subjects research, a group of faculty members, administrators, and federal agency employees held a brainstorming session at an FDP meeting in 2008.*

*The striking consensus arising out of this session was that much of the regulatory workload does not come from the regulations, but rather from overly burdensome institutional policies created to implement these regulations.”*

Two important practical recommendations in the guide are of concern: “Just-in-time research compliance,” and the concept of “triaging” research compliance activities. Both speak to timing and efficiency of research compliance, a necessary part of reducing faculty workload. This practical guide also provides a model for other areas of research compliance efficiency.

*“Work to lessen, not increase, the paperwork burden on faculty. The advent of systems like Kualu and MyGrant have significantly increased paperwork workloads. If Compliance could actually give faculty more help, this would be a refreshing and welcome change!”*

There are more and less desirable methods of meeting research compliance requirements. Such requirements that are external to the University of Hawai‘i could be met by simply eliminating research activities; in some ways this would be very efficient, insofar as it would eliminate the need for research compliance activities. However, universities are not just places of knowledge dissemination; they are distinguished by knowledge creation, which is a result of active research. Conveying this new knowledge to students in the classroom, the laboratory, and the field is an exciting, vital part of the University. Training students and staff in how to conduct research using both standard and experimental techniques is a critical role for the faculty. Engaging undergraduates in research is an important tool for increasing STEM participation, especially in under-represented student groups. Therefore, restricting research activities must be done carefully. Every effort should be made to smooth pathways for teaching faculty to involve undergraduate students in STEM research, including navigating research compliance.

Faculty PIs (and in most aspects, the University) are held responsible for compliance. The compliance implementation groups under the auspices of ORC, ORS, and EHSO are there to assist them. In other words, faculty are clients. And the success of these compliance groups must be measured in terms of client success and satisfaction, as well as the avoidance of violations.

The ORC should have knowledgeable staff who will reach out to faculty and assist them to meet research compliance requirements. As discussed previously, several people interviewed and/or

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responding to the survey expressed concern about the termination of competent and helpful staff with historical institutional knowledge which may now be lost.

Transparency is an important element of compliance—it is essential for building and maintaining the UH research community. Except for very narrowly defined areas of national security, there is no need for secrecy. Committee memberships and any compliance agreements with the government should be publicly available. Committees should have regular turnover. Members should be nominated and selected by administration and faculty external to the compliance activity committees.

Accountability is a basic principle of good management, and two-way accountability is essential to an effective and efficient research community. Although there are a few situations in which information should not be widely shared (e.g., when public safety is jeopardized), in most cases the information should be available to the UH community. This is particularly true for reports relating to the functioning of research compliance at UH, which should be shared with administrators and faculty groups with responsibility for the oversight and review of compliance programs. Without complete and relevant information and data, it is difficult, if not impossible, to make improvements.

The University's compliance groups should produce annual reports and plans. These should include information about activities, committee meetings, budgets, peer group comparisons, and long-term planning. In the many reports commissioned and received over the decades relating to compliance issues, a recurring concern was the lack of response, or lack of any documentation of response, to any of the previous reports. It was not clear that the recommendations in each of those documents had received attention or, if they had received attention, what action if any was planned or taken in response. While we do not doubt that the documents were shown respect and very likely generated actions, there is no audit trail that allows us to identify what those actions were. A useful corrective action to take would be the development of an ongoing tabular audit that assists the responsible administrator, as well as the UH community, in identifying at a glance the progress of actions relating to these recommendations, thus expediting identification of next steps. At a minimum, such documentation could reduce wastage of effort and redundancy among the recommendations. An example of an Outcome of Report Recommendations table that can be used to monitor follow-up actions can be found in Table 7.

The RCTF's investigation of research compliance yielded an unexpected finding: the processes surrounding research compliance at UH are almost impenetrable. Even after one year, a knowledgeable group of RCTF members who were informed by interviews, a broad survey, and numerous fact-finding activities could not describe the entirety of the UH research compliance structure, let alone comprehensively assess its components. Moreover, task force members could not readily navigate the terrain of research compliance at the University without considerable

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mutual consultation. This underscores the RCTF's finding that a great amount of effort is required to negotiate the corridors of adherence to regulations and recommendations. While the responsibility for this complexity cannot be laid at the doorstep of UH's research enterprise alone—much of the difficulty arises from the interpretive challenges posed by federal and state regulations—it creates a disproportionate demand on the time of the investigators that distracts their attention from the research subject matter.

To improve service and make most efficient use of scarce resources, compliance committees must streamline their procedures. A proposal for any new form should explain how it will improve things compared to existing forms. New forms should be justified in terms of actual federal, state, or UH requirements. Forms must be beta-tested by those who will use them. The average measured user-time burden to complete each form should be specified on the form. The total additional burden for each proposed form should be estimated across the UH System.

There are many compliance areas in which technology can be used to ease the administrative burden on faculty and improve the efficiency of the compliance process. These areas include, but are not limited to, filing applications, enrolling and engaging in training, tracking approvals, and requesting information and assistance. There must be a compelling justification for continued use of paper forms. Otherwise forms should be web-based, form-fillable, and able to be signed electronically.

Technology should be interoperable and available in areas where it presently is not, especially ORS and ORC, where it can be used to facilitate pre- and post-proposal compliance activities. Purchases of major IT systems by ORC and related units should be reviewed by a central coordinating body to ensure that they are integrated with each other to the extent possible. The initial purchase and installation costs are generally recognized, but maintenance costs are less considered. What is often overlooked is the exorbitant cost of faculty time and effort to file reports and data regarding the same subject on two different systems. These burdens negatively affect the research success of UH and also hinder the advancement of STEM education.

Facilities Management has an important role in developing an effective and efficient compliance system, notably in disaster planning and management. This is an area that deserves attention but was beyond the scope of the RCTF. Another group should be tasked with reviewing Facilities Management's current structures and responsibilities in relation to research compliance and determining how they can be improved and better coordinated with those of other UH units that deal with compliance.

### **3. Reorganize to Enable the UH Research Community to Be More Successful and Efficient, While Maintaining Compliance With Regulations**

While necessary, university research compliance activities are often not productive—they may act like friction, dissipating the overall energy of the research community. Some costs of compliance are recoverable as overhead from funding agencies, while much of the costs are not recovered. In particular, the time that faculty, project staff, and students spend on compliance is not recoverable. Barriers to collaboration among research administrative units and between campuses are costly.

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Relationships among the UH research community must be strengthened to cope with the growing regulatory burden. Stronger relationships should lead to an efficient compliance ethic throughout the research community.

ORS pre-proposal and post-award services are not integrated with relevant ORC activities. Interoperability of electronic systems between ORC and ORS (both pre-proposal and post-award) is essential to improve communication, collaboration, and efficiency. There should be greater collaboration between ORC and other units, such as Information Technology Services (ITS). ORC can benefit from the expertise of these other units. The VPRI should provide the leadership and facilitation for collaboration among ORS, ITS, RCUH, and the UH Business Process Council to assist ORC and EHSO to provide seamless services.

The ORC should report to the UH Vice President for Research and Innovation (VPRI). The VPRI has oversight over all campuses in the UH System, and every campus has some activities that deal with research compliance issues. While the ORC currently reports to the UH Mānoa Vice Chancellor for Research, compliance issues and activities are not restricted to that campus alone. As mentioned above, there are also other entities besides ORC that are responsible for research compliance. This reorganization of reporting structure is also needed for consistency across campuses and units. It will increase transparency and accountability, and it will enable a realistic and comprehensive assessment of budget needs. The UH System level is the appropriate level for oversight of purchase of major technology and IT systems supporting compliance. Only the VPRI can ensure that research compliance services are distributed across the UH System and that authority is appropriately delegated while responsibility is consolidated. The reorganization will have impact on the functions currently assigned to administrators (e.g., UH Mānoa VCR and VPA) at both the campus (e.g., EHSO) and System (e.g., Facilities Management) levels. Overlapping functions should be reviewed to resolve problematic issues and to foster greater collaboration among all units with compliance responsibilities.

*“Our current system is fragmented. Other institutions FACILITATE regulatory requirements for researchers with the implicit understanding that this leads to more productive research by streamlining the process of fulfilling requirements and streamlining the access of information. Many also streamline the information itself to highlight what is relevant for particular areas of research. That message has not re[a]ched the UH offices in charge of regulatory issues.”*

There should be a permanent joint committee of faculty and administrators that has oversight of the state of research compliance at UH. The faculty research compliance ombudsman should chair the Oversight Committee. This committee should “stand alone” and not be populated by staff or committee members from the different compliance groups. Membership should turn over slowly but regularly to maximize and sustain institutional knowledge.

The committee overseeing compliance should review annual reports from the compliance groups as well as annual customer satisfaction reviews. The committee might be used as a source of nomination of faculty for committees. Finally, the oversight committee should also address substantial issues that arise.

**Table 7**

**Outcome of Report Recommendations: Sample Table**

The table below presents a format for monitoring the outcome of recommendations contained in the reports by committees, task forces, and consultants established or contracted by UH administrators. Updates to the tables should be available to the University community to enable tracking of implementation actions. The following sample table presents recommendations from the present report, with task, agencies, and action officer to the recommendations and timeline delineated for the subtopics of each major recommendation. It is intentionally incomplete to serve as a template for mapping courses of action.

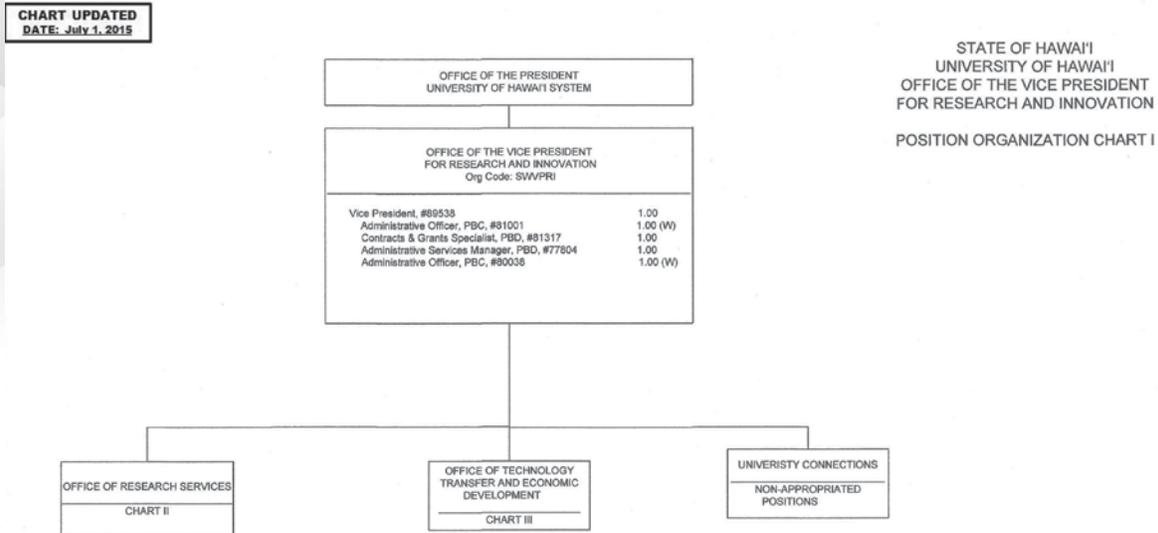
RECOMMENDATION	TASKS	AGENCIES	ACTION OFFICER	TIMELINE
<b>1. Build an effective research community in compliance with statutes and regulations</b>	a. Improve and streamline web-based information about regulatory requirements, required procedures, and best practices.	ITS, ORC	ORC Director	1 year
	b. Target Biosafety and IACUC for immediate improvements.	ORC	ORC Director	1 year
	c. Provide research compliance services to faculty engaged in research activities for which there is little or no support including those involving HIPAA privacy rules, classified/restricted/sensitive research information, and locational permits.			
	d. Improve customer service to assist faculty and students; provide training in customer relations to compliance staff, as well as all other UH research support units.			
	e. Enhance education and training, especially on non-UHM campuses			
	f. Provide research compliance training and support STEM undergraduate research and research-related education			
	g. Appoint a knowledgeable senior faculty member to a Research Compliance Ombudsman position			
	h. Hire knowledgeable staff; provide opportunities for professional training; create culture of service			
<b>2. Improve compliance efficiency... balancing risks, costs, benefits</b>	a. C/W the Federal Demonstration Partnership's (FDP) recommendations, implement "just-in-time" reviews (e.g., IRB, IACUC) of research protocols in grant proposals	ORC	ORC Director	Ongoing
	b. Improve communication, transparency, and accountability by disseminating reports widely.	All compliance offices	Administrators and Directors of compliance units that receive reports.	0-3 months and ongoing
	c. UH research compliance programs and committees should produce annual reports of meetings, activities, budgets, etc.			

Table 7 (continued)

RECOMMENDATION	TASKS	AGENCIES	ACTION OFFICER	TIMELINE
	d. To address recurring issues/problems UH administration should develop an audit system.			
	e. Streamline compliance business processes and procedures; beta-testing of forms & procedures			
	f. Improve efficiency of the research compliance process with use of web-based form-fillable applications, tracking approval status			
	g. Coordinate purchase & development of major IT systems and compel interoperability across ORC, et al.			
	h. Ad hoc committee to review Facilities Management re research compliance needs of other UH units.			
	i. Post reports by internal and external groups and consultants, committee members, and other information. Explanations should be provided for reports that are not released publicly.			
<b>3. Reorganize to realize success and efficiency while maintaining compliance</b>	a. Office of Research Compliance (ORC) should report to the UH Vice President for Research and Innovation (VPRI)	Office of the President and BOR approval	President	1 year
	b. Provide leadership and facilitation to ensure seamless compliance services	OVPRI	VPRI	Ongoing
	c. Improve coordination between ORC and other units with compliance-related responsibilities, such as the ORS, OEC, OTTED, ITS			
	d. 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			
	e. Integrate ORS pre-proposal/post-award services with ORC activities			

# APPENDIX A

## ORGANIZATIONAL CHART AND FUNCTIONAL STATEMENT FOR OFFICE OF THE VICE PRESIDENT FOR RESEARCH AND INNOVATION



### INTRODUCTION

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

### MAJOR FUNCTIONS

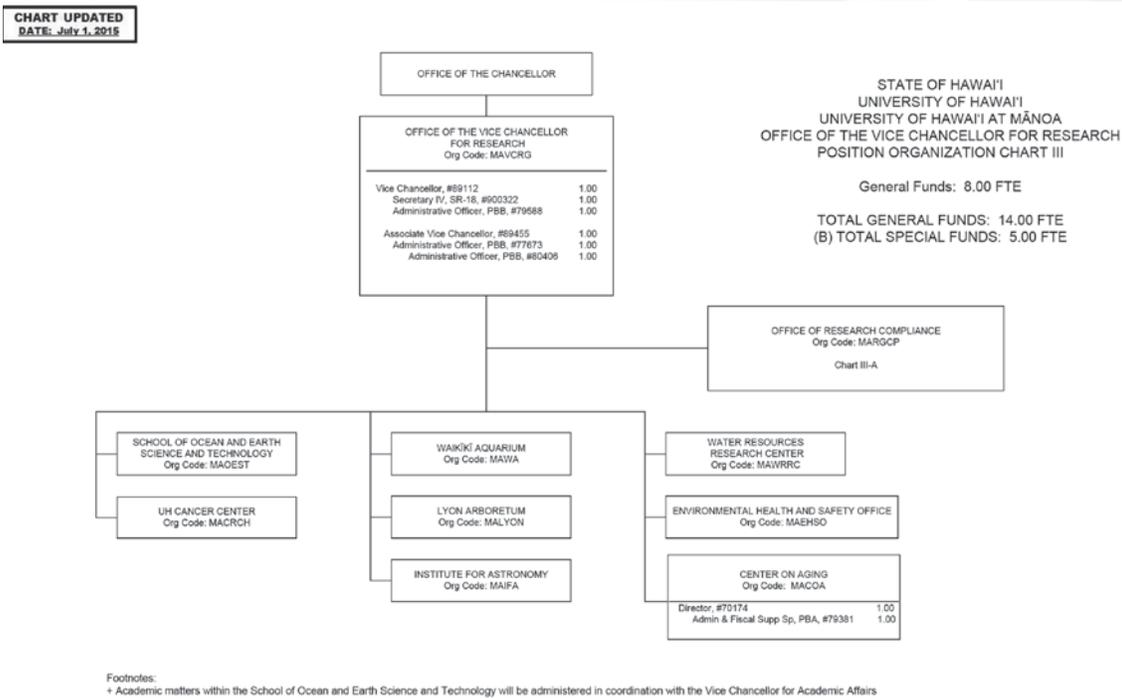
- Provides policy leadership and administrative support to system wide and Mānoa campus research institute and programs. Fosters and monitors inter-campus collaborative research efforts.
- Develops system wide research plans, goals, policy, and objectives in consultation with campus senior executives.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

<http://www.hawaii.edu/budget/oia/docs/15C-SAvpresearch.pdf>

<http://www.hawaii.edu/budget/oia/docs/15F-SAvpresearch.pdf>

# APPENDIX B

## ORGANIZATIONAL CHART AND FUNCTIONAL STATEMENT FOR UH MĀNOA OFFICE OF THE VICE CHANCELLOR FOR RESEARCH



### 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 programs of the University of Hawai‘i at Mānoa. The Vice Chancellor for Research (VCR) serves as the chief policy advisor to the Chancellor in these areas and the chief operating officer for University of Hawai‘i at Mānoa research programs.

### Authority

The OVCR 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 Hawai‘i at Mānoa. Leadership, direction and oversight is provided to select organized research units (ORUs) and to the School of Ocean and Earth Science and Technology.

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### Interactions With Other UHM Vice Chancellors

The VCR works with the Vice Chancellor for Academic Affairs to ensure that the research 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 Hawai'i at Mānoa.

### Major Functions of the Office

In support of and under the direction of the Chancellor, the Office directs the University of Hawai'i at Mānoa's research 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 Hawai'i at Mānoa.

The responsibilities of this Office also include the following:

- Initiates and develops long-range planning studies for research at the University of Hawai'i at Mānoa.
- 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 VCR, 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.

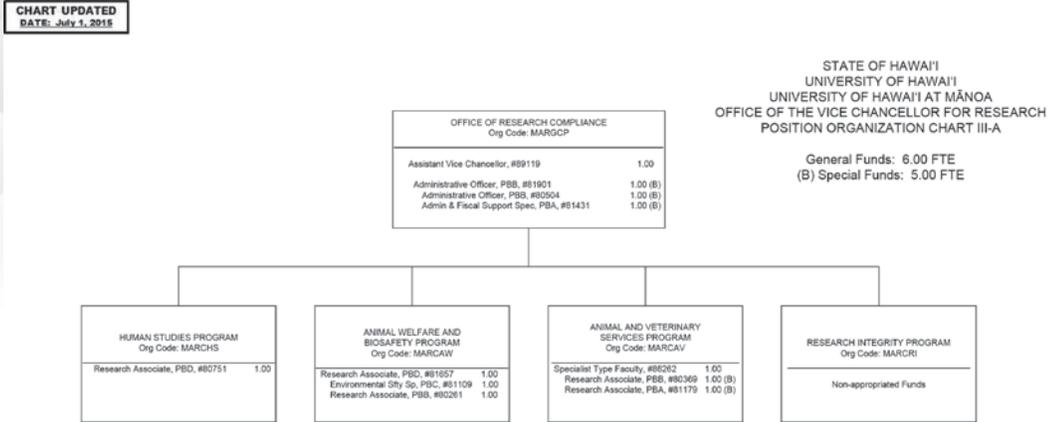
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- Manages the Research and Training Revolving Funds, the fiscal management of campus wide research initiative headed by the office of the VCR, the management of internal resource allocations within the office of the VCR and the interaction with the 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 Mānoa.
  - 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.

<http://www.hawaii.edu/budget/oia/docs/15C-UNuhmvcresearch.pdf>

<http://www.hawaii.edu/budget/oia/docs/15F-UNuhmvcresearch.pdf>

# APPENDIX C

## ORGANIZATIONAL CHART AND FUNCTIONAL STATEMENT FOR UH MĀNOA OFFICE OF RESEARCH COMPLIANCE



### Major Functions of the Office

In support of and under the direction of the Vice Chancellor for Research, the Office is responsible for ensuring compliance of research and scholarly work involving the use of vertebrate animals, human participants, microbiological materials, and issues related to the research and scholarly misconduct, and responsible conduct of research. 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 Mānoa campus and at the John A. Burns School of Medicine at Kaka’ako.

<http://www.hawaii.edu/budget/oia/docs/15C-UNuhmvcresearch.pdf>

<http://www.hawaii.edu/budget/oia/docs/15F-UNuhmvcresearch.pdf>

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## APPENDIX D

### OFFICE OF RESEARCH COMPLIANCE ADVISORY COMMITTEES

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1. Animal and Veterinary Program
  - a. Fish Advisory Committee
  - b. Vivarium Space Committee
2. Animal Welfare and Biosafety Programs
3. Dual Use Research of Concern (DURC) Policies and Procedures Working Group
4. Institutional Animal Care and Use Committee (IACUC)
5. Institutional Biosafety Committee (IBC)
6. Institutional Review Boards (IRBs)
  - a. Biomedical (IRB00000279)
  - b. Cooperative (IRB00003433)
  - c. Social & Behavioral Sciences (IRB00001353)
7. Suitability Assessment
8. University of Hawai'i Ethics Committee

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## APPENDIX E

### PEOPLE INTERVIEWED BY THE RCTF

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1. Alvarez, Anne, Plant Pathologist, Plant and Environmental Protection Sciences, College of Tropical Agriculture and Human Resources (CTAHR), UH Mānoa (UHM)
2. Berestecky, John, Professor, Math and Sciences, Kāpiʻolani Community College
3. Bingham, Jon-Paul, Assistant Professor, Molecular Biosciences and Bioengineering, CTAHR, UHM
4. Chandler, Susan, Professor & Director, Public Policy Center, College of Social Sciences, UHM
5. Cooper, Patricia, Interim Research Integrity Officer, Office of Research Compliance, UHM
6. Fong, Yaa-Yin, Director, Office of Research Services, UH System
7. Galland, John, Assistant Vice Chancellor for Research Compliance, Office for Research Compliance, UHM
8. Gerschenson, Mariana, Professor, Cell and Molecular Biology, John A. Burns School of Medicine (JABSOM), UHM
9. Hammatt, Zoë, Director, Division of Education Integrity, Office of Research Integrity (ORI), U.S. Department of Health and Human Services; former Director of Research Integrity Program, Office of Research Compliance, UHM
10. Hu, C.Y., former Interim Assistant Vice Chancellor for Research and Graduate Education
11. Kumar, Mukesh, Instructor, Tropical Medicine and Medical Microbiology, JABSOM, UHM
12. Measures, Chris, Vice Chair, UH Ethics Committee
13. Ogata, Kathleen, Assistant Professor, Math and Sciences, Kāpiʻolani Community College
14. Ohlson, Edward, Director of Facilities, Operations and Planning, JABSOM, UHM
15. Perkins, Frank, former Assistant Vice Chancellor for Research and Graduate Education
16. Schroeder, Tom, former Interim Research Integrity Officer, Office of Research Compliance
17. Seifried, Steven, Associate Professor, Cell and Molecular Biology, JABSOM, UHM
18. Smith, Steven, Interim Vice President for Information Technology and Chief Information Officer, UH System
19. Takekawa, Roy, Director, Environmental Health and Safety, UHM
20. Tallquist Seidel, Michelle, Associate Professor, Center for Cardiovascular Research, JABSOM, UHM
21. Tam, Elizabeth, Professor & Chair, Internal Medicine, JABSOM, UHM

\* Brian Taylor, Interim Vice Chancellor for Research, UH Mānoa, was invited to meet with the RCTF but declined.

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## APPENDIX F

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2015 UH Faculty Survey on Research Compliance Data

## APPENDIX G

### FEDERAL AND STATE RESEARCH COMPLIANCE REGULATIONS

FEDERAL/STATE AGENCY	REGULATION TITLE	SOURCE
OFFICE OF SCIENCE AND TECHNOLOGY POLICY	Federal Policy on Research Misconduct; Preamble for Research Misconduct Policy	Federal Register: December 6, 2000 (Volume 65, Number 235) [Notices] [Page 76260-76264] <a href="http://www.gpo.gov/fdsys/pkg/FR-2000-12-06/pdf/00-30852.pdf">http://www.gpo.gov/fdsys/pkg/FR-2000-12-06/pdf/00-30852.pdf</a>
DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS)	Public Health Service Policies on Research Misconduct	Federal Register / Vol. 70, No. 94 / Tuesday, May 17, 2005 / Rules and Regulations <a href="http://ori.hhs.gov/sites/default/files/42_cfr_parts_50_and_93_2005.pdf">http://ori.hhs.gov/sites/default/files/42_cfr_parts_50_and_93_2005.pdf</a>
DHHS	Update on the Requirement for Instruction in the Responsible Conduct of Research	NOT-OD-10-019, November 24, 2009 <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html</a>
DHHS	Draft Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care	Federal Register / Vol. 79, No. 206 / Friday, October 24, 2014 / Notices
DHHS	Meeting on the Secretary's Advisory Committee on Human Research Protections	Federal Register / Vol. 79, No. 37 / Tuesday, February 25, 2014 / Notices
DHHS	Meeting of the Secretary's Advisory Committee on Human Research Protections	Federal Register / Vol. 79, No. 128 / Thursday, July 3, 2014 / Notices
DHHS	Meeting of the Secretary's Advisory Committee on Human Research Protections	Federal Register / Vol. 79, No. 192 / Friday, October 3, 2014 / Notices
DHHS	Title 45—Public Welfare DHHS, Part 46—Protection of Human Subjects; Common Rule - Subpart A, Vulnerable Pop - Subparts B-D	45 CFR 46
DHHS	Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request	Federal Register / Vol. 79, No. 98 / Wednesday, May 21, 2014 / Notices

DHHS	Agency Information Collection Activities; Proposed Collection; Public Comment Request	Federal Register / Vol. 79, No. 44 / Thursday, March 6, 2014 / Notices
DHHS	Title 45—Public Welfare DHHS, Part 46—Protection of Human Subjects; Common Rule - Subpart A, Vulnerable Pop - Subparts B-D	45 CFR 46
NATIONAL SCIENCE FOUNDATION (NSF)	Research Misconduct	<a href="http://www.nsf.gov/oig/_pdf/cfr/45-CFR-689.pdf">www.nsf.gov/oig/_pdf/cfr/45-CFR-689.pdf</a>
NSF	Responsible Conduct of Research	<a href="http://www.gpo.gov/fdsys/pkg/FR-2009-08-20/html/E9-19930.htm">http://www.gpo.gov/fdsys/pkg/FR-2009-08-20/html/E9-19930.htm</a>
Other federal agencies, departments, centers that provide extramural funding such as NASA, EPA, USDA, DOT, Energy, Education, DOL, DHS, DOD, VA, NEH, HUD, SBA	Research Misconduct/ Responsible Conduct of Research	<a href="http://ori.hhs.gov/federal-policies">http://ori.hhs.gov/federal-policies</a>
HEALTH AND HUMAN SERVICES (HHS)/NATIONAL INSTITUTES OF HEALTH (NIH)	Human Studies	45 CFR 46 (the HHS Human Research Regulations) FAQs (PDF-38KB)
HHS/NIH	Human Studies	AIDS Research, Guidance for IRBs (1984)
HHS/NIH	Human Studies	Approval of Research with Conditions: OHRP Guidance (2010) (PDF -63KB)
HHS/NIH	Human Studies	Assurance Process FAQs (PDF - 68KB)
HHS/NIH	Human Studies	Belmont Report
HHS/NIH	Human Studies	Certificates of Confidentiality - Privacy Protection for Research Subjects: OHRP Guidance (2003) (PDF -18.9KB)
HHS/NIH	Human Studies	Children: Information on Special Protections for Children as Research Subjects
HHS/NIH	Human Studies	Children Involved as Subjects in Research: Guidance on the HHS 45 CFR 46.407 ("407") Review Process (2005) (PDF -113KB)
HHS/NIH	Human Studies	Children: Research with Children FAQs (PDF -69KB)

HHS/NIH	Human Studies	Clinical Trial Websites: When Is IRB Review Required and What Should IRBs Consider with Reviewing? (OHRP Guidance, 2005) (PDF - 33.5KB)
HHS/NIH	Human Studies	Coded Private Information or Biological Specimens: Issues to Consider in the Research Use of Stored Data or Tissues, Operation of Biological Repositories: OPRR Memoranda (1996, 1997)
HHS/NIH	Human Studies	Coded Private Information or Biological Specimens: OHRP Guidance on Research (2008) (PDF - 37.5KB)
HHS/NIH	Human Studies	Coded Private Information or Biological Specimens, Research Use (Video)
HHS/NIH	Human Studies	Compliance Oversight Procedures Used by OHRP (2009) (PDF - 47KB)
HHS/NIH	Human Studies	Continuing Review: OHRP Guidance (2010) (PDF - 52KB)
HHS/NIH	Human Studies	Correspondence
HHS/NIH	Human Studies	Emergency Medical Care and Research: OPRR Letter (1991)
HHS/NIH	Human Studies	Emergency Research Informed Consent Requirements (OPRR Letter, 1996)
HHS/NIH	Human Studies	Engagement of Institutions in Human Subjects Research: OHRP Guidance (2008) (PDF - 66 KB)
HHS/NIH	Human Studies	Engagement of Institutions in Human Subjects Research: Correspondence Regarding "Non-engagement" Scenarios (2011) (PDF - 28KB)
HHS/NIH	Human Studies	Engagement: When are Survey Firms Engaged in Research?; Clarification Regarding the Relationship between Institutional Engagement and the Federalwide Assurance (FWA) (January 13, 2009, OHRP Letter)
HHS/NIH	Human Studies	Exculpatory Language in Informed Consent Documents: Examples of Acceptable and Unacceptable Language (OPRR Letter, 1996)

HHS/NIH	Human Studies	Exempt Research and Research That May Undergo Expedited Review
HHS/NIH	Human Studies	Exempt Research Determination FAQs (PDF -26KB)
HHS/NIH	Human Studies	Exempt Research: Exemptions for Public Benefit and Service Programs (OPRR Guidance)
HHS/NIH	Human Studies	Expedited Review: Categories of Research That May Be Reviewed Through an Expedited Review Procedure (1998)
HHS/NIH	Human Studies	Expedited Review Procedures: OHRP Guidance (2003) (PDF - 207KB)
HHS/NIH	Human Studies	Expedited Review: Clarification of “Noninvasive” in Expedited Review Category 3
HHS/NIH	Human Studies	Extension of an Institutional FWA via an Individual Investigator Agreement: OHRP Guidance (2005) (PDF - 43.9KB)
HHS/NIH	Human Studies	Fetal Tissue Transplantation: OHRP Guidance (2003) (PDF - 14.7KB)
HHS/NIH	Human Studies	Fetal Tissue Transplantation Research, Public Law 103-43, Section 498A (1993)
HHS/NIH	Human Studies	Financial Conflict of Interest: HHS Guidance (2004) (PDF - 85 KB)
HHS/NIH	Human Studies	Genetic Information Nondiscrimination Act (GINA): OHRP Guidance (2009) (PDF- 38 KB)
HHS/NIH	Human Studies	HIV Serostatus, Informing Those Tested, PHS Policy (1988)
HHS/NIH	Human Studies	HIV Serostatus, Sex-Partner Notification, PHS Policy (1990)
HHS/NIH	Human Studies	Human Embryonic Stem Cells, Germ Cells, and Cell-Derived Test Articles: OHRP Guidance (2002)

HHS/NIH	Human Studies	Human Subject Regulations Decision Charts (2004)
HHS/NIH	Human Studies	Informed Consent Checklist (1998)
HHS/NIH	Human Studies	Informed Consent FAQs (PDF - 135KB)
HHS/NIH	Human Studies	Informed Consent, Legally Effective and Prospectively Obtained (OPRR Letter, 1993)
HHS/NIH	Human Studies	Informed Consent: Obtaining and Documenting Informed Consent of Non-English Speakers (OPRR Memo, 1995)
HHS/NIH	Human Studies	Informed Consent Requirements (Video)
HHS/NIH	Human Studies	Informed Consent Requirement for In Vitro Medical Device Clinical Investigations Conducted Under FDA's Interim Final Rule at 21 CFR 50.23(e) (OHRP Guidance, 2006) (PDF - 46KB)
HHS/NIH	Human Studies	Informed Consent Tips (1993)
HHS/NIH	Human Studies	Investigator Responsibility FAQs (PDF-44KB)
HHS/NIH	Human Studies	IRB Meetings Convened via Telephone Conference Call: OPRR Memorandum (2000) (PDF - 54KB)
HHS/NIH	Human Studies	IRB Membership (Video)
HHS/NIH	Human Studies	IRB Records, Part One (Video)
HHS/NIH	Human Studies	IRB Records, Part Two (Video)
HHS/NIH	Human Studies	IRB Registration Process FAQs (PDF - 34KB)
HHS/NIH	Human Studies	IRB Review of Applications for HHS Support: OPRR Memorandum (2000)
HHS/NIH	Human Studies	IRB Review of Protocol and Informed Consent Changes in Cooperative Group Protocols (OHRP Memo to the National Cancer Institute, 2008)
HHS/NIH	Human Studies	Prisoner Research Certification

HHS/NIH	Human Studies	Prisoner Research: OHRP Guidance (2003) (PDF - 22KB)
HHS/NIH	Human Studies	Prisoner Research FAQs (PDF - 64KB)
HHS/NIH	Human Studies	Quality Improvement Activities FAQs (PDF - 37 KB)
HHS/NIH	Human Studies	Quality Improvement Activities: OHRP Correspondence Regarding Indwelling Catheter Procedures (2008)
HHS/NIH	Human Studies	Reporting Incidents to OHRP: Guidance on When and How to File Incident Reports (2011) (PDF - 51.6KB)
HHS/NIH	Human Studies	Research Involving Vulnerable Populations (Video)
HHS/NIH	Human Studies	Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events: OHRP Guidance (2007) (PDF -180KB)
HHS/NIH	Human Studies	Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events (Video)
HHS/NIH	Human Studies	Secretarial Waiver
HHS/NIH	Human Studies	Use of a Central Institutional Review Board (OHRP Letter, 2010)
HHS/NIH	Human Studies	Use of Penalties for Students Who Fail to Show up for Scheduled Research Appointments (OHRP Letter, 2010)
HHS/NIH	Human Studies	Viewpoint on Conflicting Interests of Pediatric Central IRB (PedCIRB) Members (2005)
HHS/NIH	Human Studies	Withdrawal of Subjects from Research: Data Retention and Other Related Issues: OHRP Guidance (2010) (PDF-45KB)
HHS/NIH	Human Studies	Written Institutional Review Board (IRB) Procedures: OHRP Guidance (2011) (PDF -58KB)
DHHS/NIH	Announcement of a Draft NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research	Federal Register / Vol. 80, No. 3 / Tuesday, January 6, 2015 / Notices

HHS/NIH/OFFICE OF LABORATORY ANIMAL WELFARE (OLAW)	PHS Policy on Humane Care and Use of Laboratory Animals, 2002	<a href="http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf">http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf</a> - 282 KB
HHS/NIH/OLAW	Guide for the Care and Use of Laboratory Animals, 8th Edition	<a href="http://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf">http://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf</a> -1.2 MB
HHS/NIH/OLAW	AVMA Guidelines for the Euthanasia of Animals: 2013 Edition	<a href="https://www.avma.org/KB/Policies/Documents/euthanasia.pdf">https://www.avma.org/KB/Policies/Documents/euthanasia.pdf</a> -1.4 MB
HHS/NIH/OLAW	U.S. Government Principles	<a href="http://grants.nih.gov/grants/olaw/references/phspol.htm#USGovPrinciples">http://grants.nih.gov/grants/olaw/references/phspol.htm#USGovPrinciples</a>
HHS/NIH/OLAW	Public Law 99-158, Animals in Research	<a href="http://grants.nih.gov/grants/olaw/references/hrea1985.htm">http://grants.nih.gov/grants/olaw/references/hrea1985.htm</a>
HHS/NIH/OLAW	Public Law 103-43, Plan for Use of Animals in Research, 1993	<a href="http://grants.nih.gov/grants/olaw/pl103-43.pdf">http://grants.nih.gov/grants/olaw/pl103-43.pdf</a> -22 KB
HHS/NIH/OLAW	International Guiding Principles for Biomedical Research Involving Animals,	<a href="http://grants.nih.gov/grants/olaw/Guiding_Principles_2012.pdf">http://grants.nih.gov/grants/olaw/Guiding_Principles_2012.pdf</a> -123 KB
OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (OSHA)	Enforcement Guidance for Personal Protective Equipment (PPE) in General Industry	29 C.F.R. § 1910.132
OSHA	Bloodborne Pathogens Standard	29 C.F.R. § 1910.1030
OSHA	Requires employers to train employees on hazards in the workplace, to provide information to employees, to report occupational injuries and illnesses to the federal government, and to keep records of same, and to provide controls and protective equipment as well.	29 U.S.C. § 651-678 29 C.F.R. §§ 1900-2400
OSHA	Hazard Communication Standard	29 C.F.R. § 1910.1200
ENVIRONMENTAL PROTECTION AGENCY (EPA)	Resource Conservation and Recovery Act	42 U.S.C. §§ 6901-6992k 40 C.F.R. § 98.250 40 C.F.R. § 260

EPA	The Public Health Security and Bioterrorism Preparedness and Response Act	18 U.S.C. § 175b
NSF	Institutional plan to provide appropriate training and oversight in the responsible and ethical conduct of research to undergraduate students, graduate students, and postdoctoral researchers participating in the proposed research project.	America COMPETES Act § 7009 42 U.S.C. § 1862o-174 Fed. Reg. 42126
UNITED STATES DEPT OF AGRICULTURE (USDA)	Treatment of animals used for research: dogs, cats, monkeys, guinea pigs, hamsters, and other warm-blooded animals	Animal Welfare Act 7 U.S.C. §§ 2131-2159 9 C.F.R. §§ 1-4
HAWAII DEPT OF AGRICULTURE (HDOA)	Subtitle 3—Division of Animal Industry	
HDOA	16 Cattle, Sheep, and Goats	AR-16.PDF
HDOA	17 Swine	AR-17.PDF
HDOA	19 Poultry and Birds - REPEALED (see chapter 28)	
HDOA	19 Subchapter 6 - West Nile Virus - Import Requirements for Birds and Poultry - REPEALED (see chapter 28)	
HDOA	20 Non-domestic Animals	AR-20.PDF
HDOA	21 Vaccines, Microorganisms, and Parasites	AR-21.PDF
HDOA	22 Reporting of Animal Diseases	List of Diseases, AR-22.PDF
HDOA	23 Horses	AR-23.PDF
HDOA	24 Meat Grading	AR-24.PDF
HDOA	27 Brands	AR-27.PDF
HDOA	28 Poultry and Birds	AR-28.PDF
HDOA	29 Dogs, Cats, and Other Carnivores	Hospital Form.PDF, Notice of AT Insp.PDF, AR-29.PDF

HDOA	Subtitle 6—Division of Plant Industry	
HDOA	66 Pesticides	AR-66.PDF
HDOA	67 Seed Rules	AR-67.PDF
HDOA	68 Noxious Weed Rules	AR-68.PDF
HDOA	69A Pests for Control or Eradication	AR-69A.PDF
HDOA	70 Plant and Non-Domestic Animal Quarantine, Plant Import Rules, Amendment, Amendment on Bromeliad Import	AR-70.PDF, AR-70-Bromeliads.PDF
HDOA	71 Plant and Non-Domestic Animal Quarantine, Non-Domestic Animal Import Rules	AR-71.PDF
HDOA	- List of Conditional Approved Animals	AR-71C.PDF
HDOA	- List of Restricted Animals - For Research and Exhibition	AR-71RA.PDF
HDOA	- List of Restricted Animals - For Private and Commercial Use	AR-71RB.PDF
HDOA	- List of Prohibited Animals	AR-71P.PDF
HDOA	71A Plant and Non-Domestic Animal Quarantine, Microorganism Import Rules	AR-71A.PDF
HDOA	- List of Restricted Microorganisms Part A	AR-71A-RA.PDF
HDOA	- List of Restricted Microorganisms Part B	AR-71A-RB.PDF
HDOA	- List of Selected Human Pathogens	AR-71A-SP.PDF
HDOA	- List of Nonrestricted Microorganisms	AR-71A-N.PDF

HDOA	72 Plant and Non-Domestic Animal Quarantine, Plant Intrastate Rules - Amended	AR-72A.PDF
HDOA	73 Plant and Non-Domestic Animal Quarantine, Quarantine Plant Export Rules	AR-73.PDF
DEPT OF HEALTH	11-104.1 Management and Disposal of Infectious Wastes	<a href="http://health.hawaii.gov/opppd/files/2015/06/11-104.1.pdf">http://health.hawaii.gov/opppd/files/2015/06/11-104.1.pdf</a>
DEPT OF LABOR	12-08-221. Boiler & Pressure Vessel - Existing and New Boiler and Pressure Vessel (Autoclave Certification)	Title 12, Subtitle 8, Part 10
DEPT OF LAND AND NATURAL RESOURCES (DLNR) Division of Aquatic Resources	Aquatic Resources Special Activity Permit: Scientific, Educational or Propagation Purposes	HRS 187A-6
DLNR	Activities Involving Native Wildlife, Introduced Wild Birds and Game Animals (Wildlife Permit Guidelines)	Permit Guidelines Contact: Jason Omick (jason.d.omick@hawaii.gov)
DLNR	Activities Involving Native Invertebrates	Permit Guidelines Contact: Cynthia King (cynthia.b.king@hawaii.gov)
DLNR	Activities Involving Rare, Threatened or Endangered Plants (Plant Permit Guidelines)	Permit Guidelines Contact: Charmian Dang (charmian.c.dang@hawaii.gov)
DLNR	Collection or Exportation of Injurious wildlife (Wildlife Permit Guidelines)	Permit Guidelines Contact: DOFAW Main Office at (808) 587-0166
DLNR	Activities within a Natural Area Reserve (NARS Permit Guidelines)	Permit Guidelines Contact: Charmian Dang (charmian.c.dang@hawaii.gov)
FEDERAL OSHA	Personal Protective Equipment (Respirator, Eye Wear, Foot, Hand)	Part 1910, Subpart I, 1910.132-1910.138

FEDERAL OSHA	Bloodborne Pathogens (Bloodborne Pathogens and Needle Stick Prevention Program)	Part 1910, Subpart Z, 1910.1030
FEDERAL OSHA	Hazard Communication (Letter of Interpretation of Established Human Cell Lines)	Part 1910, Subpart Z, 1910-1200
FEDERAL CENTER FOR DISEASE CONTROL (CDC)	Biosafety in Microbiological and Biomedical Laboratories 5th Ed. Dec 2003	<a href="http://www.cdc.gov/biosafety/publications/bmb15/">http://www.cdc.gov/biosafety/publications/bmb15/</a>
FEDERAL CDC	CDC Import Permit Applications	Applications
FEDERAL CDC	Interstate Shipment of Etiologic Agents	42 CFR Part 72
FEDERAL CDC	Etiologic Agent Import Permit Program	42 CFR Part 71
FEDERAL CDC	CDC Morbidity and Mortality Weekly Report (MMWR), Recommendations for Safe Laboratory Practices	Supplement / Vol. 60 / April 15, 2011, MMWR Guidelines for Biosafety Laboratory Competency, MMWR Supplements: Past Volume (2011) Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories)
FEDERAL CDC	2014 ISAC Biosafety Standards	Cytometry Cell Sorter Biosafety Standards Cytometry Part A85A: 434-453, 2014
NIH (Program on Biosecurity and Biosafety Policy)	NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules	November 2013 NIH Guidelines (PDF)
FISH AND WILDLIFE SERVICE	Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)	Endangered Species Act (ESA)
USDA	BRS Plant Pest Biotechnology	7CFR 340
USDA	Permits - for Introduction of GE Organisms	
USDA	Notifications - to Submit a Notification	

USDA	Report an Accidental Release of Genetically Modified Organism	
USDA	Plant Pest Program Information	
USDA	Agricultural Select Agent Program	
USDA	Biotechnology Title IV Plant Protection Act Introduction of Organism Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests	7 CFR 340
USDA	Agricultural Bioterrorism Protection Act of 2002; Possession, Use and Transfer of Biological Agents and Toxins	7 CFR 331, 9 CFR 121 USDA Final Rule
USDA	Import and Shipment Permits for Animal and Plant Pathogens as Well as Biotechnology (Plant and Agricultural Microorganism) Permits	Import Export
USDA	USDA Veterinary Services National Center for Import and Export	Import Export
EPA	Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)	List A: EPA's Registered Antimicrobial Products as Sterilizers (PDF)
EPA	Anti-Microbial Pesticide Products & Registration, Products Used to Disinfect, Sanitize, Reduce, or Mitigate Growth or Development of Microbiological Organisms on Inanimate Objects and Surfaces	List B: EPA Registered Tuberculocide Products Effective Against Mycobacterium tuberculosis (PDF)
EPA		List C: EPA's Registered Antimicrobial Products Effective Against Human HIV-1 Virus (PDF)

EPA		List D: EPA's Registered Antimicrobial Products Effective Against Human HIV-1 and Hepatitis B Virus (PDF)
EPA		List E: EPA's Registered Antimicrobial Products Effective Against Mycobacterium tuberculosis Human HIV-1 and Hepatitis B Virus (PDF)
EPA		List F: EPA's Registered Antimicrobial Products Effective Against Hepatitis C Virus (PDF)
EPA		List G: EPA's Registered Antimicrobial Products Effective Against Norovirus (PDF)
EPA		List H: EPA's Registered Antimicrobial Products Effective Against Methicillin Resistant Staphylococcus aureus (MRSA) and Vancomycin Resistant Enterococcus faecalis or faecium (VRE) (PDF)
EPA		List J: EPA's Registered Antimicrobial Products for Medical Waste Treatment (PDF)
EPA		List K: EPA's Registered Antimicrobial Products Effective Against Clostridium difficile Spores (PDF)
EPA		List L: EPA's Registered Antimicrobial Products that Meet the CDC Criteria for Use Against the Ebola Virus
AMERICAN SOCIETY OF MICROBIOLOGY (ASM)	Guidelines for Biosafety in Teaching Laboratories	<a href="http://www.asm.org/images/asm_biosafety_guidelines-FINAL.pdf">http://www.asm.org/images/asm_biosafety_guidelines-FINAL.pdf</a>
ASM	Appendix to the Guidelines for Biosafety in Teaching Laboratories	<a href="http://www.asm.org/images/Education/FINAL_Biosafety_Guidelines_Appendix_Only.pdf">http://www.asm.org/images/Education/FINAL_Biosafety_Guidelines_Appendix_Only.pdf</a>
THE AMERICAN COMMITTEE OF MEDICAL ENTOMOLOGY OF THE AMERICAN SOCIETY OF TROPICAL MEDICINE AND HYGIENE	Arthropod Containment Guidelines (Version 3.1)	<a href="http://www.astmh.org/AM/Template.cfm?Section=ACME&amp;Template=/CM/ContentDisplay.cfm&amp;ContentID=1444">http://www.astmh.org/AM/Template.cfm?Section=ACME&amp;Template=/CM/ContentDisplay.cfm&amp;ContentID=1444</a>

The table above was provided by the Office of Research Compliance. In reviewing the contents, the RCTF substituted current hyperlinks for those that had expired.

## APPENDIX H

### FEDERAL AND STATE ENVIRONMENTAL HEALTH AND SAFETY COMPLIANCE REGULATIONS

FEDERAL/STATE AGENCY	REGULATION TITLE	SOURCE
<b>ENVIRONMENTAL COMPLIANCE</b>		
Environmental Protection Agency	Clean Water Act	<a href="http://www.epa.gov/agriculture/lcwa.html">http://www.epa.gov/agriculture/lcwa.html</a>
Hawai'i State Department of Health, Clean Water Branch	Hawaii Administrative Rule, Title 11 Department of Health Chapter 54, Water Quality Standards	<a href="http://health.hawaii.gov/opppd/administrative-rules/">http://health.hawaii.gov/opppd/administrative-rules/</a>
Hawai'i State Department of Health, Safe Drinking Water Branch	Hawaii Administrative Rule, Title 11 Department of Health Chapter 23, Underground Injection Control	<a href="http://health.hawaii.gov/opppd/administrative-rules/">http://health.hawaii.gov/opppd/administrative-rules/</a>
Hawai'i State Department of Health, Solid and Hazardous Waste Branch	Hawaii Administrative Rule, Title 11 Department of Health Chapter 58.1, Solid Waste Management Control	<a href="http://health.hawaii.gov/opppd/administrative-rules/">http://health.hawaii.gov/opppd/administrative-rules/</a>
Hawai'i State Department of Health, Clean Air Branch	Hawaii Administrative Rule, Title 11 Department of Health Chapter 60.1, Air Pollution Control	<a href="http://health.hawaii.gov/opppd/administrative-rules/">http://health.hawaii.gov/opppd/administrative-rules/</a>
State of Hawai'i, Department of Health, Hazard Evaluation and Emergency Response Office	Hawaii Administrative Rule, Title 11 Department of Health Chapter 451, State Contingency Plan	<a href="http://health.hawaii.gov/opppd/administrative-rules/">http://health.hawaii.gov/opppd/administrative-rules/</a>
State of Hawai'i, Department of Health, Hazard Evaluation and Emergency Response Office	Hawaii Administrative Rule, Title 11 Department of Health Chapter 453, Emergency Planning & Community Right-to-Know Act (EPCRA)	<a href="http://health.hawaii.gov/opppd/administrative-rules/">http://health.hawaii.gov/opppd/administrative-rules/</a>
State of Hawai'i, Department of Health, Hazard Evaluation and Emergency Response Office	Hawaii Revised Statute, 128D Environmental Response Law (HERL)	<a href="http://www.capitol.hawaii.gov/">http://www.capitol.hawaii.gov/</a>
<b>RADIATION SAFETY</b>		
U.S. Nuclear Regulatory Commission (NRC)	Standards for Protection Against Radiation	<a href="http://www.nrc.gov/reading-rm/doc-collections/cfr/">http://www.nrc.gov/reading-rm/doc-collections/cfr/</a>
U.S. Dept. of Transportation	Hazardous Materials Regulations	49 CFR Subtitle B Chapter 1 Subchapter C Part 171.1 to 171.26, <a href="http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title49/49cfrv2_02.tpl">http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title49/49cfrv2_02.tpl</a>

International Air Transport Association (IATA)	Transport of Radioactive Materials by Air	Section 10 (no website available online)
State of Hawai'i, Department of Health (DOH)	Radiation Control	Hawaii Administrative Rules, Title 11, Chapter 45 <a href="http://health.hawaii.gov/opppd/files/2015/06/11-45.pdf">http://health.hawaii.gov/opppd/files/2015/06/11-45.pdf</a>
U.S. Food and Drug Administration	Radiation Emitting Electronic Systems	Title 21, Code of Federal Regulations, Part 1020 <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1020&amp;howFR=1">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1020&amp;howFR=1</a>
U.S. Food and Drug Administration	MRI Regulations	<a href="http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/ucm200086.htm">http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/ucm200086.htm</a>
U.S. Federal Communications Commission	Tower and Antenna Regulations	<a href="https://www.fcc.gov/encyclopedia/tower-and-antenna-siting">https://www.fcc.gov/encyclopedia/tower-and-antenna-siting</a>
<b>OCCUPATIONAL SAFETY AND HEALTH</b>		
State of Hawai'i, HIOSH (Hawaii Occupational Safety and Health)	General Safety and Health Requirement	Hawaii Administrative Rules (HDR), Title 12 Department of Labor and Industrial Relations (DLIR), Subtitle 8 HIOSH Division, Part 2 General Industry Standards, Chapter 60 General Safety and Health Requirements
HIOSH	Recording and Reporting Occupational Injuries and Illnesses	Title 12, Subtitle 8, Part1, Chapter 52.1 (Recording and Reporting Occupation Injuries and Illnesses) 29 CFR (Code of Federal Regulation) 1904
U.S. Occupational Safety and Health Administration (OSHA)	Occupational Noise Exposure	29 CFR 1910.95
OSHA	Hazardous Materials	29 CFR 1910 Subpart H (1910.101- 107; 1910.109-111)
OSHA	Personal Protective Equipment	29 CFR 1910 Subpart I (1910.132-138)
OSHA	The Control of Hazardous Energy (Lockout/Tagout Program)	29 CFR 1910.147
OSHA	Medical Services and First Aid	29 CFR 1910.151
OSHA	Toxic and Hazardous Substances	29 CFR 1910.1000 (Air Contaminant -8 hour Exposure Limits)
OSHA	Bloodborne Pathogens	29 CFR 1910.1030
OSHA	Hazard Communication	29 CFR 1910.1200
OSHA	Occupational exposure to hazardous chemicals in laboratories	29 CFR 1910.1450

<b>HAZARDOUS MATERIALS MANAGEMENT</b>		
U.S. Environmental Protection Agency	Hazardous Waste Regulations	40 CFR Subchapter, Solid Wastes Part 260 to part 370
U.S. Department of Transportation	Transportation of Hazardous Material Regulations	49 CFR Subchapter A, Hazardous materials and Oil Transportation. Parts 105 to 180
U.S. Occupational Safety and Health Administration (OSHA)	Emergency Plans	29 CFR 1910.38
	Hazardous Waste Operations and Emergency Response	29 CFR 1910.120
	Hazard Communication	29 CFR 1910.1200
<b>DIVING SAFETY</b>		
U.S. Occupational Safety and Health Administration (OSHA)	Commercial Diving Regulations (CDR)	29 CFR Part 1910, Subpart T <a href="https://www.osha.gov/SLTC/commercialdiving/standards.html">https://www.osha.gov/SLTC/commercialdiving/standards.html</a>
OSHA	CDR - Scientific Diving Exemption	29 CFR Part 1910, Subpart T, Appx B <a href="https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&amp;p_id=10141">https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&amp;p_id=10141</a>
OSHA	CDR-SDE, Final Rulemaking	Fed. Register 50:1046-50, Clarification of eligibility for inclusion of diving activity under the SDE. Not all diving in support of science is exempt.
OSHA	Instructions to Inspectors: CDR	Directive No. CPL 02-00-151
State of Hawai'i, Dept. of Labor and Industrial Relations, HIOSH	Commercial Diving Regulations	HAR Title 12, Subtitle 8, Pt 2, Chapter 97 Identical to Federal Standard.
U.S. Coast Guard	Commercial Diving Operations	46 CFR, Chapter 1, Part 197, Subpart B
U.S. Army Corps of Engineers	Contract Diving Operations	US Army Regulation, ER 385-1-86 Applies to UH research conducted under contract from US military agencies. Effectively identical to the OSHA CDR. <u>No exemption for scientific research.</u>
<b>FIRE SAFETY</b>		
Uniform Fire Code	2006 National Fire Protection Assn. (NFPA), Article 1	<a href="http://labor.hawaii.gov/wp-content/uploads/2013/02/State-Fire-Code-1-1-10-w-signatures.pdf">http://labor.hawaii.gov/wp-content/uploads/2013/02/State-Fire-Code-1-1-10-w-signatures.pdf</a>
Uniform Building Code		
National Fire Alarm and Signaling code.	2010 NFPA Article 72	
National Electric code	2008 National Electrical Code. Special conditions Chapter 7, Article 760 Fire Alarm Systems	<a href="http://www.necconnect.org/">http://www.necconnect.org/</a>
United States Fire Administration	Training and Professional Development	<a href="http://www.usfa.fema.gov/training/nfa/">http://www.usfa.fema.gov/training/nfa/</a> <a href="http://www.honolulu.gov/hfd/default.html">http://www.honolulu.gov/hfd/default.html</a>

The table above was provided by the Environmental Health and Safety Office. In reviewing the contents, the RCTF substituted current hyperlinks for those that had expired.

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# APPENDIX I

## SURVEY INSTRUMENT

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### 2015 Faculty Survey on Research Compliance

What is your academic rank or position title?

- Tenured faculty
- Untenured faculty
- Staff member (UH or RCUH)
- Graduate student
- Other: \_\_\_\_\_

How long have you been at the UH or RCUH (round to nearest year)?

What is your campus?

- UH Manoa
- UH West Oahu
- UH Hilo
- UH Community Colleges/Maui College

What is your principal field of study?

- Agricultural Sciences
- Biological; Biomedical Sciences
- Business; Law
- Clinical Sciences; Medicine
- Education
- Engineering; Computer Sciences
- Environmental Sciences
- Humanities/Arts; Architecture
- Physical Sciences; Mathematics
- Social and Behavioral Sciences
- Other: \_\_\_\_\_

We would like to know the full range of compliance/regulatory issues with which UH faculty, staff, and graduate students must deal in the course of their work. If the following compliance areas are relevant to your work, or are areas that you are familiar with, please answer the associated questions. Click 'Next.'

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## Human Subjects—Institutional Review Board (IRB)

I am familiar with Human Subjects—Institutional Review Board

- Yes
- No

Human subjects—Institutional Review Board (IRB)

- Human Subjects—Institutional Review Board (IRB) is relevant to my work.
- Human Subjects—Institutional Review Board (IRB) does not apply to my work.

We would like to know about your experiences in meeting IRB/human subjects research compliance requirements at UH. Please rate your experiences with each of the following tasks related to IRB/human subjects research:

Understanding what is required and why

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

Preparing IRB protocols and consent forms for initial review

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

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Completing protocol revisions requested by reviewers

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

Waiting for feedback from review

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

Completing annual continuing review of protocols

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

Ensuring that study procedures meet protocols

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

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If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

Fulfilling federal requirements for training in human subjects protections

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

Please rate the quality of the information you have been provided to comply with regulatory requirements regarding IRB/human subjects for research and education.

- Excellent
- Above average
- Average
- Below average
- Poor
- Not available

Please rate the training on IRB/human subjects you received at UH.

- Excellent
- Above average
- Average
- Below average
- Poor
- Not available

Please provide any other suggestions that may help improve your ability to meet IRB/human subjects requirements for your research and/or teaching.

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## Institutional Animal Care and Use Committee (IACUC)

I am familiar with Institutional Animal Care and Use Committee (IACUC)

- Yes
- No

Select the statement that best describes your involvement with the Institutional Animal Care and Use Committee (IACUC)

- Institutional Animal Care and Use Committee (IACUC) is relevant to my work.
- Institutional Animal Care and Use Committee (IACUC) does not apply to my work.

We would like to know about your experiences in meeting IACUC research compliance requirements at UH. Please rate your experiences with each of the following tasks related to IACUC requirements:

Understanding what is required and why

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

Preparing IACUC protocols and consent forms for initial review

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

---

Completing annual IACUC reviews and three-year renewals

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

Completing protocol revisions requested by reviewers

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

Fulfilling federal and state requirements for training in animal care and use

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

---

Satisfying federal and state requirements for funded projects (e.g. tracking animal numbers)

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

Maintaining veterinary medical records

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

Please rate the quality of the information you have been provided to comply with regulatory requirements regarding IACUC for research and education.

- Excellent
- Above average
- Average
- Below average
- Poor
- Not available

Please rate the training on IACUC you received at UH.

- Excellent
- Above average
- Average
- Below average
- Poor
- Not available

Please provide any other suggestions that may help improve your ability to meet IRB/human subjects requirements for your research and/or teaching.

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## **Biosafety (includes infectious agents, recombinant materials, import/export of microorganisms)**

I am familiar with Biosafety.

- Yes
- No

Select the statement that best describes your involvement with Biosafety.

- Biosafety is relevant to my work.
- Biosafety does not apply to my work.

We would like to know about your experiences in meeting biosafety (i.e., exposure and release of hazardous biological materials) requirements at UH. Please rate your experiences with each of the following tasks related to biosafety requirements:

Understanding what is required and why

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

Fulfilling federal requirements for training in biosafety

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

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Establishing protocols to comply with federal and state requirements for handling biohazards

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

Establishing protocols to comply with federal and state requirements for handling blood-borne pathogens

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

Filing applications to comply with state requirements for the use of microorganisms

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

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Please rate the quality of the information you have been provided to comply with regulatory requirements regarding biosafety in research and education.

- Excellent
- Above average
- Average
- Below Average
- Poor
- Not available

Please rate the training on biosafety you received at UH.

- Excellent
- Above average
- Average
- Below Average
- Poor
- Not available

Please provide any other suggestions that may help improve your ability to meet biosafety subjects requirements for your research and/or teaching.

## Laboratory Safety/Security

I am familiar with Laboratory safety/security.

- Yes
- No

Select the statement that best describes your involvement with Laboratory safety/security.

- Laboratory safety/security is relevant to my work.
- Laboratory safety/security does not apply to my work.

We would like to know about your experiences in meeting laboratory safety and security requirements at UH. Please rate your experiences with each of the following tasks related to laboratory safety and security: (Note that “laboratory” in this context refers to all of your research work spaces.)

Understanding what is required and why

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

---

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

General laboratory safety requirements

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

Laboratory inspections

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

Fulfilling federal requirements for training in laboratory safety and security

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

---

Controls on access to computers and data/information

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

Controls on access to facilities, equipment and/or supplies

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

Personnel issues related to laboratory security (e.g. foreign nationals)

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

---

Please rate the quality of the information you have been provided to comply with regulatory requirements regarding laboratory safety/security in research and education.

- Excellent
- Above average
- Average
- Below average
- Poor
- Not available

Please rate the training on laboratory safety/security you received at UH.

- Excellent
- Above average
- Average
- Below average
- Poor
- Not available

Please provide any other suggestions that may help improve your ability to meet laboratory safety/security requirements for your research and/or teaching.

## Chemical Safety

I am familiar with chemical safety.

- Yes
- No

Select the statement that best describes your involvement with chemical safety.

- Chemical safety is relevant to my work.
- Chemical safety does not apply to my work.

We would like to know about your experiences in meeting chemical safety requirements at UH. Please rate your experiences with each of the following tasks related to chemical safety requirements:

General chemical safety/security responsibilities

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

---

Chemical cataloging and inventory management

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

Fulfilling federal requirements for training in chemical safety

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

Please rate the quality of the information you have been provided to comply with regulatory requirements regarding chemical safety in research and education.

- Excellent
- Above average
- Average
- Below average
- Poor
- Not available

Please rate the training on chemical safety you received at UH.

- Excellent
- Above average
- Average
- Below average
- Poor
- Not available

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Please provide any other suggestions that may help improve your ability to meet chemical safety requirements for your research and/or teaching.

## Radiation Safety

I am familiar with radiation safety.

- Yes
- No

Select the statement that best describes your involvement with radiation safety.

- Radiation safety is relevant to my work
- Radiation safety does not apply to my work.

We would like to know about your experiences in meeting radiation safety requirements at UH. Please rate your experiences with each of the following tasks related to radiation safety requirements:

Fulfilling federal requirements for training in radiation safety

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

Dealing with federal requirements for handling radioisotopes

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

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Ensuring security of machines and radioisotopes, including personnel procedures

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

Dealing with federal requirements for X-ray machines and other radiation-producing equipment

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

Please rate the quality of the information you have been provided to comply with regulatory requirements regarding radiation safety in research and education.

- Excellent
- Above average
- Average
- Below average
- Poor
- Not available

Please rate the training on radiation safety you received at UH.

- Excellent
- Above average
- Average
- Below average
- Poor
- Not available

Please provide any other suggestions that may help improve your ability to meet radiation safety requirements for your research and/or teaching.

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## Ethical Issues

I am familiar with ethical issues.

- Yes
- No

We would like to know about your experiences in meeting ethical issues requirements at UH. Please rate your experiences with each of the following tasks related ethical issues requirements:

Understanding what is required and why

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

Fulfilling requirements for training

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

Filing conflict of interest forms

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

---

Reporting an ethical issue

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

The procedures following reporting an ethical issue

- Not a problem
- A little problematic
- Somewhat problematic
- Quite problematic
- Very problematic
- Not applicable; no experience

If you experienced any problem(s), would you briefly describe the problem(s) and provide any suggestion you may have for fixing the problem(s).

Please rate the quality of the information you have been provided to comply with regulatory requirements regarding ethical issues in research and education.

- Excellent
- Above average
- Average
- Below average
- Poor
- Not available

Please rate the training on ethical issues you received at UH.

- Excellent
- Above average
- Average
- Below average
- Poor
- Not available

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Please provide any other suggestions that may help improve your ability to meet ethical issue requirements for your research and/or teaching.

## Additional Compliance Areas

Select the statement that best describes your involvement or familiarity with the following additional compliance areas.

Classified/Restricted/Sensitive research information

- Relevant to your work
- Familiar with, but not relevant to your work
- Not applicable

Currency movement between countries

- Relevant to your work
- Familiar with, but not relevant to your work
- Not applicable

Dive Safety

—The University of Hawai'i Diving Safety Program is responsible for the authorization of UH scientific divers, evaluation and approval of dive plans, training and program support for UH-authorized divers, coordination of diver medical exam scheduling, and investigation of SCUBA diving accidents.

- Relevant to your work
- Familiar with, but not relevant to your work
- Not applicable

Endangered Species Act

—To protect critically imperiled species from extinction.

- Relevant to your work
- Familiar with, but not relevant to your work
- Not applicable

Federal Cave Protection Act

—To secure, protect, and preserve significant caves on Federal lands, and to foster increased cooperation and exchange of information between governmental authorities and those who utilize caves located on federal lands for scientific, education, or recreational purposes.

- Relevant to your work
- Familiar with, but not relevant to your work
- Not applicable

---

Health Insurance Portability and Accountability Act (HIPAA)

—Title I of HIPAA protects health insurance coverage for workers and their families when they change or lose their jobs. Title II of HIPAA requires the establishment of national standards for electronic health care transactions and national identifiers for providers, health insurance plans, and employers.

- Relevant to your work
- Familiar with, but not relevant to your work
- Not applicable

International Traffic in Arms Regulations (ITAR)/Export Controls

—Government regulations that control the export and import of defense-related articles and services on the United States Munitions List (USML).

- Relevant to your work
- Familiar with, but not relevant to your work
- Not applicable

Locational permits (to conduct research in a particular area)

- Relevant to your work
- Familiar with, but not relevant to your work
- Not applicable

National Environmental Policy Act (NEPA)

—Environmental law that established a U.S. national policy promoting the enhancement of the environment.

- Relevant to your work
- Familiar with, but not relevant to your work
- Not applicable

Native American Graves Protection and Repatriation Act (NAGPRA)

—Requires federal agencies and institutions that receive federal funding to return Native American cultural items to lineal descendants and culturally affiliated Indian tribes and Native Hawaiian organizations.

- Relevant to your work
- Familiar with, but not relevant to your work
- Not applicable

Unmanned Aerial Vehicles (UAV) and/or Drones

- Relevant to your work
- Familiar with, but not relevant to your work
- Not applicable

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Unmanned Underwater Vehicles (UUV) and/or Deploying Moorings

- Relevant to your work
- Familiar with, but not relevant to your work
- Not applicable

Add any other areas not listed here that are relevant to your work.

## Institutional Practices

Which of the following would be most important for you in meeting regulatory requirements in teaching and research? (Select all that apply)

- Integrated electronic system for compliance applications, training, and communication with faculty and others
- Orientation training on compliance requirements, procedures, and assistance for new faculty, staff, and graduate students
- Seamless interface between Office of Research Services (ORS) and Office of Research Compliance systems
- Information re: research compliance mandates and requirements
- Assistance for faculty and others on filing compliance applications and documents
- Other:.....

What other comments or suggestions do you have regarding compliance requirements at UH?

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## APPENDIX J

### SURVEY RESULTS

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The number (n) of responses for each question is based on the respondents' self-reported relevance of, and experience with, each compliance area. Respondents who claimed the respective area was not relevant to their work or that they had no experience with a particular topic were not factored into n, which is represented by the equation  $n=a-b-c-d$  where a represents the total number of survey respondents, b represents the number of respondents who claimed the respective area was not relevant to their work, c represents the number of respondents who answered "not applicable; no experience", and d represents the number of respondents who chose not to answer the question. The number of respondents who skipped the question was calculated by adding c and d together.

To protect respondents' confidentiality, identifying information such as names and college/school affiliations were redacted from the comments. This was done by a staff member whose work was reviewed by another person. In cases where there was uncertainty whether the comment could be traced to the respondent, caution prevailed and the entry was redacted. Individuals who were the object of respondents' comments, whether positive or negative, also had their names redacted, but administrative offices and units remained identified.

## 2015 Faculty Survey on Research Compliance

### What is your academic rank or position title?

Option	# Responses	Response %
Tenured faculty	548	58.61%
Untenured faculty	311	33.26%
Staff member (UH or RCUH)	33	3.53%
Graduate student	29	3.10%
Other	14	1.50%
<b>4</b> skipped this question	Total responses <b>935</b>	100.00%

### How long have you been at the UH or RCUH (round to nearest year)?

Option	# Responses	Response %
Responded	939	100.00%
No response	0	0.00%
<b>0</b> skipped this question	Total <b>939</b>	100.00%

### What is your campus?

Option	# Responses	Response %
UH Manoa	640	69.34%
UH West Oahu	19	2.06%
UH Hilo	43	4.66%
UH Community Colleges/Maui College	221	23.94%
<b>16</b> skipped this question	Total responses <b>923</b>	100.00%

### What is your principal field of study?

Option	# Responses	Response %
Agricultural Sciences	43	4.67%
Biological; Biomedical Sciences	134	14.57%
Business; Law	37	4.02%
Clinical Sciences; Medicine	76	8.26%
Education	96	10.43%
Engineering; Computer Sciences	51	5.54%
Environmental Sciences	57	6.20%
Humanities/Arts; Architecture	157	17.07%
Physical Sciences; Mathematics	71	7.72%
Social and Behavioral Sciences	145	15.76%
Other	53	5.76%
<b>19</b> skipped this question	Total responses <b>920</b>	100.00%

### I am familiar with Human Subjects—Institutional Review Board

Option	# Responses	Response %
Yes	609	65.13%
No	326	34.87%
<b>4</b> skipped this question	Total responses <b>935</b>	100.00%

### Human subjects—Institutional Review Board (IRB)

Option	# Responses	Response %
Human Subjects—Institutional Review Board (IRB) is relevant to my work.	393	41.85%
Human Subjects—Institutional Review Board (IRB) does not apply to my work.	546	58.15%
<b>0</b> skipped this question	Total responses <b>939</b>	100.00%

### Understanding what is required and why

Option	# Responses	Response %
Not a problem	187	52.09%
A little problematic	85	23.68%
Somewhat problematic	48	13.37%
Quite problematic	21	5.85%
Very problematic	18	5.01%
<b>34</b> skipped this question	Total responses <b>359</b>	100.00%

### Preparing IRB protocols and consent forms for initial review

Option	# Responses	Response %
Not a problem	193	57.10%
A little problematic	81	23.96%
Somewhat problematic	37	10.95%
Quite problematic	15	4.44%
Very problematic	12	3.55%
<b>55</b> skipped this question	Total responses <b>338</b>	100.00%

### Completing protocol revisions requested by reviewers

Option	# Responses	Response %
Not a problem	200	65.15%
A little problematic	63	20.52%
Somewhat problematic	20	6.51%
Quite problematic	9	2.93%
Very problematic	15	4.89%
<b>86</b> skipped this question	Total responses <b>307</b>	100.00%

**Waiting for feedback from review**

Option	# Responses	Response %
Not a problem	176	54.32%
A little problematic	68	20.99%
Somewhat problematic	37	11.42%
Quite problematic	19	5.86%
Very problematic	24	7.41%
<b>69</b> skipped this question	Total responses <b>324</b>	100.00%

**Completing annual continuing review of protocols**

Option	# Responses	Response %
Not a problem	185	70.34%
A little problematic	42	15.97%
Somewhat problematic	23	8.75%
Quite problematic	7	2.66%
Very problematic	6	2.28%
<b>130</b> skipped this question	Total responses <b>263</b>	100.00%

**Ensuring that study procedures meet protocols**

Option	# Responses	Response %
Not a problem	240	75.47%
A little problematic	42	13.21%
Somewhat problematic	13	4.09%
Quite problematic	10	3.14%
Very problematic	13	4.09%
<b>75</b> skipped this question	Total responses <b>318</b>	100.00%

**Fulfilling federal requirements for training in human subjects protections**

Option	# Responses	Response %
Not a problem	208	68.65%
A little problematic	51	16.83%
Somewhat problematic	24	7.92%
Quite problematic	8	2.64%
Very problematic	12	3.96%
<b>90</b> skipped this question	Total responses <b>303</b>	100.00%

Please rate the quality of the information you have been provided to comply with regulatory requirements regarding IRB/human subjects for research and education.

Option	# Responses	Response %
Excellent	84	24.93%
Above average	111	32.94%
Average	111	32.94%
Below average	13	3.86%
Poor	18	5.34%
<b>56</b> skipped this question	Total responses <b>337</b>	100.01%

Please rate the training on IRB/human subjects you received at UH.

Option	# Responses	Response %
Excellent	68	21.86%
Above average	81	26.05%
Average	121	38.91%
Below average	18	5.79%
Poor	23	7.40%
<b>82</b> skipped this question	Total responses <b>311</b>	100.01%

Please provide any other suggestions that may help improve your ability to meet IRB/human subjects requirements for your research and/or teaching.

Option	# Responses	Response %
Responded	86	21.88%
No response	307	78.12%
	Total <b>393</b>	100.00%

I am familiar with Institutional Animal Care and Use Committee (IACUC)

Option	# Responses	Response %
Yes	287	30.89%
No	642	69.11%
<b>10</b> skipped this question	Total responses <b>929</b>	100.00%

Select the statement that best describes your involvement with the Institutional Animal Care and Use Committee (IACUC)

Option	# Responses	Response %
Institutional Animal Care and Use Committee (IACUC) is relevant to my work.	116	12.35%
Institutional Animal Care and Use Committee (IACUC) does not apply to my work.	823	87.65%
<b>0</b> skipped this question	Total responses <b>939</b>	100.00%

### Understanding what is required and why

Option	# Responses	Response %
Not a problem	48	45.71%
A little problematic	25	23.81%
Somewhat problematic	14	13.33%
Quite problematic	9	8.57%
Very problematic	9	8.57%
<b>11</b> skipped this question	Total responses <b>105</b>	99.99%

### Preparing IACUC protocols and consent forms for initial review

Option	# Responses	Response %
Not a problem	35	35.71%
A little problematic	23	23.47%
Somewhat problematic	22	22.45%
Quite problematic	11	11.22%
Very problematic	7	7.14%
<b>18</b> skipped this question	Total responses <b>98</b>	99.99%

### Completing annual IACUC reviews and three-year renewals

Option	# Responses	Response %
Not a problem	47	49.47%
A little problematic	19	20.00%
Somewhat problematic	21	22.11%
Quite problematic	7	7.37%
Very problematic	1	1.05%
<b>21</b> skipped this question	Total responses <b>95</b>	100.00%

### Completing protocol revisions requested by reviewers

Option	# Responses	Response %
Not a problem	50	54.95%
A little problematic	14	15.38%
Somewhat problematic	18	19.78%
Quite problematic	7	7.69%
Very problematic	2	2.20%
<b>25</b> skipped this question	Total responses <b>91</b>	100.00%

### Fulfilling federal and state requirements for training in animal care and use

Option	# Responses	Response %
Not a problem	59	62.11%
A little problematic	17	17.89%

Somewhat problematic	17	17.89%
Quite problematic	1	1.05%
Very problematic	1	1.05%
<b>21</b> skipped this question	Total responses <b>95</b>	99.99%

**Satisfying federal and state requirements for funded projects (e.g. tracking animal numbers)**

Option	# Responses	Response %
Not a problem	56	63.64%
A little problematic	18	20.45%
Somewhat problematic	9	10.23%
Quite problematic	2	2.27%
Very problematic	3	3.41%
<b>28</b> skipped this question	Total responses <b>88</b>	100.00%

**Maintaining veterinary medical records**

Option	# Responses	Response %
Not a problem	60	78.95%
A little problematic	8	10.53%
Somewhat problematic	7	9.21%
Quite problematic	1	1.32%
Very problematic	0	0.00%
<b>40</b> skipped this question	Total responses <b>76</b>	100.01%

**Please rate the quality of the information you have been provided to comply with regulatory requirements regarding IACUC for research and education.**

Option	# Responses	Response %
Excellent	19	19.00%
Above average	29	29.00%
Average	38	38.00%
Below average	8	8.00%
Poor	6	6.00%
<b>16</b> skipped this question	Total responses <b>100</b>	100.00%

**Please rate the training on IACUC you received at UH.**

Option	# Responses	Response %
Excellent	12	12.50%
Above average	24	25.00%
Average	43	44.79%

Below average	7	7.29%
Poor	10	10.42%
<b>20</b> skipped this question	Total responses <b>96</b>	100.00%

Please provide any other suggestions that may help improve your ability to meet IACUC subjects requirements for your research and/or teaching.

Option	# Responses	Response %
Responded	28	24.14%
No response	88	75.86%
	Total <b>116</b>	100.00%

I am familiar with Biosafety.

Option	# Responses	Response %
Yes	430	45.99%
No	505	54.01%
<b>4</b> skipped this question	Total responses <b>935</b>	100.00%

Select the statement that best describes your involvement with Biosafety.

Option	# Responses	Response %
Biosafety is relevant to my work.	233	24.81%
Biosafety does not apply to my work.	706	75.19%
<b>0</b> skipped this question	Total responses <b>939</b>	100.00%

Understanding what is required and why

Option	# Responses	Response %
Not a problem	123	54.19%
A little problematic	49	21.59%
Somewhat problematic	32	14.10%
Quite problematic	8	3.52%
Very problematic	15	6.61%
<b>6</b> skipped this question	Total responses <b>227</b>	100.01%

Fulfilling federal requirements for training in biosafety

Option	# Responses	Response %
Not a problem	140	63.93%
A little problematic	39	17.81%
Somewhat problematic	22	10.05%
Quite problematic	8	3.65%
Very problematic	10	4.57%
<b>14</b> skipped this question	Total responses <b>219</b>	100.01%

**Establishing protocols to comply with federal and state requirements for handling biohazards**

Option	# Responses	Response %
Not a problem	120	57.14%
A little problematic	44	20.95%
Somewhat problematic	21	10.00%
Quite problematic	13	6.19%
Very problematic	12	5.71%
<b>23</b> skipped this question	Total responses <b>210</b>	99.99%

**Establishing protocols to comply with federal and state requirements for handling blood-borne pathogens**

Option	# Responses	Response %
Not a problem	92	65.71%
A little problematic	24	17.14%
Somewhat problematic	10	7.14%
Quite problematic	3	2.14%
Very problematic	11	7.86%
<b>93</b> skipped this question	Total responses <b>140</b>	99.99%

**Filing applications to comply with state requirements for the use of microorganisms**

Option	# Responses	Response %
Not a problem	67	43.51%
A little problematic	20	12.99%
Somewhat problematic	21	13.64%
Quite problematic	11	7.14%
Very problematic	35	22.73%
<b>79</b> skipped this question	Total responses <b>154</b>	100.01%

**Please rate the quality of the information you have been provided to comply with regulatory requirements regarding biosafety in research and education.**

Option	# Responses	Response %
Excellent	53	24.54%
Above average	60	27.78%
Average	62	28.70%
Below Average	25	11.57%
Poor	16	7.41%
<b>17</b> skipped this question	Total responses <b>216</b>	100.00%

**Please rate the training on biosafety you received at UH.**

Option	# Responses	Response %
Excellent	55	25.46%
Above average	62	28.70%
Average	66	30.56%
Below Average	20	9.26%
Poor	13	6.02%
<b>17</b> skipped this question	Total responses <b>216</b>	100.00%

**Please provide any other suggestions that may help improve your ability to meet biosafety subjects requirements for your research and/or teaching.**

Option	# Responses	Response %
Responded	35	15.02%
No response	198	84.98%
	Total <b>233</b>	100.00%

**I am familiar with Laboratory safety/security.**

Option	# Responses	Response %
Yes	460	49.30%
No	473	50.70%
<b>6</b> skipped this question	Total responses <b>933</b>	100.00%

**Select the statement that best describes your involvement with Laboratory safety/security.**

Option	# Responses	Response %
Laboratory safety/security is relevant to my work.	309	32.91%
Laboratory safety/security does not apply to my work.	630	67.09%
<b>0</b> skipped this question	Total responses <b>939</b>	100.00%

**Understanding what is required and why**

Option	# Responses	Response %
Not a problem	202	68.24%
A little problematic	42	14.19%
Somewhat problematic	33	11.15%
Quite problematic	13	4.39%
Very problematic	6	2.03%
<b>13</b> skipped this question	Total responses <b>296</b>	100.00%

**General laboratory safety requirements**

Option	# Responses	Response %
Not a problem	217	74.57%
A little problematic	42	14.43%
Somewhat problematic	22	7.56%
Quite problematic	7	2.41%

Very problematic	3	1.03%
<b>18</b> skipped this question	Total responses <b>291</b>	100.00%

#### Laboratory inspections

Option	# Responses	Response %
Not a problem	194	72.39%
A little problematic	40	14.93%
Somewhat problematic	23	8.58%
Quite problematic	7	2.61%
Very problematic	4	1.49%
<b>41</b> skipped this question	Total responses <b>268</b>	100.00%

#### Fulfilling federal requirements for training in laboratory safety and security

Option	# Responses	Response %
Not a problem	189	72.41%
A little problematic	36	13.79%
Somewhat problematic	20	7.66%
Quite problematic	12	4.60%
Very problematic	4	1.53%
<b>48</b> skipped this question	Total responses <b>261</b>	99.99%

#### Controls on access to computers and data/information

Option	# Responses	Response %
Not a problem	180	74.07%
A little problematic	35	14.40%
Somewhat problematic	18	7.41%
Quite problematic	3	1.23%
Very problematic	7	2.88%
<b>66</b> skipped this question	Total responses <b>243</b>	99.99%

#### Controls on access to facilities, equipment and/or supplies

Option	# Responses	Response %
Not a problem	173	63.84%
A little problematic	41	15.13%
Somewhat problematic	31	11.44%
Quite problematic	17	6.27%
Very problematic	9	3.32%
<b>38</b> skipped this question	Total responses <b>271</b>	100.00%

**Personnel issues related to laboratory security (e.g. foreign nationals)**

Option	# Responses	Response %
Not a problem	187	78.57%
A little problematic	24	10.08%
Somewhat problematic	15	6.30%
Quite problematic	6	2.52%
Very problematic	6	2.52%
<b>71</b> skipped this question	Total responses <b>238</b>	99.99%

**Please rate the quality of the information you have been provided to comply with regulatory requirements regarding laboratory safety/security in research and education.**

Option	# Responses	Response %
Excellent	64	23.62%
Above average	82	30.26%
Average	89	32.84%
Below average	24	8.86%
Poor	12	4.43%
<b>38</b> skipped this question	Total responses <b>271</b>	100.01%

**Please rate the training on laboratory safety/security you received at UH.**

Option	# Responses	Response %
Excellent	60	22.56%
Above average	83	31.20%
Average	86	32.33%
Below average	23	8.65%
Poor	14	5.26%
<b>43</b> skipped this question	Total responses <b>266</b>	100.00%

**Please provide any other suggestions that may help improve your ability to meet laboratory safety/security requirements for your research and/or teaching.**

Option	# Responses	Response %
Responded	26	8.41%
No response	283	91.59%
	Total <b>309</b>	100.00%

**I am familiar with chemical safety.**

Option	# Responses	Response %
Yes	415	44.53%
No	517	55.47%
<b>7</b> skipped this question	Total responses <b>932</b>	100.00%

Select the statement that best describes your involvement with chemical safety.

Option	# Responses	Response %
Chemical safety is relevant to my work.	257	27.37%
Chemical safety does not apply to my work.	682	72.63%
<b>0</b> skipped this question	Total responses <b>939</b>	100.00%

#### General chemical safety/security responsibilities

Option	# Responses	Response %
Not a problem	185	73.12%
A little problematic	40	15.81%
Somewhat problematic	17	6.72%
Quite problematic	7	2.77%
Very problematic	4	1.58%
<b>4</b> skipped this question	Total responses <b>253</b>	100.00%

#### Chemical cataloging and inventory management

Option	# Responses	Response %
Not a problem	161	65.98%
A little problematic	44	18.03%
Somewhat problematic	30	12.30%
Quite problematic	3	1.23%
Very problematic	6	2.46%
<b>13</b> skipped this question	Total responses <b>244</b>	100.00%

#### Fulfilling federal requirements for training in chemical safety

Option	# Responses	Response %
Not a problem	173	76.21%
A little problematic	36	15.86%
Somewhat problematic	12	5.29%
Quite problematic	3	1.32%
Very problematic	3	1.32%
<b>30</b> skipped this question	Total responses <b>227</b>	100.00%

Please rate the quality of the information you have been provided to comply with regulatory requirements regarding chemical safety in research and education.

Option	# Responses	Response %
Excellent	70	29.54%

Above average	66	27.85%
Average	86	36.29%
Below average	11	4.64%
Poor	4	1.69%
<b>20</b> skipped this question	Total responses <b>237</b>	100.01%

Please rate the training on chemical safety you received at UH.

Option	# Responses	Response %
Excellent	68	29.18%
Above average	64	27.47%
Average	79	33.91%
Below average	17	7.30%
Poor	5	2.15%
<b>24</b> skipped this question	Total responses <b>233</b>	100.01%

Please provide any other suggestions that may help improve your ability to meet chemical safety requirements for your research and/or teaching.

Option	# Responses	Response %
Responded	24	9.34%
No response	233	90.66%
	Total <b>257</b>	100.00%

I am familiar with radiation safety.

Option	# Responses	Response %
Yes	276	29.61%
No	656	70.39%
<b>7</b> skipped this question	Total responses <b>932</b>	100.00%

Select the statement that best describes your involvement with radiation safety.

Option	# Responses	Response %
Radiation safety is relevant to my work	60	6.39%
Radiation safety does not apply to my work.	879	93.61%
<b>0</b> skipped this question	Total responses <b>939</b>	100.00%

Fulfilling federal requirements for training in radiation safety

Option	# Responses	Response %
Not a problem	43	81.13%
A little problematic	9	16.98%
Somewhat problematic	1	1.89%
Quite problematic	0	0.00%
Very problematic	0	0.00%
<b>7</b> skipped this question	Total responses <b>53</b>	100.00%

**Dealing with federal requirements for handling radioisotopes**

Option	# Responses	Response %
Not a problem	34	82.93%
A little problematic	6	14.63%
Somewhat problematic	0	0.00%
Quite problematic	1	2.44%
Very problematic	0	0.00%
<b>19</b> skipped this question	Total responses <b>41</b>	100.00%

**Ensuring security of machines and radioisotopes, including personnel procedures**

Option	# Responses	Response %
Not a problem	36	85.71%
A little problematic	3	7.14%
Somewhat problematic	2	4.76%
Quite problematic	1	2.38%
Very problematic	0	0.00%
<b>18</b> skipped this question	Total responses <b>42</b>	99.99%

**Dealing with federal requirements for X-ray machines and other radiation-producing equipment**

Option	# Responses	Response %
Not a problem	30	83.33%
A little problematic	6	16.67%
Somewhat problematic	0	0.00%
Quite problematic	0	0.00%
Very problematic	0	0.00%
<b>24</b> skipped this question	Total responses <b>36</b>	100.00%

**Please rate the quality of the information you have been provided to comply with regulatory requirements regarding radiation safety in research and education.**

Option	# Responses	Response %
Excellent	15	31.25%
Above average	13	27.08%
Average	16	33.33%
Below average	3	6.25%
Poor	1	2.08%
<b>12</b> skipped this question	Total responses <b>48</b>	99.99%

Please rate the training on radiation safety you received at UH.

Option	# Responses	Response %
Excellent	14	30.43%
Above average	12	26.09%
Average	16	34.78%
Below average	3	6.52%
Poor	1	2.17%
<b>14</b> skipped this question	Total responses <b>46</b>	99.99%

Please provide any other suggestions that may help improve your ability to meet radiation safety requirements for your research and/or teaching.

Option	# Responses	Response %
Responded	6	10.00%
No response	54	90.00%
	Total <b>60</b>	100.00%

I am familiar with ethical issues.

Option	# Responses	Response %
Yes	843	91.63%
No	77	8.37%
<b>19</b> skipped this question	Total responses <b>920</b>	100.00%

Understanding what is required and why

Option	# Responses	Response %
Not a problem	615	74.82%
A little problematic	110	13.38%
Somewhat problematic	59	7.18%
Quite problematic	19	2.31%
Very problematic	19	2.31%
<b>117</b> skipped this question	Total responses <b>822</b>	100.00%

Fulfilling requirements for training

Option	# Responses	Response %
Not a problem	558	76.97%
A little problematic	91	12.55%
Somewhat problematic	48	6.62%
Quite problematic	11	1.52%
Very problematic	17	2.34%
<b>214</b> skipped this question	Total responses <b>725</b>	100.00%

### Filing conflict of interest forms

Option	# Responses	Response %
Not a problem	670	86.23%
A little problematic	53	6.82%
Somewhat problematic	30	3.86%
Quite problematic	12	1.54%
Very problematic	12	1.54%
<b>162</b> skipped this question	Total responses <b>777</b>	99.99%

### Reporting an ethical issue

Option	# Responses	Response %
Not a problem	378	70.13%
A little problematic	63	11.69%
Somewhat problematic	38	7.05%
Quite problematic	30	5.57%
Very problematic	30	5.57%
<b>400</b> skipped this question	Total responses <b>539</b>	100.01%

### The procedures following reporting an ethical issue

Option	# Responses	Response %
Not a problem	314	65.28%
A little problematic	66	13.72%
Somewhat problematic	42	8.73%
Quite problematic	27	5.61%
Very problematic	32	6.65%
<b>458</b> skipped this question	Total responses <b>481</b>	99.99%

### Please rate the quality of the information you have been provided to comply with regulatory requirements regarding ethical issues in research and education.

Option	# Responses	Response %
Excellent	130	17.66%
Above average	189	25.68%
Average	309	41.98%
Below average	60	8.15%
Poor	48	6.52%
<b>203</b> skipped this question	Total responses <b>736</b>	99.99%

Please rate the training on ethical issues you received at UH.

Option	# Responses	Response %
Excellent	121	17.41%
Above average	156	22.45%
Average	295	42.45%
Below average	63	9.06%
Poor	60	8.63%
<b>244</b> skipped this question	Total responses <b>695</b>	100.00%

Please provide any other suggestions that may help improve your ability to meet ethical issue requirements for your research and/or teaching.

Option	# Responses	Response %
Responded	108	11.50%
No response	831	88.50%
	Total <b>939</b>	100.00%

**Classified/Restricted/Sensitive research information**

Option	# Responses	Response %
Relevant to your work	180	48.65%
Familiar with, but not relevant to your work	190	51.35%
<b>569</b> skipped this question	Total responses <b>370</b>	100.00%

**Currency movement between countries**

Option	# Responses	Response %
Relevant to your work	35	29.41%
Familiar with, but not relevant to your work	84	70.59%
<b>820</b> skipped this question	Total responses <b>119</b>	100.00%

**Dive Safety**

—The University of Hawai'i Diving Safety Program is responsible for the authorization of UH scientific divers, evaluation and approval of dive plans, training and program support for UH-authorized divers, coordination of diver medical exam scheduling, and investigation of SCUBA diving accidents.

Option	# Responses	Response %
Relevant to your work	43	38.05%
Familiar with, but not relevant to your work	70	61.95%
<b>826</b> skipped this question	Total responses <b>113</b>	100.00%

**Endangered Species Act**

—To protect critically imperiled species from extinction.

Option	# Responses	Response %
Relevant to your work	62	31.16%
Familiar with, but not relevant to your work	137	68.84%
<b>740</b> skipped this question	Total responses <b>199</b>	100.00%

**Federal Cave Protection Act**

—To secure, protect, and preserve significant caves on Federal lands, and to foster increased cooperation and exchange of information between governmental authorities and those who utilize caves located on federal lands for scientific, education, or recreational purposes.

Option	# Responses	Response %
Relevant to your work	8	19.51%
Familiar with, but not relevant to your work	33	80.49%
<b>898</b> skipped this question	Total responses <b>41</b>	100.00%

**Health Insurance Portability and Accountability Act (HIPAA)**

—Title I of HIPAA protects health insurance coverage for workers and their families when they change or lose their jobs. Title II of HIPAA requires the establishment of national standards for electronic health care transactions and national identifiers for providers, health insurance plans, and employers.

Option	# Responses	Response %
Relevant to your work	189	50.67%
Familiar with, but not relevant to your work	184	49.33%
<b>566</b> skipped this question	Total responses <b>373</b>	100.00%

**International Traffic in Arms Regulations (ITAR)/Export Controls**

—Government regulations that control the export and import of defense-related articles and services on the United States Munitions List (USML).

Option	# Responses	Response %
Relevant to your work	33	40.24%
Familiar with, but not relevant to your work	49	59.76%
<b>857</b> skipped this question	Total responses <b>82</b>	100.00%

**Locational permits (to conduct research in a particular area)**

Option	# Responses	Response %
Relevant to your work	128	63.05%
Familiar with, but not relevant to your work	75	36.95%
<b>736</b> skipped this question	Total responses <b>203</b>	100.00%

**National Environmental Policy Act (NEPA)**

—Environmental law that established a U.S. national policy promoting the enhancement of the environment.

Option	# Responses	Response %
Relevant to your work	68	36.36%
Familiar with, but not relevant to your work	119	63.64%
<b>752</b> skipped this question	Total responses <b>187</b>	100.00%

**Native American Graves Protection and Repatriation Act (NAGPRA)**

—Requires federal agencies and institutions that receive federal funding to return Native American cultural items to lineal descendants and culturally affiliated Indian tribes and Native Hawaiian organizations.

Option	# Responses	Response %
Relevant to your work	14	10.85%
Familiar with, but not relevant to your work	115	89.15%
<b>810</b> skipped this question	Total responses <b>129</b>	100.00%

**Unmanned Aerial Vehicles (UAV) and/or Drones**

Option	# Responses	Response %
Relevant to your work	31	29.52%
Familiar with, but not relevant to your work	74	70.48%
<b>834</b> skipped this question	Total responses <b>105</b>	100.00%

**Unmanned Underwater Vehicles (UUV) and/or Deploying Moorings**

Option	# Responses	Response %
Relevant to your work	37	46.84%
Familiar with, but not relevant to your work	42	53.16%
<b>860</b> skipped this question	Total responses <b>79</b>	100.00%

**Add any other areas not listed here that are relevant to your work.**

Option	# Responses	Response %
Responded	29	3.09%
No response	910	96.91%
	Total <b>939</b>	100.00%

**Which of the following would be most important for you in meeting regulatory requirements in teaching and research? (Select all that apply)**

Option	# Responses	Response %
Integrated electronic system for compliance applications, training, and communication with faculty and others	532	61.65%
Orientation training on compliance requirements, procedures, and assistance for new faculty, staff, and graduate students	480	55.62%
Seamless interface between Office of Research Services (ORS) and Office of Research Compliance systems	335	38.82%
Information re: research compliance mandates and requirements	332	38.47%
Assistance for faculty and others on filing compliance applications and documents	488	56.55%
Other	46	5.33%
<b>76</b> skipped this question	Total <b>863</b>	

**What other comments or suggestions do you have regarding compliance requirements at UH?**

<b>Option</b>	<b># Responses</b>	<b>Response %</b>
Responded	106	11.29%
No response	833	88.71%
	Total <b>939</b>	100.00%

## IRB Understanding what is required and why

- 1 I did not personally experience problems, but my colleague who applied for clearance recently told me that, after the previous director stepped down, somehow the requirements for clearance changed in a direction that is opposite to the national trend (i.e., what the National Research Council suggests on the practice of IRB approval for behavioral-science experimental research).
- 2 The process/application itself is not difficult to complete, but sometimes the information is difficult to find on the web-site. As of the last application I submitted, the information was all over the place and I ended up sending a clarification email to the office because I remembered reading a protocol point but could not again locate it...all of the information is there, it is just scattered.
- 3 Not always consistent reviews.
- 4 The forms include double negatives and layers of check boxes that are unclearly defined. The application process is cumbersome and time consuming. Virtually all my research qualifies as expedited review and yet it takes considerable time and effort to coordinate with the IRB.
- 5 It is not always clear what the appropriate procedures are to follow/applicable. Many times several revisions are needed to the initial application.
- 6 When I applied to get IRB approval, the IRB did not know that I had IBC approval for the the proposed research. There must be a system-wide data entry for all IBC, IRB, IACUC approvals, so the IRB knows I have IBC approval for the same research. IRB needs to communicate with the IBC, to ensure that we stay in compliant and to ensure oversight, rather than PI's getting an e-mails saying "your IRB application is approved, please make sure you have IBC approval." Right now the left hand don't know what the right hand is doing.
- 7 long waits for approval, limited communication or updates along the way.
- 8 Not very responsive or effective.
- 9 The fact that is is so difficult to get IRB to work with human subjects within certain areas.
- 10 Unpredictable in the past, unclear as to what doesn't qualify.
- 11 The review of materials is too variable. It is abundantly clear that the way a protocol is handled/how many things are requests depends on who reviews your paperwork.
- 12 IRB folks are very helpful with advice. For those of us in the Social Sciences, the problem is just the IRB as a field appears to be driven by Natural Science concerns and regulations that aren't consistent with an understanding of research as value-based (rather than value-free), inherently subjective (as opposed to objective), engaged with a desire to improve society, interpretive, and political.
- 13 The forms and procedures change constantly, so that what you were told to do for one application gets rejected when you file another application just a few months later. This gets particularly irritating when the changes are not substantive (e.g., not related to human subjects protection), but rather are bureaucratically-initiated changes in formatting. ALSO, the IRB instructions are NOT clear on which CITI modules completion forms are to be submitted, and why. CITI has many modules, issues many different forms and reports, and I find the IRB instructions on which ones need to be submitted with the application to be clear as mud. There always seems to be something else required, or something different than what I appended.
- 14 I'm sometimes not clear on which research needs IRB approval. I typically call IRB to find out or review online documents.
- 15 Human Subjects Committee continues to be an impediment to research as they go out of their way to find any reason to revise and resubmit. They seem to believe if they cannot find some trivial thing for researchers to redo, they have failed in their duty.
- 16 my research as always been exempt.
- 17 Timely responses
- 18 Faculty not handling medical records should not have to complete training on that. Most studies in my field are exempt, and there should be an easier way to get the papers filed.
- 19 As a grant writer understanding the requirements of working with participants to help improve potential workplace development and studies.
- 20 I have generally received help from the office when I needed it.
- 21 Sometimes hard to determine what is considered exempt, expedited, etc.
- 22 My research is on a war zone and most of my respondents only agree to share their thoughts if I assure them their anonymity
- 23 The way in which the questions on the application form related to my particular discipline and project were somewhat unclear.
- 24 I was recently applied for a renewal application--a project I have had for about 6 years. This year, I was asked to submit

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information regarding how many of each participant type was enrolled. This is not on the form nor did I have to submit the information in the past. I do not understand why this level of detail is needed. If additional information is needed, I suggest the reviewers explain why. [REDACTED]

- 25 Sometimes it is not always clear when a change to the protocol needs to be reported.
- 26 I am experienced with this at several different universities so knew what to do. But I can see how this would be the biggest problem for anyone unfamiliar with the process. I think it would be good for people involved with the IRB to offer trainings several times a year, focused on particular methods so that researchers could attend and learn from the IRB staff and from each other. Also, sharing methods and their level of acceptability for the IRB across disciplines is helpful, and the iRB could facilitate this. One example I can think of is when someone used to doing archival research began to work with human subjects, and found that the people he was interviewing would not use consent forms. He found himself in a quandary, thought about doing recorded oral consent, and did so, but basically he had to “invent” oral consent procedures for himself (he actually told me he invented the idea of oral consent). Using oral consent scripts is standard procedure in anthropology when consent forms are inappropriate as they often are, and sharing this with this researcher could have helped him develop research procedures that were both compliant with IRB guidelines and with his subjects’ expectations, without him having to rack his brain to reinvent the wheel.
- 27 Unclear policy on what to do with consent forms when closing a project.
- 28 Nearly completely irrelevant to my research -- to slanted too much towards medical research and a few social sciences -- there are myriads of ways to be unethical in fieldwork research that are left entirely out while most IRB concerns are in applicable and inappropriate for most of my research. The required examination for me and my research students is a huge utter waste of time.
- 29 We have had to seek IRB waivers for things that are so obviously not relevant for IRB when assessing anonymous feedback from students as a form of evaluation and assessment of novel educational programs. Seems a completely unnecessary set of hassles that add to an already cumbersome administrative process.
- 30 [REDACTED] has been very helpful - she helped me complete and understand forms
- 31 changes in requirements for training prior to submitting an application. Differences in training required for completing different applicants.
- 32 Some policies are not well defined... this is good and bad. It allows flexibility but some research sponsors don’t like flexibility.
- 33 I do different types of research with and without students and there are different requirements for which trainings I have to complete. It is very confusing. I should just be able to complete the highest level of training and be done with it.
- 34 No centralized IRB. Have to write too many protocols for different hospitals and sites.
- 35 Normally the IRB has been very helpful, but we need to get letters of exception for far too many types of minor studies or surveys.
- 36 Not really so much a problem, but there are some questions as to why we need to go through IRB when we have students who are developing web sites as part of a project and want to gather information from users about the web site -- aesthetics, usability, quality of information, etc. The questions are about the product, not about the human being using it, but we currently submit iRBs for all of those.
- 37 The requirements for minors is a bit onerous, but the staff at the IRB are very helpful.
- 38 Many studies in my field involve some type of deception. For example, we may not completely disclose the specific purpose of the study but may give a more general purpose. Now, the IRB has said that anything deception related in any aspect goes to the full committee. This is problematic., not only from a conceptual standpoint, but this also creates excessively long delays in obtaining approval for studies. I think policies regarding what constitutes deception (as intended by the various compliance agencies and other regulatory bodies) needs to be examined more carefully. The policy that is implemented right now by the IRB is overly conservative.
- 39 Online survey research should have one simple form used by both faculty and students. It should be uniform for all.
- 40 The information on the website is incomplete - there are only a few templates and instructions for completing the forms are often difficult to understand.
- 41 Reviews are very, very slow. A student of mine last year submitted her initial application in November of 2013, and did not get approval until April 2014. Second, reviews are often not informed at all by our field, requiring things that are not standard. We comply, but feel we are under a greater burden than colleagues at other institutions.
- 42 The office has done a good job of updating its website. But sometimes they use terms that, while common in their office, are terms that those of us seeking clearance encounter only occasionally. Or, we might have completed certification yet not remembered exactly where to put our hands on the document. A little more user-centered online coaching via their site would be helpful.
- 43 I’m no longer new, but somebody new learns in bits and pieces and through making mistakes. There’s no online class that

- REALLY teaches the nuts and bolts of human research. These IRB classes are engineered so that the bullet points are not presented in a clear manner. It's scary really.
- 44 Not clear where the line is drawn for requiring approval and consent forms, especially for activities, such as extension or consulting or providing advice, that may later be reported in aggregate. This is especially problematic given the state Freedom of Information Act requirements, which allows people to request data on individuals I have worked with while completely bypassing the IRB process.
- 45 IRB was not visible enough on campus when I started. Coming from a non-human-research background I was unaware of IRB requirements and did not learn about it nor hear about it for a long time after I was hired. Although there is now a CTE series on it (which is excellent), I would suggest expanding it for new faculty orientation if possible.
- 46 As Chair, some of the faculty experience problems in determining exactly what project is subject to IRB subject protection rules and what is not.
- 47 The workflow could be more clear and efficient, and many trivial studies should not have to be approved through them.
- 48 requiring illiterate non-English speaking peoples to sign a written consent form they cannot read or understand.
- 49 I missed some of the required elements because the instructions on the website were not clear.
- 50 I like the Review Category Flowchart on the Human Studies website to help determine what type of application form to submit - very helpful
- 51 inconsistent feedback but issues are minor
- 52 CITI certification requirements for students and instructions for completion. Perhaps a module in Laulima providing clear links and student requirements would be helpful.
- 53 Instructions are complicated, the process is opaque, and there is little help to navigate the system quickly
- 54 The recent director, [REDACTED] has asked us to take way too many trainings. I have been an investigator for decades. I don't need any more trainings. It's absurd. This is an academic issue that should have gone through the Faculty Senate. It's crazy that this woman is in the way of research progress. New investigators, i.e., graduate students, should have to do trainings, not seasoned faculty.
- 55 The IRB is really out of touch. Things students take for granted (like scholars rating asking about sexual activity (as part of a research paradigm) are taboo here . . . although routinely approved on the mainland. I have pretty much given up. If approved, approval takes so long that students' graduation is delayed.
- 56 Although when I have applied for a waiver in the past, nobody every replied.
- 57 The process in ethnographic research seems intrusive and unnecessary to any scholar that is attempting to published in peer review journals.
- 58 What kind of research requires approval by IRB.
- 59 In putting together grant applications, PIs are generally aware when IRB approval is required. There have been instances where PIs needed to be reminded/asked about IRB status or planned application to IRB.
- 60 IRB staff is unfamiliar with the type of research I do, and the populations I work with. Forms and protocols do not apply well to my research. Forms are designed for clinical trials. An introduction to one's research inserted where not requested seems to help the IRB respond more reasonably and appropriately to the context. The IRB turnaround is way too slow, especially for expedited submissions causing difficulties in meeting research timelines. IRB staff need to be allocated proportionately and thoughtfully according to the complexity and the familiarity with the type of research.
- 61 The IRB website is very clear and user friendly. The IRB coordinators are very helpful, all it takes it ask questions. They even come to classes to give presentations about how to do this.
- 62 Understanding which types of research is fitting for which types of approvals (exempt, expedited, full)
- 63 IRBs are geared towards lab work. My research involves field research, naturalistic observation, and participant observation. At times it is difficult to see how IRB standards apply to these research methods.
- 64 My students have been misinformed by the current staff of IRB. That office is a mess. Most of these protocols have no relevance to our department or what our students are doing, but when IRB doesn't waive, they have been absurd.
- 65 The problem is not with UH, but the the DOE, which is an absolute fortress and you just can't get any research approved. The process at UH is transparent and easy to navigate but much education research is impossible to conduct in the state. I will complete the remaining items related to UH only.
- 66 Trying to understand when a, project is exempt usually requires a phone call. I've limited the scope of my research to avoid human subjects regulation. For example interviewing adolescents.
- 67 lengthy delays in reviews, no pre submission assistance available
- 68 I have not submitted for IRB myself but have worked with others in its preparations related to work on which I've been involved
- 69 Rules keep changing and clarifications are not given on timely basis or they were never given at all. It comes as a surprise and this is not helpful. Rules are made without realism. For instance, certain experiments requires green house use, but

- the green house has been under construction since the year 2009 and yet to be available for research use.
- 70 The IRB has provided people in my department with contradictory advice. When the head of the IRB gave a presentation in our dept, it was confused and she did not have a clear idea about the procedures or rules involved. Her answers to the various questions and issues raised were superficial and indicated a lack of experience and knowledge.
- 71 time for evaluation and decision
- 72 A lot of paperwork
- 73 New laws and societal norms about privacy over time make it a moving target.
- 74 There has been some change in when my work is exempted and when it is not.
- 75 Responsiveness of the IRB to our inquiries and clarity of explanation can be improved -- really depends on who you talked to. The director and some staff are extremely helpful while some of my experience with a few staff is the opposite.
- 76 Doing community engaged research with undeserved populations raises issues about the differences in the values which underlie the ethics of research. Each community has informal and formal protocols that impact upon how research protocols are assessed as appropriate. It is not usually clear what these are until one is in the field.
- 77 There are definite understanding problems. They rest not with me or the students I supervise. The main problem is that the IRB staff has an insufficient grasp of standard practices in contemporary social science research. I also have the strong sense that the consulting faculty members are not conversant with the style of research we conduct, although our approach has existed for 50 years and has a solid basis in the social sciences. Solution: add a reviewer with relevant expertise.
- 78 Difficult to communicate with Manoa. Like everything else [REDACTED] is its own, isolated, entity. Might be more helpful to have a satellite office here
- 79 We are only dealing with fixed tissues and it is unclear how that fits into our biosafety protocol.
- 80 Just new to it
- 81 Sometimes you can submit a study for review and receive it back with adjustments. However the responses don't tell you how to make those adjustments satisfactorily, so you end up having to submit revisions multiple times.
- 82 need to post information on which CITI certificates are required to accompany the IRB submission
- 83 Not always sure about online subjects that may be anonymous.
- 84 Sometimes it's a little hard to figure out which exemption category is most appropriate. Also, the issue of differing permission levels based on the types of data gathered (with audio vs video being a big dividing line) takes a while to figure out.
- 85 it isn't clear on their website as to what forms and certifications are applicable to the type of research project being conducted
- 86 Inexperienced junior faculty making unnecessary pedantic and obstreperous demands
- 87 Online information was helpful
- 88 as a newby learning the ropes takes time.
- 89 I have not actually conducted human subjects research, but it is always a potential issue in literary/cultural studies in Hawaii and the Pacific. I am therefore familiar with the law/protocols, but have not had to fill out paperwork in my own work.
- 90 Phone assistance was prompt and very helpful
- 91 It's not as clear sometimes if our projects fall under biomedical or social & behavioral research. The CITI training requirements are different. I submitted 2 similar projects and they each fell under different categories and had different CITI requirements. Don't know if it depends on the reviewer.
- 92 Forms are unclear and overly complicated. Why aren't these forms online? Form fillable PDFs? Really? Is it still 2005?
- 93 My research involves interviewing [REDACTED] theatre artists about their work, and observing them at work. They do not consider themselves "human research subjects," and tend to be offended by all the paper work and terminology involved in IRB compliance.
- 94 Procedures change with staff changes. What is expected also changes with reviewer changes who are not familiar with a project. Assign review to reviewers who have some experience reading about a project and have some context so they are more able to understand a modification request.
- 95 I am usually a co-investigator or co-researcher so I usually do not directly deal with the IRB. Based on prior project with my colleagues, we've run into issues or obstacles but I am not able to elaborate on the details since I am not privy with them.
- 96 Much of our research is done in [REDACTED] and it has taken quite a bit of time, discussion, and negotiation to figure out when exemptions are appropriate and not and which data collection methods trigger more IRB procedures. The time needed to get clearance before collecting data very often hinders our work since it is done as part of the students' normal (which is often experimental because of the nature and purpose of the school) school curricu-

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lum. In the past, blanket permissions by parents to cover the ongoing research were sufficient. Apparently with changes in the law or perceptions of it, such general permissions are not sufficient, and the new procedures require specifying/submitting instruments and even the amount of time that data collection takes from the school day for those things deemed beyond the normal curriculum. We are coping, but it makes doing research difficult.

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- 97 Far too restrictive and slow. Rules about student involvement, lotteries, and specific wording for VERY SIMPLE surveys really put me at a disadvantage compared to collaborators at other universities.
- 
- 98 graduate and undergraduate students having to go through review and instruction when not really necessary according to federal or other rules/law
- 
- 99 Some of the forms and instructions can hard to understand. The website is also difficult to navigate. I ended up having to call the office to get help several times.
- 
- 100 established rules do not work when research involves illiterate rural peoples.
- 
- 101 My research grants includes travel expenses and I always have to pay out of pocket in advance because the travel grant is not released on time.
- 
- 102 The reach and scope of the requirements (like EVERY piece of research must be reviewed by the CHS) is problematic.
- 
- 103 It is common for studies to be designed in the clinical arena to avoid UH IRB and use other entities solely.
- 
- 104 The only problem I've experienced is recently. I have a couple of master's students who completed the Human Subjects Training (CITI Modules) last semester. They just turned in their IRB proposals, and IRB says they need to redo the training. This is probably only a one time issue. But it is frustrating. We have our students complete the CITI training as a requirement in a research course. Now only one semester later
- 
- 105 the wording of the instructions on the forms can be a little challenging, it can be clearer and simpler.
- 
- 106 The IRB regulations & requirements do not apply to my research or that of my students. The current IRB is based on a medical model which does not apply to social sciences. There has been a great deal written about this problem by social science researchers. My experience as a doctoral student was excellent--rather than forcing inappropriate medical model compliance, they counseled applicants on how best to address ethical issues that can arise with complex social science/participatory research, such as found with engaging in ethnographic research. The IRB had highly trained and experienced personnel for this purpose.
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- 107 Students get confused if approval is needed.
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- 108 Communication and approvals slow. With changes in staff over the past 6 years, the "ethical standards" have also changed, so I often have to revise materials when I submit my renewal applications. I am in week 5 of waiting to receive approval for a study protocol that previously approved via expedited review. If 5+ weeks is expedited, I would hate to know how long full approval takes.
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- 109 I found it a bit difficult to know which CITI program
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- 110 Good: Clear, updated website, very helpful IRB Coordinator that I dealt with, excellent customer service that this coordinator provided. This question seems very biased to negative options!
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- 111 My protocols are usually exempt because they only indirectly involve human subjects.
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### **IRB Preparing IRB protocols and consent forms for initial review**

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- 1 The time and resources it takes to prepare the documents is cumbersome, preventing some colleagues from carrying out pilot-study data collection (after earlier revisions) between the call for proposals and the due date, weakening the proposals.
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- 2 Ask staff to help fill out paperwork and give real guidance rather than just sending PIs to the web site to read incomprehensible instructions.
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- 3 Having exempt consent form samples online would be helpful
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- 4 expectation is that all details of survey or interview protocols are 100% complete and immutable is unrealistic. Much of this research is clearly not harmful to research participants (eg a confidential surveys about media use)so IRB bureaucracy is not really necessary, plus any potential harm would unlikely be highlighted by this process.
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- 5 Software not intuitive
- 
- 6 overkill for the type of research I do, wish new federal regs on exempt research would be instituted
- 
- 7 The templates are very helpful
- 
- 8 The assumptions that appear to govern the IRB protocols seem to stem more from a medical model of research than a social science model.
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- 9 On my first IRB review, I used the models provided. My reviewers then asked me to change the language in significant ways. The model did not match the feedback.
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- 10 Affects the anonymity of surveys, because the consent forms collect identifying data even though this is not tied to particular surveys.

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  - 11 The problem has less to do with UH and more to do with the fact that my grad students and I research in DOE schools. In trying to meet expectation of two groups students can and do receive contradictory expectations as to what needs to be included on the form

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  - 12 pedantic committee responses

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  - 13 In the past, I have encountered some niggling about small stuffs that really isn't central to the project itself. When the research process is slowed through requests for changing minutiae, it can be frustrating.

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  - 14 It is not clear whether our studies should be exempt, expedited or subjected to full review. We eventually figure it out (it varies by study), but the instructions are not specific enough to our field. I can't blame the IRB for this though.

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  - 15 Templates for clinical research would be hugely helpful- we start from scratch and hope to get all of the boilerplate required language correct. It would be much easier if up to date examples of standard language were available for reference.

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  - 16 deadlines for study implementation and frantic students complicate things. Online survey research should be exempted from the process completely. This type of research is not why the IRB exists.

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  - 17 Same as above.

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  - 18 Not a problem because we have learned to prepare everything ourselves. No assistance from the Office was provided.

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  - 19 Each clinical site has a different IRB application.

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  - 20 I really wish applications could be submitted electronically

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  - 21 It would be helpful if we had a designated person on our campus to work on IRB issues, even if that was only one of his/her responsibilities.

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  - 22 It has gotten a little more stream-lined, but is still time-consuming. Please create an online form.

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  - 23 The instructions for the forms seemed much more oriented toward scientific or psychological research rather than humanities concerns such as interviews for oral history projects. Still, this was a relatively minor problem for which I was able to get advice easily.

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  - 24 No training has been provided for staff to understand the timeline needed for IRB review.

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  - 25 Explaining the role of community partners who are sometimes in dual roles of participants and research partners can be difficult.

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  - 26 I had to retype the entire application form, because it was not compatible with my iMac computer.

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  - 27 Timely responses

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  - 28 I have had to resubmit and argue against positions they have taken that would have hurt my research (e.g., I had no intention of telling research subjects how many subjects I intended to use in my study -- some reviewer at IRB said I had to do that!).

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  - 29 Unnecessarily time-consuming, because you have to go back to the IRB website and go through the instructions with a fine-toothed comb for every single protocol, due to the constantly changing expectations.

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  - 30 Recently IRB protocols and consent forms have got much better, though the new webpage is not as good as the old one, which had a greater range of template consent forms if memory serves.

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  - 31 The materials provided as a template for the consent form is not at all exhaustive. If I were to turn in a document identical to the template, I am confident the Board would tell me that something is missing. The issue is that the template never gives enough information about what materials must be in the consent form in accordance with federal law. I am also perplexed with the some of the recommendations made by the Board. Some reviewers seem to comment on things that reflect their own predilections when it is not relevant to ethical or federal standards.

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  - 32 Sometimes the standard consent forms don't apply to education opportunities that also involve evaluation. For example, it is not acceptable to allow an intern receiving a stipend from a grant to simply "opt out" of the evaluation portion, because then there would be no data/impacts to report back to NSF. I've had to explain this a couple of times to IRB reviewers (for exempt proposals).

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  - 33 some of the questions can be confusing because you are not sure if they really pertain to your research

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  - 34 Take too long of time to start.

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  - 35 Unclear what details need to be provided. Several revisions needed.

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  - 36 The IRB process expects a very specific form of protocols designed for lab work and very structured studies. If you are collecting qualitative data, doing participant observation or open ended surveys there is no good way to acquire IRB approval. They require the specific questions you will ask, which of course undermines the entire point of open ended interview protocols. Furthermore, while in theory an "expedited review" there seems to be no distinction made between doing research where you are interviewing experts about a subject area and research ON subjects. There is a huge distinction between these activities and yet they are all lumped together by the IRB process in the most unhelpful of manners.
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- 37 Even when using templates and versions I've used previously, sometimes reviewers request changes.
- 38 -see previous comment-
- 39 Don't understand why consent is necessary for class projects, general online surveys, or focus groups, especially when participation is optional.
- 40 When advising students
- 41 IRB comes back and asks for things that are not in the instructions. Having an IRB member assigned to each project whose job includes assisting PI's and their staff to submit protocols would help both parties understand each other.
- 42 The instructions are very clear, the coordinators and staff are helpful and promptly answer my questions.
- 43 how to describe possible risks and the degree of detail needed in the description of the project
- 44 IRB staff are very good at clarifying their expectations.
- 45 Most of these rules and protocols are designed with the natural/physical sciences in mind - all they do is come in the way of Humanities and Social Science scholars going about their field-work and their research.
- 46 However, I have a grants manager who helps me.
- 47 I experienced problems for application that involves new study method, or vulnerable population. It took several rounds to get approve. I think more examples would be helpful.
- 48 Not clear on whether results from university student surveys needs IRB approval (i.e., faculty uses non-identifiable data from university student survey results, students sign consent)
- 49 Doing community engaged research with undeserved populations raises issues on what is submitted for a study protocols when these are still in the process of being finalized as part of engaging community members in the best way to design the study for rigor and acceptability in the community.
- 50 It is inappropriate and disturbing that social scientists have to use consent forms designed for biomedical research. It is disrespectful to the social scientists, a waste of our time, and a clear indication that the entire IRB requirement is fundamentally geared towards biomed research.
- 51 The people are very helpful, I'm just new at it
- 52 Process sometimes time consuming. Perhaps more and clearer individualized guidance can be provided up front, rather than after mistakes are made. IRB staff, however, are extremely helpful and responsive when needed.
- 53 provide a checklist of the required sections in the consent document
- 54 Basically, it's a pain in the @&& but we all know it's important!
- 55 there needs to be regular training and technical assistance. the "rules" seem to be different all the time.
- 56 Whole system requires systematic review and process needs to be online, streamlined and made less onerous
- 57 Could be a higher degree of computerization. And turnaround time is sloooooow.
- 58 Preparing the protocols and forms are straightforward, but time-consuming.
- 59 Online information was helpful
- 60 The supposedly fillable form has odd formatting
- 61 Time intensive
- 62 As a [REDACTED] I use pre-existing,public anonymous data sets such as the US Health and Retirement study, the Census and the National Survey of Adolescent and Adult Health.
- 63 More guidance or samples of appropriate consent forms for various types of projects would be helpful.
- 64 Filling out forms and emailing them is inefficient. It's like sending them into a black hole. There is no indication from the IRB office of progress either. If there were an online IRB system that tracked the IRB submission's progress, that would be much more useful.
- 65 Please see above.
- 66 I am usually a co-investigator or co-researcher so I usually do not directly deal with the IRB. Based on prior project with my colleagues, we've run into issues or obstacles but I am not able to elaborate on the details since I am not privy with them. However, the process is usually delayed when translation into a different language (language of the subjects) is involved.
- 67 get rid of unnecessary cover-your-ass reviews
- 68 i was asked to have illiterate interviewees sign consent forms they cannot read or understand.
- 69 Only problematic because it is an enigma to know how to structure it to appease the review board.
- 70 same as above
- 71 See above. The problems & possible solutions are the same throughout IRB regulations.
- 72 sample forms are helpful
- 73 Timing. Many schools are easier about fast-tracking approvals.
- 74 Good: Clear, updated website, very helpful IRB Coordinator that I dealt with, excellent customer service that this coordinator gave Again, this question seems very very biased to negative options!
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## IRB Completing protocol revisions requested by reviewers

- 1 There are people on the IRB who don't know what they are talking about when it comes to protecting participants. The community members often have no clue. The IRB has a very bad reputation for not letting meaningful research get through that would not cause harm. It's very bad. Also, it is taking way too long to get approval. Grad students need to graduate. Funding needs to be used. But when we are held up in six months of review and revision with the IRB, we miss some opportunities.
  - 2 Generally not a problem, but there is very little consistency in reviews. I have received very different feedback on nearly-identical protocols.
  - 3 See above.
  - 4 Give more examples of what is exempt versus non-exempt types of studies.
  - 5 Easily done, but never ending.
  - 6 I am usually a co-investigator or co-researcher so I usually do not directly deal with the IRB. Based on prior project with my colleagues, we've run into issues or obstacles but I am not able to elaborate on the details since I am not privy with them.
  - 7 The reviewers are far, far too overzealous in their interpretation of their role. I have had suggestions for how I should revise specific items in an instrument – a validated instrument with decades of research supporting it. I wasn't sure if I should laugh or cry.
  - 8 Having to prepare dual language consent forms affects some researchers.
  - 9 Sometimes the reviewers seem to want to comment on minor study design issues or similar points that seems to be a distraction from the main purpose of ensuring safe treatment and transparency for participants. I work [REDACTED] children and some of the suggestions for assent are not age-appropriate.
  - 10 still familiarizing myself with the protocol
  - 11 Revisions were not required
  - 12 They don't care about sensible rebuttal arguments. They just make demands without adequate consideration or attempting to understand
  - 13 Some issues can be avoided with clearer guidance up front.
  - 14 Sometimes the reviewer tries to comment on or request revisions to things like the appropriateness of a certain scale. I don't think that is their concern since they aren't designing the study. Generally, however, I haven't had many issues with the revisions.
  - 15 Timelines at times a challenge.
  - 16 Sometimes what they ask for isn't clear and so it feels like you are guessing at what they want you to fix. Also, getting conflicting requests by different review committees (e.g., initial to renewal might have different things they want fixed). Seems to me that if the initial proposal was approved, we should not have to make changes at the renewal (unless the change was initiated by the PI).
  - 17 My cross-cultural research, in places where consent forms and signing one's name to a document breed suspicion rather than trust, has sometimes been a problem in the past.
  - 18 It is standard in naturalistic qualitative research that social interaction is videorecorded. Videorecords are indispensable to address key issues of social life. Academic journals require videorecorded data. In ordinary social life, people regularly take photographs and videos, and post them on social media for public consumption. Unlike in social media, in our research we never use any footage that could be in the least compromising. Research participants can always veto the use of material they appear in. It is a matter of fundamental social science ethics to respect participants' privacy concerns. We observe ethical procedures as social scientists, not because an IRB tells us so. The IRB should align its requirements with the discipline-specific codes of ethics as they are formulated by the relevant professional organizations, eg ASA, AAA, AERA, LSA.
  - 19 Sometimes, in doing community engaged research with undeserved populations, as the researcher, I am the negotiator and must discuss with communities on the best way to address the IRB revisions with the community members interpreting these from their perspective. sometimes it's difficult to figure out how to meet the IRB when the community is not in agreement with the conditions expressed by IRB review. I.e. cultural and IRB protocols are not coherent.
  - 20 See above.
  - 21 The revisions are usually clear, and if not, all I have to do is ask. The revisions usually make my research better, and make me a better researcher
  - 22 Review members change and so does what they want. Consistency of IRB members assigned to a project is needed.
  - 23 When grantors have their own human subjects requirements, must depend on IRB to ensure that UH staff & admin are aware and have a stake in complying with these as well as UH requirements. Esp. with regards to training requirements.
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- 24 Reviewers are usually clear on what is needed for changes.
- 25 In my experience they requested revisions have seemed so minor and detail oriented that it appeared that the committee was looking for ways to force me to revise. Another way to look at the process is that if you don't align exactly with their specific way of doing something, then they will require you to revise the application. Such rigid standards may make sense if you are doing some sort of invasive surgery or psychological manipulation, but they just don't make sense when you are interviewing book publishers about their approach to copyright law or pirate party members about why they joined a third party.
- 26 In cases not all aspects are clear. This may be due to our frustration with the extensive protocols, details and justifications.
- 27 People who know well of certain fields should be invited
- 28 some of the questions can be confusing because you are not sure if they really pertain to your research
- 29 The main problem I've had is one reviewer asking for revisions and then not being available anymore to follow through. The review then had to be begun again with a new reviewer who did not seem to have any of the notes from the previous reviewer.
- 30 First, I believe that members who sit on the CHS should not be able to do so anonymously. There should be some culpability for the decisions that come out of the committee meetings. Intentionally shielding the names of IRB members is not in line with the open and decentralized flow of information for which an institute of higher education should stand. Additionally, the composition of the IRB, particularly in social and behavioral sciences, must include more social scientific researchers. The composition as it currently stands includes too many individuals whose knowledge of human studies' research is limited at best. Replacing those faculty representative who have no track record of human studies' research would go a long way in improving the dire IRB problem I feel we have on this campus. Second, the current IRB, following the departure of ██████████ is in a state of legitimate crisis. Our university's IRB acts like probably no other in the nation. Our response times from initial review to approval letter in hand is far behind the national standards. From a personal standpoint, I have seen the IRB move to far to the right; they have become too conservative about what they see as a nonexempt project. The use of mild deception, for instance, should not automatically trigger nonexempt status. Some of the things they flag (e.g., wording of established scales, an established experimental procedure) are so beyond their expertise/area of research that often I feel they should show more restraint when commenting on the procedure/instruments of a study.
- 31 My main problem (which applies to several of these questions) is working with multiple IRBs (UH, funding agency, collaborators' institutions). Each one has its own procedures and requirements - yet we are supposed to submit the same protocol to each, and produce one consent form that satisfies all. This process is highly iterative, and can take a very long time to complete - meanwhile, the clock is running on the grant. This problem is not just at the initial review, but also when modifications are submitted and at the annual review (albeit to a lesser extent). I do realize this problem is not the fault of the UH IRB as such. However, it would help if one institution on a project could be designated the lead, and that institution's IRB would handle all the reviews.
- 32 Timely responses
- 33 1) Delays due to manini GRAMMAR issues -- was required to change consent form phrase ██████████ to ██████████ although BOTH constructions are considered acceptable, leading to unnecessary 1 month delay in implementation 2) IRB pre-approval was sought for grant being submitted to ██████████ -- IRB idiots refused approval because they required that the research design be revised to include ██████████ without any consideration of increased effort and budget that would be required for this topic of very limited relevance to ██████████ SOLUTIONS: All IRB members should have lots of experience with research and applying for research grants, and they need to be better trained, e.g., it is up to the funding agency (NOT the IRB) to determine if the research design is appropriate
- 34 I had to do a few changes in the past but it was not a problem
- 35 See above. More of an irritation. There is always so much that needs to be done. If something additional is added, I would prefer to know why.
- 36 For the most part, they do provide specific comments that can be easily addressed.
- 37 On rare occasion, new reviewer comments will be provided after a first round of comments. Preferably, all relevant reviewer comments should be provided on the first round of the review.
- 38 The CITI tests are very frustrating because they leave out and do not represent the kind of research I do but force me and my research students to pass an examination on things irrelevant to us, leaving out all the many ways we could be unethical and harm the individuals and communities where we work. It is a frustrating waste of time.
- 39 sometimes the reviewers are not clear in their request for revision
- 40 It's not always obvious how one is to respond to reviewers comments (informally in an email, through a full revision of the protocol, etc).
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- 41 Being consistent with what reviewers want. One year they will approve a study and next when go to renew they all of sudden have a problem what 1 minor thing and hold up the whole process.

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  - 42 Pedantic requirements are not fun to address, but we do them. E.g., a parental consent form for a study of [REDACTED] speaking children - we were asked to provide the English version, the translation into [REDACTED], and then a reverse translation back into English. That reverse translation is unnecessary.

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  - 43 Same comment as above.

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  - 44 Some of these reveiwers are not science oriented and their comments create unneeded revision. It's like they have to say something to appear useful. There's no checks and balances on these non-clinical researchers and so more time and money and energy is wasted. It's not a clean process.

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  - 45 At all the places I've been, the UH IRB Is the worst. The reviewers are very inconsistent on what they ask for on a project. This makes sense because there are different reviewers for different projects. But, I've had projects go through 6+ reviews (which has taken up to 9 months to get approval), and by the end they are asking me to undo changes that they made me do in the first couple rounds of review. It doesn't make sense and it is not efficient. 90% of their comments are about the informed consent form. In my project that took 9 months for approval- literally nothing changed about the project except the informed consent form. In one instance, it took them over a month to approve a change of font size in the informed consent form.

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  - 46 Sometimes reviewers don't understand the issues. It would be great if the IRB would ask the PI to be on call during the meeting - then the committee could call the PI to clarify things right away. Kaiser IRB does this and it's very efficient and works well. Saves time in the long run because most issues can be addressed immediately.

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  - 47 At times, there is a conflict between Subject protection and confidentiality mandated by IRB versus, extraordinary HI fiscal requirements at UH [REDACTED] that require subjects to sign tax forms with social security numbers, THUS violating subject confidentiality (forms seen by department fiscal, college fiscal, Kualii uploads, etc.) Many universities do not collect these tax forms unless the amount for subject incentives rise to \$200.

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  - 48 Slow turn around time.

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  - 49 some suggestions are meaningless

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  - 50 I had to figure out ways to translate what I do into the terms of the protocols.

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  - 51 extra and unnecessary paperwork

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  - 52 Problematic when reviewers want changes made to questions in a standardized measure

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  - 53 Had to go back and forth a few times to deal with issues of children as subjects.

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### IRB Waiting for feedback from review

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- 1 Good: fast turnaround and review. Again, this question seems very very biased to negative options!

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  - 2 Have waited over 4 months; minor changes going back to the full board (adding additional months)

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  - 3 As noted previously: I am in week 5 of waiting to receive approval for a study protocol that previously approved via expedited review. If 5+ weeks is expedited, I would hate to know how long full approval takes.

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  - 4 The timeframe for reviews is much, much too long. I usually plan on a month or two, but it has taken longer than that. This becomes especially problematic when we're working with timelines imposed by funders or students who are relying on approval to conduct research necessary to obtain their degrees.

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  - 5 See above.

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  - 6 Sometimes the turnaround for approval is too long

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  - 7 Process was slow.

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  - 8 Takes too long to expedite clinical projects.

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  - 9 allow research that is not likely to need full review to proceed while review occurring

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  - 10 Knowing an approximate window of when feedback might be expected would be nice

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  - 11 Waiting 2 months for approval. Some staff will not "triage" or assess priority of an expected or unexpected request for approval. While it is important for researchers to plan and avoid these situations, sometimes things happen and we may need priority attention due to some urgent need or scheduled event. Fix: Have timely approval process. Have mechanism to assess priority need of requests.

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  - 12 There is too little communication about progress.

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  - 13 Feedback was very quick

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  - 14 It often takes a long time to get feedback from the review board, and the last time I submitted an application, I never received an email with a number to look up the status of my application and the system did not work when I tried to search by my username.

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  - 15 Suggest a specific turn around time for different types of applications.

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- 16 I have not had to wait an inordinate amount of time, but have heard horror stories from several colleagues.
- 17 Sometimes responses can be a bit slow.
- 18 Review was done within the time frame that was posted on the website
- 19 Yay I got feedback! Oh wait... They didn't understand aspects and made unreasonable demands...
- 20 time lag is very variable; has been getting better over the past year
- 21 I almost graduated late because of delayed response from IRB. My study did not include any deception or potential harmful content, yet it took over six weeks to receive a response. My study required five weeks of data collection, so to wait around for six weeks was a big risk to my research and thesis completion.
- 22 Feedback times are very inconsistent--sometimes it takes months to hear back on the status of your study, and other times it seems like only a week or two.
- 23 Timelines at times a challenge.
- 24 Length of time to turn this around is a problem, especially when dealing with multiple IRBs. Now that we can go electronic it seems silly to require three weeks lead time prior to a meeting (when I know these are not getting to reviewers that quickly). Also, expedited and exempt reviews should not take as long as they do. These should be about one to two weeks maximum. To wait a full month or longer for an exempt or expedited review is ridiculous.
- 25 Sometimes email communications from the IRB office aren't timely, or do not come, so you have to chase them around a little bit.
- 26 My students and I have sometimes experienced very long wait times, even for exempt studies.
- 27 It's usually pretty quick, in my experience (if you start early enough)
- 28 Turn around varies, but mostly acceptable.
- 29 Sometimes take too long, special project work with other universities
- 30 In one application two years ago, I had to wait for long time to get the feedback after the review committee met. In one recent application, the waiting time was reasonable. I guess it really depends on the level of staffing.
- 31 Sometimes time is protracted.
- 32 see above
- 33 It would be helpful to know a window of time in which feedback will be received
- 34 the research team was fractured and the funding opportunity missed due to lack of reporting of the results of the review to the entire team. [REDACTED] we lost the grant due to this complete lack of appropriate communication.
- 35 It would be helpful to have the IRB meet every month as not everyone is on a 9-month schedule. Not meeting in the summer impacts projects, grant timelines, etc.
- 36 This process can sometimes take a bit more time that would be preferable.
- 37 Judging from my students' experiences, responses are confusing. My best advice: fire the current staff, including [REDACTED] and hire someone who is not only trained in the medical field. [REDACTED] seminar for my department was filled with inaccuracies, absurdities, and several retractions a few days later. Keystone cops.
- 38 Awaiting feedback took a long time
- 39 The amount of time I have to wait is reasonable considering the resources allocated to the IRB office, and they consistently communicate the status. And anyway, all I have to do is ask and they are so helpful and friendly.
- 40 Way too long, especially for expedited review. Throws us months off of timeline and decreases our ability to generate results and to compete.
- 41 Wait time is too long, especially when the research must begin immediately or students must complete projects before the semester ends.
- 42 I have found the IRB office here to be extremely efficient. The only time I have had to push them a bit has been on a modification application that, I have a feeling, got lost in the email shuffle.
- 43 This area has definitely improved!
- 44 You must allow for the process to work itself out.
- 45 not sure where the delay is but IRB is not an efficient, transparent process. Previous institution has on-line process that displays status and review dates for all my studies. Strongly encourage UH to go this route!
- 46 sometimes takes longer than we have as grad students
- 47 See above.
- 48 The time it takes to get an initial review is unreasonably long. For exempt applications, the process could be reviewed by an IRB-trained representative at the Departmental level like they do at our peer institutions (e.g., University of Arizona), and the review would take no longer than a day. The CHS takes at minimum two weeks for initial review of an exempt application, and that's when the number of protocols being processed is relatively light. The other vexing part of submitting protocols is their different forms for exempt and nonexempt studies, which essentially ask for the same information. It annoys me when I feel a study is exempt, the IRB disagrees and determines it is an exempt study, and I have to complete

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- a brand new form, which wastes precious time. I also suspect they treat this revised nonexempt application as a new submission, so my protocol is placed at the bottom of the pile, which translates into another four weeks in the queue.
- 49 takes a while to receive final report
- 50 It's just time. Program evaluation work involves many changes to protocols as you work with stakeholders, and very short timelines, which makes the turnaround time challenging.
- 51 I received comments from the review about 45 days after I submitted the application. The comments indicated useful but minor improvements to the research protocol from my perspective.
- 52 Tried writing a grant this past summer and was advised IRB needed to review the grant in which we decided again submission of the grant due to the additional time frame required to meet IRB's requirement.
- 53 The time it takes for review can be quite long (more than 2 months) - even for exempted research
- 54 It takes quite a while and given that my research depends usually of having my students, I may loose precious weeks of class waiting for the approval.
- 55 Review took a long time.
- 56 When short-staffed, response times can be slow.
- 57 It is done well here, though sometime things need to be expedited.
- 58 times have varied greatly. Do not have a predictable time frame for expecting feedback or a decision.
- 59 I think we always wish IRB turnaround could be quicker but I haven't found it to be a huge problem
- 60 Not the fastest turn around in my experience.
- 61 Long review times, but I know from colleagues who have served on it that the board has a LOT of volume they are working with. Perhaps consider expanding the size of the board and/or office?
- 62 takes a long time to respond
- 63 No real-time tracking of where the review process is. This has become somewhat better with the online status but that is not always up-to-date.
- 64 Have had some delays, especially with ones sent back for revisions. Not sure if they get lost in the resubmission, but they seem to take longer. Doesn't happen that often, however, so not a big deal.
- 65 If I want my class to conduct a research study over the course of a semester, it is nearly impossible to do (even with an exempt or expedited review because it has sometimes taken over a month to obtain approval. I think this can be fixed by revisiting who has authority to review theses cases. In some instances, I wonder if there might be a designated departmental faculty member who could give approval of such studies. Previously, ██████ made these reviews and it was somewhat more efficient. I also think IRB could use more staff if it has to be done in their office. They are short-handed and are trying to do the best they can. However, if we really want to be a world-class research institution, these delays need to be reduced.
- 66 it takes a very long time, even for proposals for exempt status. On average, it takes 3 days just to get a response to the email that acknowledges receipt!
- 67 students have deadlines -- this process makes it very, very difficult for students to complete research during a typical degree program
- 68 Speed of reviewer feedback
- 69 See above.
- 70 It would be really nice if the office were staffed adequately to enable them to review applications more often than once a month per category. I realize that a rolling application process is probably out of the question, but maybe some kind of compromise?
- 71 There's rarely a review that is not pushed back another month or two so the entiprocess for many dedicated dedicated researchers have to wait months to the point that the WHOLE semester is gone. Forget about hiring graduate students or researchers in a guess to find out when you can actually start. VERY problematic.
- 72 It takes way too long. It impedes progress by researchers.
- 73 Same - time issues.
- 74 One of my reviews took quite a long time to receive the feedback/approval. It was over three months before final approval.
- 75 Slow turn around time.
- 76 long waits, even for exempt studies, sometimes requiring numerous e-mails and phonecalls to CHS to find out what the delay is.
- 77 Feedback was prompt.
- 78 It takes too long for protocol applications to be reviewed because the Human Studies office is extremely understaffed given the number of applications they receive.
- 79 some studies arise quickly, are exempt but then take too long to process given changing social situations
- 80 Some of my students have waited nearly three months for review and then been exempt.
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- 81 It takes longer than expected. Perhaps knowing in advance when the request will be reviewed and when dis/approval will be given would be helpful.
- 82 Too long, to circuitous
- 83 Sometimes it takes too long to get feedback
- 84 It takes too long. They need to be more realistic about the definition of “possible harm,” and not dream up absurd possibilities. [REDACTED] I know these crazy possibilities some of these people come up with. We need not be worried about psychological risks that have virtually no chance of occurring. E.g., asking people to think about their weight will not make them bulimic. Let’s get real, people.
- 85 Since nobody replied, I assumed the little anonymous survey I wanted to complete was not a problem.
- 86 Getting feedback sometimes takes time, but in general it’s not too bad.
- 87 Can take a bit long for simple questionnaire studies (exempt studies)
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### IRB Completing annual continuing review of protocols

- 1 not getting reminders before they are due
- 2 Again, one would hope by the time they have PH.D in research that they would internalize the ethics of research without watch dogs needed. Furthermore, peer review process should handle any issues. But then again, I understand the need for the process if just one person violates ethics or legal standards.
- 3 A ping email about a month ahead of the deadline would be helpful. I can’t remember if they’re already doing that.
- 4 difficult for students doing dissertation research, non-threatening process but with minors given education
- 5 The IRB is very disorganized. They don’t keep adequate records of what was approved before. Submitting a modification or an annual review can trigger a new full review that can take months to approve. For example, they do not keep the final approved informed consent forms on file, apparently.
- 6 Being consistent year to year.
- 7 I appreciate the reminders.
- 8 When there are no changes to a project, it seems a little bit of a waste of time to have to renew annually. There was some confusion on how often exempt vs. non-exempt projects needed to be renewed.
- 9 For exempt, I haven’t always been clear what I need to do with regard to this requirement.
- 10 See above.
- 11 Training should be provided for staff to be aware of these processes.
- 12 Training is too time consuming.
- 13 There have been some discrepancies with what type of information/level of detail has been asked of us in the past compared to now.
- 14 I can complete the review but it’s never been clear to me what I do with it or if IRB wants it.
- 15 deadlines are rushed.
- 16 Enormous amount of time and effort goes into these renewals.
- 17 Not sure how to respond to this since I have not been prompted to do an annual review of protocols.
- 18 Expectations change frequently, so the PI can easily be unprepared for the changed requirements.
- 19 The IRB office is very helpful in letting me know with plenty of time that it is time for me to submit a renewal application. I really appreciate that. They are clear about the amount of time it takes, so all I have to do is get the application in on time.
- 20 Again, project staff do this.
- 21 The IRB’s conception of research is based on research styles in which the data collection is a matter of weeks and months not years. Longitudinal research, typically ethnographies but also other kinds of naturalistic observational research, requires more than a year, often several years of field work. It is an imposition on the researcher’s time to have to re-request continued approval of an ongoing study that has already been approved. Again, the IRB’s one-size-fits all approach ignores the diversity of social science research.
- 22 Never received any notice that it had expired.
- 23 As noted above, new revisions should not be raised if the initial protocol was approved by the IRB. This is not fair to the PIs to have to change things each year.
- 24 Did not realize I didn’t need one for an exempt study. Submitted it and was told afterward, but it was not a lengthy process.
- 25 Process could be simplified.
- 26 staff there are very helpful
- 27 It came out during the summer (9-month faculty), and I missed the renewal
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- 28 The “protocols” do not change for the research I am doing, and because of the timing, every summer while either conducting research or on family vacation I have to resubmit in order to keep the approval current.
  - 29 annual review should only be necessary on projects law requires
  - 30 Some of the forms and instructions can hard to understand. The website is also difficult to navigate. I ended up having to call the office to get help several times.
  - 31 Is there a way to have a blanket approval for ongoing projects that may take 10 years to do instead of having to renew every year?
  - 32 See above.
  - 33 Why can’t we have multiple year approvals?
  - 34 This is mostly in regards to renewals. As staff have changed, consent and other study forms have needed modification for the renewal to be approved.
  - 35 Study sent to full board when no changes were being made/no problems had occurred; Asked to make changes to methodology of an approved study during data collection that would negatively impact participants; these issues were resolved but caused a significant delay in data collection (which impacted community partners)
  - 36 Do not think there should be annual reviews unless there are changes.
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### IRB Ensuring that study procedures meet protocols

- 1 Ideally changes can be made to take advantage of opportunities that arise in the classroom, but this flexibility is somewhat reduced by the requirements for specificity in the forms. It takes a lot more planning up front.
  - 2 Please see first item above; many people insist that I not tell the IRB about them, confusing IRB with an eavesdropping government.
  - 3 Tendency for qualitative researchers to restrict research methods to acquire approval.
  - 4 As a researcher, I feel very limited. There are certain studies I’d like to do, but I avoid them because I know that IRB wouldn’t let me (e.g., studies involving minute and/or innocuous deception). In order to advance fields of research, scholars need to be able to conduct research involving some risk. I think this IRB needs to be a bit more open to these types of research, and willing to work with researchers to come to a solution that both protects human subjects and allows researchers to pursue studies involving risk.
  - 5 NOT sure what you mean “meets protocols” (protocols of what?)
  - 6 The problem is not meeting protocol but developing a protocol that allows us to collect the data as needed for the study (not a problem) AND gets IRB approval (the problem).
  - 7 In doing community engaged research with undeserved populations, particularly when one is in the field, situations arise that can make it difficult to follow the protocol, especially when an alternative is suggested by a study participant or community member because it makes sense to them, and is practical in the field.
  - 8 see above
  - 9 New studies are very problematic.
  - 10 My students have had inaccurate advice and then been punished for operating on good faith. [REDACTED] has to go.
  - 11 Not knowing what means of sharing data are acceptable (e.g., sending data via email) given type of data
  - 12 Not sure what this question means - research design? Isn’t it up to me, not the IRB office, to make sure that study procedures meet protocols? Anyway, if there is a question, they just send me an email and we take care of it. I feel really supported by the IRB office.
  - 13 Having to meet protocol requirements, like using certain words and phrases, does not work for certain populations, especially those for whom English is not their first language. What results is a long protocol which subjects do not understand and runs the risk of turning them off before one can even begin the research.
  - 14 It can be a constant struggle to ensure that actual procedures match protocols as submitted to the IRB, especially when multiple staff and students are involved.
  - 15 I’m not sure this applies since my research has always been expedited.
  - 16 More relevant people should be invited in the evaluation
  - 17 See my comment above regarding the study procedures. I believe the SBS committee has on numerous occasions taken too many liberties when commenting on study procedures. Many of the comments are indicative of individuals who are not experts in my field.
  - 18 The standardized informed consent wordings for surveys and interviews are NOT user-friendly. They are probably fine for college educated research participants in biomedical studies, but they are much too wordy, and written at too high a reading level, for low-literacy and limited-English-proficiency audiences. Particularly when they need to be administered in an outdoor environment.
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- 19 Not 100% clear when an incident is “reportable” or not, and when/how it should be reported.
  - 20 In some community research, some of the protocols are not seen as being ethical. Consent forms tend to be tedious and incentives are sometimes seen as inadequate.
  - 21 see question 1
  - 22 Not always clear what will and won’t be flagged as problematic.
  - 23 Sometimes the protocols are not entirely clear. However, staff are very helpful.
  - 24 One can’t create any type of deception no matter how innocuous without going through full review. Even then, there is hesitancy to approve even when subjects are debriefed at the end of the study. Some deceptions are necessary and essentially harmless particularly with debriefing.
  - 25 Again, the many of the reviewers are not trained in clinical research and pick at little inconsequential points, but refuse to see the big picture. They approved a study where mothers could lift their babies as wieghts. Can you believe this? Well, one of the babies was dropped and had a head injury....for life. Yes, this was approved by the UHM IRB.
  - 26 Not every eventuality can be foreseen when designing protocols.
  - 27 Even minor modifications require IRB submissions. Clear outlines for when modifications are required or NOT would be helpful. Especially when piloting procedures or protocols.
  - 28 Sometimes the justifications needed are just silly.
  - 29 sometimes reviewers are not familiar with research methods, particularly qualitative or mixed method which may not be possible to detail prior to beginning the study
  - 30 Well, there’s the protocols, and then there’s the nonsense the committee dreams up. Meeting protocols is easy. Investi-gators can’t know all the nonsense the committee is going to dream up.
  - 31 I know what to do.
  - 32 Bar changes study to study.
  - 33 See above
  - 34 It’s sometimes difficult in a large study to ensure that everyone is carrying out the instructions precisely. I would rec-ommend that ALL personnel involved in administration of research and/or gathering of data be required to take the IRB training, not just those at the top of the food chain.
  - 35 Some of my colleagues have said there are problems recruiting because when payment is involved because SS# are required and many people do not like giving out for small payments like \$10 to \$40 OR T-SHIRTS. THE FISCAL OFFICE REQUIRES IT AND THE IRB FORBIDS IT SAYS ITS A PERSONAL ID, WHICH IT IS. However this contradiction between IRB and Fiscal inhibits the studies.
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### **IRB Fulfilling federal requirements for training in human subjects protections**

- 1 System uses Manoa rule, which included attendance at workshops in addition to online CITI course. This attendance was very difficult for neighbor island people, so we now simply use the CITI course for training.
- 2 The tutorial could be a little more innovative. I know that a computer-based training is less expensive than face-to-face trainings - but perhaps it could be a blended experience (online and face-to-face). This might help to build a “community of researchers” at UH who are used to collaborating with others on finding solutions to issues (both ethical and practical) that they are having with their research.
- 3 requires hours of time to review online. i’ve not participated in studies I was invited on because I didn’t have 12 hours to dedicate to doing this.
- 4 stupid modules and poorly designed
- 5 The CITI training is very long.
- 6 The tests were a bit tedious and the material often unrelated to my work.
- 7 Some of the requirements are onerous and unreasonable.
- 8 Not always clear what work needs to be included and what is exempt. Prevents post hoc use of data incidentally collect-ed during other activities, eg ecafe results.
- 9 CITI training has irrelevant section that have become required.
- 10 There are no real training modules that really cover all the essentials. Long classes that are not comprehensive on all the necessary content. At least that’s been my experience as a faculty member that knows how to teach CONTENT.
- 11 I had to spend hours taking a standardized online course, 10% of which applies to my kind of research. It was ironically a demonstration of bad teaching and learning in an age in which a better interactive interface could be developed.
- 12 Time consuming, often not very informative (common sense, or already accrued knowledge), but I suppose we must do it.
- 13 Again, a full list of which CITI courses are required for investigators would be helpful on the website. It would also help to

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understand who qualifies as an investigator and must complete CITI (ie anyone involved in the study, primary/sub investigators only,etc)

- 14 I work at [REDACTED] and have done all of the training and have the associated certifications. I have been forced to duplicate all of the training for UH as the training done at [REDACTED] is not considered acceptable. This concept is totally ludicrous.
- 15 The modules take a very long time to complete.
- 16 Still unclear at times as to which modules need to be completed by whom - - especially when working with students.
- 17 Federal requirements and local requirements can differ with little harmony across institutions. It comes across as a power struggle locally.
- 18 Again- no centralized IRB and training for UH faculty doing research off-site.
- 19 UH should line up with federal standards.
- 20 read the earlier response related to this problem.
- 21 See comments above about the utter uselessness of the CITI exams with respect to fieldwork research.
- 22 It was a little confusing on what CITI modules needed to be completed for what types of projects.
- 23 The training can be onerous. It has gotten worse because multiple entities now require us to take similar types of training just for their respective organizations.
- 24 There are sections that in the CITI training that deal with animals. I have found that this is problematic for those who only plan to work with humans. I have also found that the CITI training takes a long time for students for whom English is their second language.
- 25 The online training was very useful
- 26 I am somewhat surprised by how little graduate students (and even faculty) know.
- 27 Community partners who are research partners are required to complete the CITI training which is very tedious and is very specifically geared to academic researchers. It needs to be adapted and made more concise and relevant for community partners.
- 28 At the request of IRB, I spent the equivalent of an entire day taking two online courses from the Collaborative Institutional Training Initiative (CITI) of the University of Miami. My interviewees took only one of these courses. From my perspective, too much of the material covered by these courses was tangential to the subject of my research.
- 29 The requirements have changed.
- 30 Really, just trying to figure out \*which\* protocols one is supposed to have completed, and \*which\* compliance form needs to be turned in. There are many, and I always seem to guess wrong, which holds up the process. Also-- the requirement to do HIPAA when you are NOT dealing with medical records (or anything resembling medical records) is irritating. It's completely pointless.
- 31 I just don't know why the CITI training obliged me to learn about the preservation of medical data; the overall orientation of the CITI training materials was largely unsympathetic to anything other than medical and natural science concerns. I can't advise about fixing the problem because I don't know what pressures the Office was under.
- 32 The trainings are heavily focused on health sciences research (even for the basic training), which is completely irrelevant for our work in [REDACTED].
- 33 Required training can be very time consuming, especially when multiple institutions are involved.
- 34 Basically just finding the time for the online training but not horrible.
- 35 I truly understand the importance of the trainings, but here is my gripe: I recently came from another institution (a huge, heavy-research institution) and I had to take less trainings for them than here. I spent 1-2 days when I first arrived here just completing extra trainings to be in compliance. I suppose I just feel like there should be some sort of consistency across institutions as to what trainings are required.
- 36 Training materials for compliance are not relevant to my work (training is mostly medical)
- 37 See above.
- 38 Would be helpful to have different levels of training for different types of staff.
- 39 This is great because there is a free online training which is really easy to do. And the IRB office created a very helpful and clear instruction guideline which gives step by step instructions. This training actually made me a better researcher.
- 40 Not clear what level of training to have my students do given the type of student research they're doing
- 41 difficult to keep track of our personnel's records, exp. dates, etc. A central location that keeps these records for us with email reminders would be helpful
- 42 Website changed recently and the person who answered the phone was not particularly helpful about this.
- 43 not always clear which CITI modules are required of whom
- 44 Some extra effort is required to arrange to complete the training; that said, the game-ified structure of the training is wonderful -- the scenario with the graduate student in the lab was very interesting.
- 45 Online access to CITI training was very helpful
- 46 still learning what is in the federal requirements

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- 47 A lot of the training is out-of-field and not very relevant. It would be nice to have more specific training targeted to educators.
- 48 Time intensive.
- 49 Given that the CITI training portal is incredibly poorly designed and the pedagogy used is antiquated to say the least, I've found this to be the least onerous of the IRB requirements. Perhaps because it is incredibly easy to pass the tests in a very short amount of time without having learned anything.
- 50 time consuming
- 51 In some locations, people may not have good internet connectivity. I've been told that some have trouble staying connected/ logged in to CITI.
- 52 Don't put students through training they don't really need
- 53 The previous time I had to do the CITI quiz, I could not get to the right page to do the right quiz that's required of me. The webpage that the IRB office told me to get to, I could not access that page (even when I tried it from three different computer terminals--at work and at home).
- 54 This was insanely bureaucratic. To obtain IRB approval for a straightforward survey of visitors to [REDACTED] [REDACTED] I had to learn and pass quizzes on all the byzantine rules related to researching human subjects in hospital, school, and other settings in which I, as a [REDACTED] researcher, never have, and never will, conduct inquiry.
- 55 See comment above. Right now there is an issue because there has been a change in the training involved. EVERYONE who has not completed training since February 1, 2015 needs to retake the training. Every faculty member, every student who is submitting any proposal needs to take an extensive list of courses.
- 56 Online CITI - Federal standards and helps understand the context for oversight in the first place, better informed my research contexts.
- 57 Involves a lot of time and mostly on line training in areas not relevant to my research. Interesting to do once, but not repetitiously.
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**IRB Please provide any other suggestions that may help improve your ability to meet IRB/human subjects requirements for your research and/or teaching.**

- 1 I actually have not had any training but the materials online were quite self explanatory in my opinion.
- 2 We are expected to do way too much. This extra training should be optional for experienced investigators.
- 3 Try to more frequently bring training sessions in human subjects and RCR to neighbor island campuses.
- 4 (SAME AS ABOVE) The tutorial could be a little more innovative. I know that a computer-based training is less expensive than face-to-face trainings - but perhaps it could be a blended experience (online and face-to-face). This might help to build a "community of researchers" at UH who are used to collaborating with others on finding solutions to issues (both ethical and practical) that they are having with their research.
- 5 More Center for Teaching Excellence IRB workshops. The graduate student IRB workshops are exceptional.
- 6 it's just a matter of doing it.
- 7 I was insulated from problems with the IRB because I had a research [REDACTED] who has submitted protocols and updates. You would get best information from her rather than me.
- 8 need more specific for the types of research done in education, so different from medical models on which much regulation based
- 9 The Human Studies staff are very friendly and helpful. They are just extremely understaffed, delaying faculty and students from receiving the feedback and approval they need.
- 10 CITI
- 11 The individual who provided training in our department was not familiar with the kind of work we do.
- 12 CHS needs to process applications more quickly
- 13 My problem is not with CHS but with the HDOE research and data governance office, the approval process there is ridiculous and is harming faculty and graduate students research and degree completion.
- 14 The new requirement to obtain WH-1 forms from all study participants who receive gift cards for as little as \$5 is a major barrier to my research. The study participants are reluctant to participate as it is; if we are required to obtain and store their SSN, we will lose interested subjects.
- 15 MS [REDACTED] and PHD [REDACTED] coursework was excellent training on IRB/human subjects, included UH IRB staff or director personally talking to the class. I don't hesitate to call UH IRB for any questions, they are extremely helpful.
- 16 Some of the trainings were very specifically for bio-med research that did not apply to social sciences at all.
- 17 IRB is an important part of being a faculty member, regardless of our field of research. Although it may seem like a burden to some, faculty members should be required to go through IRB training as part of their new faculty orientation. This might take care of some "front-end" problems.
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- 18 Need to protect data on individuals from Freedom of Information Act requests, for example, observations on farm visits.
- 19 Obviously, the IRB needs an electronic system. We're 15-20 years behind other R1 institutions on that. The IRB needs a quicker turnaround on reviews, too. They need to cut down on projects taking 3-4 times to be reviewed. To prevent this--reviewers should be instructed to review the entire application and to not just review portions of it each time. There is no excuse to require 7 drafts of an informed consent form. It is not a good use of anyone's time. The IRB has been, by far, the most frustrating part of my job. I have considered leaving the university as a result. It's awful. It is so bad.
- 20 There's not a lot of turnover on this board, and there appears to be a clic that governs who does and who does not do research. They delay and delay those who they do not want to do research. It's a game, but it's unethical. That indirectly determines who does and who does not get promoted or tenured. It doesn't happen to everybody, but it happens. There needs to be an appeal process. Because there is none, this process is abused.
- 21 Although I am familiar with the IRB process in general from my graduate training and research at [REDACTED], I have not yet needed to go through the process at UH.
- 22 I checked "below average" only because of the online course discussed above. Back in the day, I did a morning's workshop with [REDACTED], and it was splendid for the ways in which we could actually discuss the particularities of our research. I also want to add that when I have contacted the office itself by e-mail or by phone, the response has been outstanding: prompt, professional, and supportive.
- 23 clearer explanations of what is exempt, expedited, and if form needs to be completed if it's for master's degree completion (not a thesis) that will not be published ([REDACTED]). Need more streamlined training for people doing exempt research. The online IRB training is too long/complex for people who are doing exempt research. I think people just don't do the online training and don't file for exemption to avoid the training and IRB process
- 24 Please develop collaborative agreements with other orgnaizations doing human research in the community
- 25 Shorter turnaround times is the most critical.
- 26 Centralized IRB!!
- 27 The biggest problem with IRBs in Hawaii in terms of clinical research is that UH IRB, HPH IRB, and Queens IRB don't accept each others approvals. It is ridiculous to have to go through multiple IRBs for the same project. Please work out an arrangement, have some trust in each other's processes, I've found each of the IRBs to be stringent and rigorous in their review.
- 28 More hand on /in person training would be helpful, to help with the UH specific forms, requirements, etc. CITI and other online training is good theoretical knowledge but insufficient practical knowledge.
- 29 A set of guidelines as to what is necessary or not necessary for IRB reviews. If things are obviously falling into the "waived" category why make PIs apply for a waiver. Perhaps trust their judgment that IRB applications are not needed. Or perhaps a simple online form to see if IRB is necessary or not.
- 30 Overall, the UH IRB system is good. This is compared to other IRBs in Hawaii. We particularly appreciate that UH accepts the Queen's Medical Center's IRB approvals.
- 31 Make it shorter and have a universally-accepted training.
- 32 A more accessible help line, so that during the application process I not only know where to go, but can contact someone who is familiar with how oral history protocols work would have been helpful.
- 33 I think it would be important to create some type of workshop for PhD students to train them. Most of the time it is up to us their professors to train them in how to create their protocols, consent forms, etc.
- 34 I think there should be courses taught at UH on research ethics. Regulatory compliance does not exhaust what researchers ought to master. They should know what these rules are necessary. Current instruction does not provide this.
- 35 Too many sessions required for non medical studies/faculty.
- 36 Really? Who would listen? This is the job of Manoa campus anyway, not System office.
- 37 Better UH IRB website with easy-to-understand information and more information. Better training provided by local IRB -- interactive, not a boring lecture, which is what I attended years ago. I go to other universities' IRB websites first (not UH) because they have flow charts, easy to understand definitions of what the feds mean by "research", better examples--including those that not clear cut.
- 38 VERY clear instructions. Also, it seems like the protocols simply do not fit very low-risk survey research on non-sensitive subjects conducted in public places -- when you're doing an anonymous intercept survey with random folks as they enter/exit a [REDACTED], the informed consent protocols are often longer and more intrusive than the survey itself!
- 39 IRB staff have been doing outreach and making department-level presentations. They did one for us and it was very helpful. More of this sort of thing will be good.
- 40 I would suggest sweeping changes for the CHS. Perhaps we need to begin with a Director who has a Ph.D., a strong grasp of different research methods, a comprehensive understanding of federal guidelines, and serve as a strong arbitrator at the IRB meetings. I see the IRB as a large part of our identity as a research-intensive university, but I have also seen it serve as far more a hindrance than a helpful unit. The ultra-conservative approach that the current IRB has adopted not

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only harms our progress toward that R1 end, but it also does not protect our participants any more.

- 41 I was a tenured faculty at [REDACTED] before I joined UH [REDACTED]. To conduct interview with theatre artists, [REDACTED] always required completion of the IRB process. I also served a liaison for the IRB office. My job was to explain requirement for foreign scholars who were not familiar with federal rules. When I joined UH [REDACTED], I was told it is not necessary to go through the IRB process as I am doing research in the field of Humanities. Seeing two radical ends, [REDACTED] and UH [REDACTED], I am not sure about if I am following the federal requirement. [REDACTED] took a position somewhere inbetween when I was doing research for my Ph.D. dissertation.
- 42 I don't think the information is different than information provided elsewhere.
- 43 Training online is too long, tedious, with duplications of information.
- 44 My experiences with IRB have been bureaucratic and unhelpful, required a lot of time but were otherwise mostly harmless. My research is primarily qualitative and open ended, making it a poor fit with how the IRB understands research. The one time I completed a survey-type project, the questions were not in any way invasive or manipulative and so that project was also for expedited review and was just a bunch of administrative hurdles that took time and energy. My bigger problem with the IRB is the mission. I get that there can be unethical research and problematic research designs and it is good to have a check on these. However, to shift policy so that ALL graduate students must submit their proposals to the IRB prior to ABD status is simply more administrative hurdles that don't make sense. A huge number of dissertations in my program are theoretical and involve no interaction with human subjects but now an unclear set of forms must be filled out by default for each of these projects and additional time must be spent clearing this hurdle when often time is at a premium. This is a waste of UH time and resources. Furthermore, when my department had a meeting with the current head of the IRB to find out how best to meet their standards, she was unable to tell us how, or if, some types of research conducted by faculty in our program required IRB review. However, her default was always that it did. In part the problem had to do with her definition of possible harm to a human subject, which was so broad that merely asking them a question about their opinion could potentially be a reason to reject a proposal. This seems to undermine the possibility of any type of research on political questions. All things considered, the IRB process may be federally required because there have been egregious lack of professional ethics on the part of some researchers. However, things have changed in many ways and the IRB was never intended to be the surveillance system for all possible types of research. When you devise a structure that assumes that all research is unethical until proven otherwise, you have not created a system to which people will have positive responses. Of course, maybe we have to change federal regulation, but I'd imagine there are things that could be done at the institutional level.
- 45 Discipline specific instructions/examples.
- 46 Cannot think of any at this time
- 47 General guidelines or reminders for PIs on when IRB is required versus not required (especially in cases where they may be 'exempt' or not subject to 'full review')
- 48 Have a more facilitative leadership. Work with ORS to reach out to PI's receiving grants to assist proactively. Acknowledge that federal research has been peer reviewed and the science is predominantly the domain of the PI, and the institutional compliance is the domain of the IRB. IRB gets too involved in the science. Work to improve turnaround.
- 49 It would be great if more funding was allocated to the IRB office so that they can hire more coordinators. That way they could put more effort and time into educating the UH population, and that would probably help with turn around time as well. More support for the IRB office who is already doing a great job would be great. Have you noticed - these survey questions have a negative bias - really inviting the person taking the survey to come up with negative things to say. This is not a well-written, non-biased survey. You would think the researchers behind this survey would know better!
- 50 The most important thing about IRB requirements is the willingness of IRB staff and administration to aid researchers in understanding what is required and how to fulfill it. They do an excellent job making sure that research which qualifies is approved and gets carried out, even if the process of passing review would be cumbersome without their help.
- 51 Officers should be available to review application drafts.
- 52 You cannot have an "one-size-fits-all" approach to this and the needs of the natural/physical sciences has to be distinct from that of the social sciences/humanities. The IRB is headed by a relatively junior person (who has an MA in Public Health) with little or no real hands-on research experience. As with a lot of other such matters at UH, its understaffed and under-budgeted.
- 53 I think the IRB is working quite well now. My biggest complaint over time has been when the IRB reviewers question the feasibility and science of a nationally reviewed project, rather than focussing on human subjects protection. Sometimes, I think teh reviewers trample the public's right to participate in research (at one time, a reviewer said the consent should not state the results could help other women was coercive!!!!)
- 54 We understand perfectly well. The training is largely irrelevant for the kind of research we do and a waste of our time. It is telling that this survey locates research compliance problems squarely with the researchers. It does not even begin to dawn on the designers of the survey that the fundamental problems rest with the IRB's inadequate understanding of the

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- diversity of contemporary social science and its unreasonable interference with standard research procedure.
- 55 The training is rather one size fits all - since I never enroll subjects for human trials, much of the training is not directly relevant to what I do, but that redundancy only comes up every few years when I recertify.
- 56 It would be good if they would address Open Data challenges for researchers with human subjects. There is very good information at ICPSR in Ann Arbor.
- 57 Some of our MA students doing summer research have been surprised by the need for IRB approval, and thus the deadlines and wait times pose problems for them. More training and awareness (IRB could hold a workshop for dept chairs, for example, who could then pass the info on to incoming students) might be helpful.
- 58 Additional staffing to reduce review time.
- 59 Provide more funding to staff this office so that researchers can be more productive and turn their protocols around more quickly. Have at least two IRBs that meet twice a month so that reviews can be turned around more quickly (each committee only meets once a month but on the alternating weeks so more protocols can be reviewed and faster).
- 60 The current on line certification is very time consuming. Under [REDACTED], the training was straightforward, efficient, face-to-face and personable, and specific questions were answered.
- 61 I'm disappointed with how long it takes to hear back from IRB regarding one's application. It can be incredibly difficult to do research knowing that you may be waiting over a month to hear back from IRB. I think this needs to be fixed immediately. I would also like to see IRB be more willing to work with scholars pursuing potentially risky researcher. Rather than simply rejecting an application, they should open a line of communication with the scholar to try and figure out a way to protect the human subjects (follow protocol) while allowing the scholar to pursue these potentially risky lines of research.
- 62 Coming from the Humanities, it is hard to avoid the impression that IRB is mostly about the hard sciences. The training is fine the way it is, but some special attention to research instances/examples from the humanities as part of the training would make it even better.
- 63 see comments above
- 64 Presence of experienced researchers and reviewers
- 65 I have not had the opportunity to submit an IRB through UH. I have submitted all via HPH as clinical studies have been done through [REDACTED] Hospital. From what I have been told by others, the UH IRB is to be avoided due to the cumbersome and lengthy nature of the process. It's good to see the problems are being addressed.
- 66 New IRB website hasn't fully transitioned (has some broken links), which can be challenging
- 67 A lot of the training is out-of-field and not very relevant. It would be nice to have more specific training targeted to educators.
- 68 Provide exemplary models of HSAs with commentary.
- 69 Except for the training I did online, I am not aware of any other training provided by UH, so my answer may not be accurate here.
- 70 personal advice
- 71 I don't recall attending any IRB workshops or completing online training.
- 72 An online IRB portal that accepted digital submissions and tracked progress, noted areas that needed updating, etc., would be useful.
- 73 Scholars in the arts should not be required to treat cooperating/collaborating artists as human research subjects!
- 74 Review materials and instructions on website to make current and to expand information to cover more types of research, situations or questions to help. Write with user in mind. The info on CITI is "hidden" on new website as the link to it is not labeled as training or CITI.
- 75 Good so far
- 76 This needs to be an enabling committee, not a policing or disabling one as it is now.
- 77 The training was online, and some wording used in the language is legal and technical language. Would be good to have face to face training so that questions can be asked and answered, and things can be clarified.
- 78 Please do whatever you can to build some flexibility into the human subjects training regimen so that it is not necessarily for researchers to spend many hours learning irrelevant protocols associated with studying human subjects in settings (e.g., hospitals, schools) in which they will never conduct inquiry.
- 79 Providing some informational sessions about IRB application for new UH staff and faculty
- 80 There is no UH training only Citi
- 81 More information needs to be provided to faculty that want to publish on the scholarship of teaching and learning, which may include student feedback.
- 82 I think the way the training is set up looks uninteresting and I believe that some people who receive the training do not really grasp the importance of the protocols. Maybe we could spice it up by giving dramatic examples of violations so that trainees would understand the need for protections and then be interested to see how we avoid such problems.
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- 83 Turn around time needs to be faster. Particularly when research funds can't be released until IRB approval is received.
  - 84 Provide more staff, more resources to the UH IRB office as there is such demand for their services. Outsourcing is not an option.
  - 85 Best training is class room and not online.
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### **IACUC Understanding what is required and why**

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- 1 As a new faculty member I tried to contact IACUC staff to sit down with me and never got a response. I understand if they don't have the staff to do this on a one on one basis but perhaps some kind of optional orientation could be offered.
  - 2 Protocols take too long to get accepted, and there are very few clear resources to get information. The veterinary staff is fantastic, but the compliance staff tend to offer no help.
  - 3 Generally, the IACUC system works well. The process is clear and generally proceeds as expected. It is frustrating that catching fish in the field (i.e., fishing) is included under IACUC. It is worth noting that IACUC regulations provide enough of a barrier that I have decided against several small, exploratory experiments with undergraduates that involve holding fish in aquaria.
  - 4 IACUC standards for euthanasia for invasive reptiles is not appropriate (i.e. "double pithing"). In our view freezing is far more humane option.
  - 5 IACUC was designed with lab animals in mind, and is largely irrelevant for those who study wild animals in the field.
  - 6 I have had a good experience working with the IACUC. Although it takes a bit of effort to create your first application, I found the review process to be both helpful and efficient.
  - 7 The quality of IACUC review is poor and somewhat arbitrary. I do not think that we have adequate experience in modern animal use on the committee.
  - 8 Costs are high and approvals are slow. We have given up on using it and have contracted with a mainland business for our needs.
  - 9 Too burdensome, subjective, debilitating.
  - 10 Citi site is hard to use. Can't renew and amend a protocol at the same time even if the amendment is very minor. Reviewers always seem to want more information each year even if the application is the same as the previous years and was satisfactory then. Inspections are too costly and no RTRF is provided for this. IACUC personnel are only Manoa personnel but we could save cost by involving neighboring island personnel in the local inspections. Reviewers and inspectors tend to be extremely nit-picky, always looking for minor things to cite even when these "deficit" have been present for years and no one has ever raised a question. Seems they just feel the need to find new problems with every inspection. Everything is too top down and Manoa-centric. Individual campus Animal Welfare Assurance statements should be revised so that ONLY federally funded research (not teaching ,not display) is covered by IACUC. Many universities do this. UH just loves to over regulate but then not provide the support to individual researchers or instructors. This has impacted instruction because most people won't do anything with animals for teaching now.
  - 11 The reasons for why a new protocol (as opposed to modification) is needed or not are unclear. Some required steps are nonsensical (and unenforceable). Support staff (excluding veterinarians) have varying levels of skill for dealing with faculty. Time to start over.
  - 12 Not enough guidance for anyone who is starting with the process and is not familiar with the ins and outs of compliance. The goal seems to be "compliance", not necessarily optimization of research/care etc... Better resources and instructions.
  - 13 Lack of support and feedback
  - 14 I began working with animal products late in my career so what I did not learn about these requirements as a graduate student or postdoc.
  - 15 no a priori boundaries, you tell them, they decide
  - 16 The compliance office tries hard to help get the protocols finished and ready for approval prior to the committee meeting. The office is helpful.
  - 17 I know now that I have to apply for approval on certain experiments, but before that I did not. There is no orientation for new faculty provide by the IACUC when they first arrive. Perhaps, there should be a research orientation offered to new faculty, or even existing faculty getting into research, by all parties Biosafety, IACUC, IRB, and ORS; This orientation would cover basics for new faculty so they understand what permitting processes are involved and that there should be integration in the system (IBC, IACUC and IRB approval are required by ORS to submit grants or to accept a grant on PIs' behalf). One afternoon orientation giving information on the "duties and need to know" by these offices for new faculty involved in research would be very helpful.
  - 18 We needed to go back and forth to make sure all aspects are addressed including personal meetings with ALS.
  - 19 Topaz is cumbersome to work with. Small changes in protocol are very time consuming, even a change in personnel
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basically requires review of entire protocol. They are starting to charge for oversight activities that they mandate, like lab inspections and their fees are significant -- hundreds of dollars per visit.

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- 20 Differences in opinion for compliance
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- 21 System designed for caged lab animals but forced to apply to projects with off-site livestock owned by private businesses. Securing animal health and welfare is understood, but projects with farmer collaborators need to be exempt or have a simpler procedure.
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- 22 Protocols resubmitted often are returned for reasons previously not considered relevant are now important enough to warrant holding up approval. It would be better if the reviewers had experience with techniques.
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- 23 IACUC committee and compliance personnel needs to be up-to-date on the literature and accept the latest finding. It seems that whatever has been started years ago at an East Coast university and rigid electronic forms became the ultimate standards. Time to review and allow updating.
- 
- 24 understanding relationship between IBC and IACUC forms and requirements can be a bit difficult
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- 25 Regulations are set at the whim of the LAS supervisor which should be independent of the IACUC committee. LAS is using IACUC infractions to earn money. They had been monitoring the colonies 4 times per day just to "catch" infractions. Waste of resources in my opinion. Now masks and hair bonnets are optional. Why were they required in first place. LAS charges for all consumables even though the lab had requested that we furnish these to save on burden. Containment housing bought and required without justification
- 
- 26 pretty straight forward
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- 27 If there is a list of the required forms, that would be very helpful at the beginning.
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- 28 It is sometimes difficult to know how many online training we need to get and how often
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- 29 Clarity surrounding the protocol approval, renewal, and amendment process is lacking and could clearly be streamlined. At present, it is impossible to submit both an amendment and renewal as a single package, which needlessly adds to the workload of both the PI and the review committee. Further, I have been unable to locate any single set of instructions or requirements for the Topaz protocols, and consequently simply submit things in a trial and error fashion.
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- 30 UH, for bureaucratic expediency, subjects all researchers to NIH standards when it could have set up a dual system where "production" research & teaching could have used USDA standards which are much more pertinent to agriculture and natural resources.
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- 31 The facilities in █████ did not meet standards to allow us to comply with regulations. We stopped our work with the animal facility on the █████ campus and proceeded to work through █████CC which now takes care of all the IACUC requirements needed for our work.
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- 32 Depending on the reviewer, comments change even for the same protocol.
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- 33 Understanding what is required is not a problem for me, because I have been submitting and holding protocols for many years. I have accommodated to the changes with time. Were I starting out, it would be a daunting process.
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- 34 Some confusion over the need to have an IACUC protocol for field surveys (assessing abundance and density of organisms) when fish are recorded (without collection of specimens nor interfering with animal behavior).
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### **IACUC Preparing IACUC protocols and consent forms for initial review**

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- 1 Sometimes the forms are confusing. However, IACUC personnel are always extraordinarily helpful when consulted.
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- 2 Having to retype information instead of copying and pasting, for example in different species sections, is annoying. The IACUC has a record of who completed training and when, and creating protocols would be easier if this auto-filled. Printing the protocol to a file record creates a humongous document with lots of wasted space.
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- 3 The degree of explanation and submission is simply too much.
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- 4 IACUC was designed with lab animals in mind, and is largely irrelevant for those who study wild animals in the field.
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- 5 Software not intuitive
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- 6 The Topaz system is not user friendly. It is difficult to navigate and find out what is actually needed for a particular proposal. Sometimes it is only after a revision request is made that we learn what was needed in the first place. Comments made to protocols that need revision are not always visible, then the protocol is sent back for further revision.
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- 7 These are just time consuming and the forms are really designed for medical laboratory mouse experiments. For example, I put in an IACUC for seining for fish a few years ago. When you seine, you don't know exactly what species you will get, so you have to list all possible species and guess how many of each species will be there. The preferred method of killing fish is MS-222, which is completely impractical for field research (and runs into other permitting problems if you introduce MS-222 into coastal waters). Most of this has been worked out with IACUC over the past several years, but the process is clearly not designed for this kind of work.
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- 8 Some of the Qs make no sense or they do not apply but NA is not an option provided.
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- 9 Convoluted, overly bureaucratic online process with unclear instructions.
  - 10 Confusing, internet system is not user-friendly neither straight forward, and we have no help from institution when we first do it.
  - 11 Each day I spend in compliance is a day lost on research productivity, and those days are continually stacking up
  - 12 They are very time consuming
  - 13 Citi is just too user unfriendly.
  - 14 The computer system could be made more user friendly.
  - 15 consent forms?
  - 16 The web based forms are a disaster and consume inordinate amounts of time. The layout and terminologies are ugly and unintuitive. Hire a consultant familiar with designing public interfaces.
  - 17 The software is not good, it is not clear what is needed in many places - so again the focus appears to be on compliance, as opposed to animal care. This is fair enough, given the governmental regulations, but to the researcher it feels like paperwork
  - 18 Lack of support and feedback
  - 19 First time through was difficult. Most of my work requires IACUC exemption.
  - 20 software is goofy, more cover your butt than in the spirit of the law
  - 21 Topaz is a bit burdensome but so much better than doing it by paper.
  - 22 We filed in new applications on Topaz and the old expired IBC approval number was entered on the Topaz forms immediately. Topaz (IACUC) automatically fill in expired IBC approved protocols and it does not update recent approved protocols from the IBC. There is no integration and database updates among different offices (IACUC, Biosafety, IRB, and ORS). Our IACUC application was approved based on an expired IBC protocol. Again, there is a lack of integration and the left hand does not know what the right hand is doing. Can we set-up a system-wide entry for approved protocols can be entered from the IACUC, biosafety, and IRB, so they and ORS can see approvals from each other? All training records given by these offices should be entered into these sections on this system, so they, reviewers, and PIs of protocols can see that training has been given/taken. Again, we need something that is integrated, so different offices can retrieve information on approvals/training that is given by another office.
  - 23 A bit hard to follow the online procedures. I needed an experienced post-doc to complete the form. It would take long time for me and/or anyone else to learn how to use the site to submit applications.
  - 24 Topaz is not easy to work with. Very clunky. The whole process seems adversarial.
  - 25 It's always a guess as to what the committee will have hang ups with. Have no idea which of their multitude of options applies to my project.
  - 26 A newcomer to the TOPAZ system will often have great difficulty with providing the "perfect" answers and new protocols could be delayed because of what seems obvious to the researcher is not to the reviewer. Many comments are vague and often require clarification from [REDACTED].
  - 27 IACUC committee and [REDACTED] compliance personnel needs to be up-to-date on the literature and accept the latest findings. It seems that whatever has been started years ago at an East Coast university and rigid electronic forms became the ultimate standards. Time to review and allow updating.
  - 28 Need veterinary approval but the website is constantly changing and sometimes the request form is unavailable. Why do we need veterinary approval even for annual renewals?
  - 29 Who reviews and monitors? No one fact checks or questions what's written in the protocol. Hazards are constantly overlooked and passed meaning that 3 more years go by until anything can be done about it. IACUC members do not do any research on the protocols put before them and pass them with no knowledge of what it even is. Who's job is it to research the chemicals, methods, biohazardous materials being used? This should not be the veterinarians job. The IACUC needs to spend more time actually dissecting and reviewing protocols not just checking a box and taking a vote.
  - 30 It requires the animal housing space, and then, required to submit the import permission in Dept Agriculture, then need facility survey. I didn't know this sequence of events and when I should prepare for each event.
  - 31 They have gotten so long that it is clear that the IACUC members do not read them thoroughly....I keep getting asked questions that were clearly answered in the initial protocol.
  - 32 The online form is a little difficult to navigate at times.
  - 33 When working with fish, there are questions re: when is a larval fish a fish and whether fish respond to stimuli or pain (i.e., is a particular intervention causing pain or not). Further, the use of anesthetic to sedate fish to protect students is assumed to be for the benefit of the fish when it is not. This then requires more paperwork.
  - 34 TOPAZ is not easy to use. Also, depending on the education of the reviewer, your protocol could get flagged for something that is not relevant, inaccurate, or not under IACUC's purview.
  - 35 Problems were associated with regulations that were too stiff for compliance. We had to discontinue our work with mice.
  - 36 Nice online system.
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- 37 Preparing protocols is problematic, because the process is always increasing in workload. More and more information is required as people think of additional things to have investigators pay attention to. This problem is typical of evolving bureaucracy. The solution is have a group of reviewers pear down the amount of information required instead of thinking of more information that could be requested.
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- 38 The software they use is clumsy. Makes you repeat many things instead of copying them from previous versions.
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- 39 Would like to see the process simplified.
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### IACUC Completing annual IACUC reviews and three-year renewals

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- 1 A hassle. But understand why it needs to be done.
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- 2 The yearly renewals are a bind. We keep on doing the same thing over and over again. If we have more than one protocol, it becomes problematic. It always comes back with errors.
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- 3 Ditto for this and all aspects of IACUC processing. Reviews and renewals are problematic, because the process is always increasing in workload. More and more information is required as people think of additional things to have investigators pay attention to. This problem is typical of evolving bureaucracy. The solution is have a group of reviewers pear down the amount of information required instead of thinking of more information that could be requested.
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- 4 No longer a problem because all the compliance and renewals are done through █CC. We pay the fees necessary to get the work done through the animal facility there.
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- 5 See response to previous question
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- 6 As I mention above, allowing both renewals and amendments to occur simultaneously would be a more efficient use of everyones time.
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- 7 just tedeus until get used to how to use TOPAZ system (staffs are very helpful to assist me).
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- 8 of course its not a problem because they just say yes to everything and dont really do any reviews. Their inspections are a joke. Its all just copy and paste each time saything everything looks good expect for a minor leak or something of that nature, etc.
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- 9 Renewals take much more time than they should if you have already outlined the numbers of animals to be used.
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- 10 took me a while to figure out which form to use for 3 y renewal, not real clear in TOPAZ
- 
- 11 IACUC committee and █ compliance personnel needs to be up-to-date on the literature and accept the latest finding. It seems that whatever has been started years ago at an East Coast university and rigid electronic forms became the ultimate standards. Time to review and allow updating.
- 
- 12 Annual reviews are not as problematic as the 3-yr renewals. Renewals every 3 years seems much too often for many projects are long term studies or are part of a Grant that spans multiple years
- 
- 13 Renewals seem to generally run smooth.
- 
- 14 Differences in opinion
- 
- 15 Same thing. The whole process is adversarial rather than supportive. The basic feeling I have is that they would rather that you not use animals for any research, period.
- 
- 16 Enormous amount of time needed to keep updating all of our protocols.
- 
- 17 The IACUC staff are very supportive, and been helpful and accommodating with respect to scheduling visits, and suggesting improvements.
- 
- 18 see above
- 
- 19 Too much paperwork for renewals. This could be streamlined.
- 
- 20 Same as above.
- 
- 21 See above. Even though we've been essentially resubmitting the same protocol for about 10 years, they always find something new to nit-pick that was apparently fine before.
- 
- 22 The three year full renewals are very time consuming and can be confusing. It would be better to make the full renewal every 5 years. Also having to do the yearly renewal when not much has changed is too much and there should be a Nothing has changed option
- 
- 23 Sometimes the forms are confusing. However, IACUC personnel are always extraordinarily helpful when consulted.
- 
- 24 Hard to keep track of animals when working on commercial farms. For example, if I show a farmer how to evaluate body condition score, I do it by pointing out animals that are normal, too thin or too fat without counting how many are in the pen or pasture.
- 
- 25 It sometimes seems to be a black box of just trying to placate the current members biases.
- 
- 26 IACUC was designed with lab animals in mind, and is largely irrelevant for those who study wild animals in the field.
- 
- 27 See previous comment.
- 
- 28 We still have to do annual review.
- 
- 29 The time
-

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## IACUC Completing protocol revisions requested by reviewers

- 1 IACUC needs greater appreciation for field research. The constraints on design are very different than lab research with animals. For example, when studying natural populations it is difficult to give estimates of the numbers of animals that will be included in the study because it depends on the density encountered in nature.
  - 2 Generally, feedback is very specific and helpful
  - 3 IACUC was designed with lab animals in mind, and is largely irrelevant for those who study wild animals in the field.
  - 4 As above. Many of the concerns are inappropriate and inject substantial delay into the process.
  - 5 Reviewers do not always understand the realities of farm animals, for example for procedures causing momentary pain anaesthesia can be far more stressful than the procedure itself. An important point to recognize is that an extension worker may never have ownership or control of the animals; ownership and control reside with the farmer, who has the ultimate responsibility for decisions. Extension workers can only advise. Everything has to be done with the permission of the farmer-owner.
  - 6 Sometimes the forms are confusing. However, IACUC personnel are always extraordinarily helpful when consulted.
  - 7 The reviewers are usually clear at what they request. They can be too concerned with animal numbers especially when we have to account for all breeding and not just the animals used in experiments. It makes it hard to justify because breeding and keeping a colony requires many more animals than the specific experiments discussed.
  - 8 reviewers occasionally appear to lack an understanding of the methods involved and make overreaching and unreasonable requests for protocol modifications. Reviewers insert new and sometimes contradictory requirements upon successive submissions, unduly delaying the entire process.
  - 9 Some requests have no logic, many are simply regarding formatting - which in turn is caused by the awful web page. One part of the solution would be to allow support staff to correct minor errors rather than repeatedly retuning them to the faculty.
  - 10 Not always clear what is needed (or why it is needed).
  - 11 often unclear what they actually want
  - 12 ██████████ is very helpful.
  - 13 On occasion, the committee/reviewer asks for changes to the protocol via email and the TOPAZ system which is no problem. Other times the protocol is not kicked back so edits cannot be made. In some cases we have been told that some basic training for some of our lab is not up to date which was found to be incorrect after we verified our own training records. That should be a trivial thing for the office to check and apparently it is not.
  - 14 A lot of back and forth over little things. I had one reviewer essentially condescend to instruct me on how to do a web search and literature review last year.
  - 15 Reviewers are generally clear what they want though I often disagree with their interpretations of requirements. This is a highly subjective process.
  - 16 I have only had one cycle of permitting for very simple fish observations. All further communication insured that our additional activities did not require a permit.
  - 17 Reviewers often ask for "clarification" which might be better answered by a site visit instead of in depth description of facilities
  - 18 IACUC committee and ██████████ compliance personnel needs to be up-to-date on the literature and accept the latest finding. It seems that whatever has been started years ago at an East Coast university and rigid electronic forms became the ultimate standards. Time to review and allow updating.
  - 19 This is one of the most convenient features of the current system. Helps protocols go through the first time.
  - 20 There are no reviewers. There is no Post Approval Monitoring either.
  - 21 Reviews that I have received historically have done little to improve the protocol and focus on unimportant details which ultimately simple waste time.
  - 22 Sometime it is obvious that the reviews do not have a clue about how commercial aquaculture works.
  - 23 Sometimes the revisions asked for just don't make sense - again, it depends on the knowledge and experience of the reviewer. We've had to call the office sometimes to figure out what the reviewer is asking for.
  - 24 Seem to make up UH-specific rules. Need to be consistent with national standards.
  - 25 Usually issues presented by reviewers are straightforward to address, and misunderstandings can be clarified by telephone conversations the the IACUC.
  - 26 They keep on changing what is allowed from year to year.
  - 27 Would like to see the process simplified.
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## IACUC Fulfilling federal and state requirements for training in animal care and use

- 1 Takes a fair amount of time.
- 2 How many times do we have to take the same exam??? Do they think we forgot what to do from the previous year???
- 3 The process is kind of silly: on-line reading and quiz taking until reaching a threshold of success on the quizzes. It is another thing that takes up time away from doing actual science. No one event takes up so much time. The whole process of university bureaucratic data churning is an example of death by 1000 cuts. As of a few years ago, it discouraged me from continuing to seek and manage large grants, and I am aware of people who left academia, because university bureaucracy is too suffocating of time available to do actual science.
- 4 Was previously a problem but no longer a problem since we pay others to do the work.
- 5 UH compliance staff are felt (by some faculty) to be “afraid of their shadows and interpret federal regulations much more narrowly than is actually required.
- 6 Online training is sometimes difficult to get, or to know how often we need to take the course
- 7 IACUC and ORC has nothing to do with any of the training. They don't even train their own IACUC members.
- 8 The external sources for this are quite amazing.
- 9 IACUC committee and [redacted] compliance personnel needs to be up-to-date on the literature and accept the latest finding. It seems that whatever has been started years ago at an East Coast university and rigid electronic forms became the ultimate standards. Time to review and allow updating.
- 10 While I have been trained academically and professionally in the care and use of animals, I have never been trained specifically on federal or state req's as they pertain to IACUC.
- 11 Its apparently required so you do it. Its not too bad but it does take time.
- 12 Enormous amount of time required for training and upkeep with training and protocols.
- 13 Actual training with the veterinary staff is not ever an issue.
- 14 Training modules offer no real training but are done just to fulfill federal requirements. CITI is mostly laughable.
- 15 fits a narrow range of lab situations
- 16 But only of limited assistance in training students in animal care and use.
- 17 There are many requirements that have absolutely nothing to do with my field. And areas that should probably be included and aren't.
- 18 Generally this is not a problem but UH doesn't provide any support or funding for it.
- 19 Some studies are very simple, and should not require oversight and approval.
- 20 IACUC was designed with lab animals in mind, and is largely irrelevant for those who study wild animals in the field.
- 21 The online coursework has made this easy.
- 22 Qs fit more for lab. animals and some do not apply to class field visits or extension work with farmers.

## IACUC Satisfying federal and state requirements for funded projects

- 1 IACUC was designed with lab animals in mind, and is largely irrelevant for those who study wild animals in the field.
- 2 Hard to keep track of animals when working on commercial farms. For example, if I show a farmer how to evaluate body condition score, I do it by pointing out animals that are normal, too thin or too fat without counting how many are in the pen or pasture.
- 3 Keeping track works well
- 4 A centralized record keeping of animals used that is readily accessible would be good.
- 5 Sometimes some reviewers seem not be clear of all the research program and ask for completely irrelevant or unpractical justification.
- 6 Time required is not insignificant.
- 7 Same thing, its apparently required so you do it.
- 8 Only researchers can track animal numbers accurately. There is no check/balance system that allows the IACUC to track numbers in some of the higher pain categories.
- 9 A hand written tally, eventually put in the computer and notifying the PIs once they have already exceeded their animal numbers. No very efficient.
- 10 because fish number especially larvae are enormous. Staffs in [redacted] helped me a lot to figure out the best solution for this.
- 11 I.e., when does a larval fish become a fish. IACUC assumes that mortality should be low but, for high fecundity fish, it is naturally very high (above 95%). So we should be applauded for getting 50% survival instead of being in trouble.

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- 12 As per comments on the previous question, I don't seek to hold large grants anymore, so it is not a problem. The only way I could do it would be to have enough funding to hire and maintain a technical secretarial staff to handle these issues.
- 

### IACUC Maintaining veterinary medical records

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- 1 Individual PI's don't do this.
- 
- 2 We have enormous problems getting access to local veterinarians in [REDACTED]. The University must invest in staff veterinarians on the outer islands.
- 
- 3 UH vets are great!
- 
- 4 N/A
- 
- 5 [REDACTED] works hard to help but he is overworked. [REDACTED] is more of an administrator than a veterinarian. They need additional staff.
- 
- 6 UH Manoa does not have specialized Veterinarian and same Veterinarian has to deal with all species. When the Species on research is different than the Vets Specialization, it seems he/she is of little help in the research program.
- 
- 7 LAS is very good at this.
- 
- 8 The veterinarian and owner keep these records.
- 
- 9 IACUC was designed with lab animals in mind, and is largely irrelevant for those who study wild animals in the field.
- 

### IACUC Other

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- 1 Unclear what training or support is available from the university other than the online certification. For example, what kinds of things can the campus vets do for us? Are they a resource or just a regulatory body? Is there a charge for vet services if they are available? None of this is clear.
- 
- 2 IACUC should offer real help to PIs, rather than putting the entire burden on them. The IACUC members are fine but the process to submit protocols is too complicated and poorly explained.
- 
- 3 - The number of inspections from IACUC can easily be reduced to half or once per year or twice per year. It takes time and resources to attend these visits, plus the annual and three-annual reviews that also take time to write. - If satisfactory compliance is demonstrated for a few years in a row, those visits can be less frequent. - Unless a very different or new method or experimental approach are proposed, or change in PI, the renewals should be automatic pending satisfactory compliance during the annual or bi-annual inspection.
- 
- 4 IACUC was designed with lab animals in mind, and is largely irrelevant for those who study wild animals in the field.
- 
- 5 The CITI training is easy, but I don't feel that it really helps PIs to understand their responsibilities. For example, many PIs are unaware of the need to report unexplained deaths or animal loss to the IACUC promptly. As a result, most of these losses are not discovered until the semiannual inspections.
- 
- 6 I have found working with the UH IACUC very easy, everyone is always very helpful and responds quickly to my questions.
- 
- 7 The quality of the web-based training is mediocre.
- 
- 8 Same comments as re: IRB. Have not needed to propose use of animal subjects at UH to date.
- 
- 9 If there could be ways to reduce the renewal time and effort that would be very helpful.
- 
- 10 Focus appears to be to reduce or eliminate liability of the university for non-compliance, rather than facilitation and support for the principal investigator
- 
- 11 Need to stop over regulating by removing teaching and related activities from IACUC oversight. Allow neighboring islands personnel to participate in inspections to cut costs and oversee non-research activities.
- 
- 12 The programs could be tailored a little more closely to the protocols themselves.
- 
- 13 my interaction with the IACUC was very minimal but I got the impression that more complex studies might have been more problematic, I just didn't run into any problems.
- 
- 14 Not clear how to answer these two questions. As mentioned before one-on-one interactions during inspections have been helpful.
- 
- 15 There should be option for some hands-on training, especially for Graduate students and new researchers.
- 
- 16 The wizard behind the cloth, with absolutely no effort for outreach or to be proactive. Insular and secretive. They are not cops.
- 
- 17 Too many instances when there is a minor problem, then a one size fits all policy gets developed. It has gotten worse since [REDACTED] was hired. His office should be there to support the PI's not criticize them. Another issue that needs to be sorted. Right now the IACUC resources are spread across the entire system, yet it is funded through UHM.
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- 18 The AVS staff are extremely uneducated on the safety issues of certain type of research and are ill-prepared; and most of the time, we have to educate them on the safety issues related to certain experiments. [REDACTED] is nowhere ever to be seen in animal facility and working with PIs the past 14 years I have been here doing numerous animal experiments, and the ill-prepared and undereducated AVS staff are left to figure things out with the PIs. This is a common complaint I have from other colleagues as well.

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  - 19 The requirements or tests IACUC recently instituted specifically for UH investigators are irrelevant. The investigator certification tests required at the national level are sufficient. I strongly recommend getting rid of these irrelevant tests and have investigators spend their time more wisely conducting research.

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  - 20 I have worked with IACUCs from different institutions and am alarmed at the degree of variation in how this process is applied. Each committee makes their own interpretation of the requirements. UH is particular about meaningless minutiae causing delays and expense to projects with no improvement of animal health or rationale toward compliance at least as it pertains to livestock. The net effect is an aversion to studying livestock directly. A “how do we help you through these hoops to meet your project goals” attitude rather than a “this, this, this, and this is wrong, figure it out and do it again, why are you doing this anyway” attitude would help researchers understand IACUC needs better and can plan accordingly.

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  - 21 The training we received was on blood borne hazards and radioactive material. There wasn’t any training by UH personnel on animal use - it was the US standard via online of a East Coast university.

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  - 22 having a central repository with all training records is helpful - [REDACTED] is great in helping us keep track.

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  - 23 Train the IACUC. Make them devote more time to the IACUC or find people that can spend the time needed to thoroughly review the protocols. Have people on the committee that are qualified to give the appropriate feedback and specialize in chemical hazards, PPE, biohazards etc. Too many protocols are being passed with lots of holes, grey areas and confusion. A protocol should not be votes past until it is polished and perfect. There should be no unanswered questions.

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  - 24 the whole process seems designed for the convenience of the staff, not for the investigator

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  - 25 This needs to be an enabling committee, not a policing or disabling one as it is now.

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  - 26 Find ways to reduce the demand for data.

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  - 27 I’m by aware of any training at UH

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  - 28 Would like to see faster turn-around on protocol review process.

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## BIOSAFETY Understanding what is required and why

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- 1 As new faculty no one at any level has given me any information about biosafety. I have tasked a technician in the lab with trying to figure out what is required.

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  - 2 What are the guidelines and where can we find them?

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  - 3 [REDACTED] have been wonderful to work with

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  - 4 My organisms aren’t considered hazardous per se and so usually aren’t a problem. But the specs and requirements are so onerous that it can be tough to figure that out.

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  - 5 The requirements for biosafety are overly punctilious. As only a few examples, the charges for evaluation of unlabeled solutions, for example, are simply inappropriate. The thinking about storage of volatile solvents is confused (alcohols do not represent an explosion risk). And there is persistent over-concern about recombinant DNA that dates from policies that are decades old. On the other hand there is negligible understanding of the very real risk of anesthetic agents used in confined spaces (in the vivarium)

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  - 6 Importing organisms and strains needed for research can be arduous. Most of the problems are related to the State Dept of Agriculture, not the IBC or Biosafety at UH.

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  - 7 Not clear what is required in terms of training, inventory, import/export, etc. A very basic and clearly written guidebook would be very useful.

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  - 8 This group is absolutely awesome. They are on the ball and teach what you need to know. They then put the material online to accommodate schedules. I can’t say enough good things about the biosafety training staff and materials. VERY helpful!

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  - 9 At times it is difficult to get information from the safety office regarding the disposal/handling of student lab materials.

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  - 10 Most biosafety personnel really don’t have a clue about requirements or what it takes to comply. Even if you ask them what they want you to do, they usually can’t give a response. [REDACTED] is the only exception, everyone else should be fired.

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  - 11 Interactions with off-site /multiple locations can be problematic as every location has their own rules.

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  - 12 Inconsistent safety officer

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  - 13 It is not made clear to new staff (except by word of mouth) exactly which training sessions are needed; Biosafety inspec-

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- tions are weak, and rules are not made clear or enforced. Also “rules” seem to change, and there is little consistency.
- 14 Difficult to find qualified instructors who have an understanding of the unique requirements of the Health Professions and the OSHA/Medicare rules and regs.
  - 15 Always seems to be a moving target.
  - 16 seemingly arbitrary requirements often change - poor communication
  - 17 Not a user friendly system in place
  - 18 There are little guidance provided to PIs on how to apply for a new protocol. E-mails from Biosafety Officers are cryptic with no exact advice on what to do to fix protocols before and during reviews. Protocols are often not approved in a timely manner because uneducated and ill-prepared biosafety officers and raised issues on the IBC by what they learned on Google, rather than more factual information from the literature. Most other institutions have assigned PhDs (faculty) as biosafety officers; we have people as biosafety officers who barely got a BS degree and extensive lack of experience/ knowledge in the potential infectious nature of microbes and safety issues; they are either too cavalier or too paranoid (we have both type of people at UH) and this hurts PIs’ protocol approvals. This office is the most problematic of all three offices (IRB, IACUC and Biosafety).
  - 19 A lot of time is required to keep up with all the regulations.
  - 20 There are SO many regulations involved with: handling, maintaining, importing, exporting, cataloging, disposal of biological materials. It takes a lot of time to be compliant. Biosafety office is doing a good job, its just the amount of regulations that must be complied with that makes it difficult. Takes a lot of time away from research.
  - 21 sometime rules change, difficult to find current requirement online at EHSO; i.e. how to deal with autoclaved waste
  - 22 Sometimes difficult to find the relevant office/expert to talk to about compliance
  - 23 The requirements are onerous and there isn’t a simple way to get at the information needed. It took me talking to many people and making many phone calls before I understood minimally what was required.
  - 24 Their change to the new website while still having the old one up is causing some confusion of information. Example - I search for information and the link leads me to the old webpage. I ask for help, and then they point me to the new webpage. The links to the new pages need to be inserted or more evident.
  - 25 Not all BSL2 organisms are the same. Some really are fairly low risk yet the regulations governing movement and use don’t acknowledge this.
  - 26 Training for support facilities workers needs to be specific to what they will do in the labs versus the training on what goes on in the labs.
  - 27 I am constantly getting confusing answers or even no help at all when I have some questions. Luckily, I came with an extensive experience to UH, so most of the time I knew what to do without any help, but I can just imagine what kind of training/help inexperienced people get when they come!!!
  - 28 Many times it is hard to get clear answers as to what procedures are required with regard to biosafety.
  - 29 They tend to use ‘umbrella’ type rules and force labs personnel to follow those rules even though they don’t apply to the kind of work that is performed in the lab. This is a waste of staff worker’s time and it is counter productive. The rules should be specific or based on kind of protocols that the labs have. In other words, the PIs and the lab staff should not be subjected to rules that do not apply to the nature of work they do. It is a waste of researcher’s time.
  - 30 Inventories for DOA and the recent request for inventories of ALL POSSIBLE biologicals including commercially sold antibodies and antigens. Most are sold in a lyophilized form and the quantities are in the milligram quantities and pose very little hazard. The WHY is not often very logical.
  - 31 Some things are not meeting full compliance (or on the lowest level of compliance perhaps) because of funding issues - for instance, flooring in the lab, outdated materials eye washes in some labs, etc. Not sure what to do about these...
  - 32 We do not have biosafety training offered enough times to accommodate all the students who need training to work in the lab on funded projects. It would be nice if they could take the course online to make it a more timely certification. Waiting for in-person classes is detrimental to timelines of funded projects. Also, students who have contacted the safety officer to schedule trainings do not have their emails answered.
  - 33 so many different records to keep track of...training, IBC expiration, inventory.
  - 34 System is totally messed up. Records have been lost. Notices aren’t sent for when renewals are needed. Import forms are impossible to fill out.
  - 35 Concept is basic enough. Training’s are a joke though. Same powerpoint every year that is sped through in 25 minutes. Then ridiculous online follow ups every year where you can just guess the answers and retake as many times as you want.
  - 36 Information is poorly presented and incomplete.
  - 37 The current staff, while friendly and helpful, are really not equipped in terms of training, experience, or vocabulary to do the job, at least in terms of [REDACTED]. I have direct experience of how their lack of knowledge of basic terms in the field has led to confusion. What is worrying about that is that they are in positions to interpret and enforce regulations,
-

and perhaps to make decisions based on those regulations. However, if they do not understand the English, specifically field-specific terms, then they really shouldn't be in these positions. It's not something that can be overcome by throwing money at training. It is a fundamental problem in their use and comprehension of English. The term I have in mind is not absolutely field-specific, but is used to mean essentially the same thing in English anywhere. It might be beyond an early teen to know what the word means, but any educated adult, specifically one in a position where such knowledge (vocabulary) is crucial, should know it. This one example suggests to me there are likely other shortcomings in the same people. Emails are often poorly written and poorly punctuated; 'messages' or the point of the email are simply obscure or non-existent. I have no idea what they're talking about, sometimes. My having to seek clarification takes my time, embroils me in further interpreting, and leaves me amazed that these are the people making decisions on permits, and how to interpret and apply regulations.

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- 38 Nothing remarkable. One must check the current rules and follow them in detail - it's a problem only in the sense of requiring some homework.
- 
- 39 It's difficult to keep up with all of the requirements. It would help if each investigator had a registry of all of his/her requirements, when reports are due, and was automatically reminded of due dates.
- 
- 40 Providing clear and unified directions on this would be helpful for new researchers coming into the UH system. I find that I have discovered one or two more requirements each time that a new member joins my lab.
- 
- 41 What samples are regulated. Online database.
- 
- 42 Training in chemical handling, transport and disposal is not offered frequently enough.
- 
- 43 The various required plans to manage spills or other possible problems are redundant and often unclear resulting in a lot of calling and going back and forth and wasted time. Disposal procedures are arcane and difficult to understand, what are the true guidelines and procedures? It's a crap shoot as to whether the PI is doing it right or not.
- 
- 44 We've had ongoing issues regarding what exactly is required of us (as Federal regulations or State regulations change), and getting this information relayed to us in a coherent and timely fashion.
- 
- 45 It is hard to initially find the correct person to contact to find out what is required.
- 
- 46 There is huge lack in understanding of ways to help PIs to achieve research in a timely manner in the Compliant Office. There is an attitude of not taking responsibility and willingness to help PIs and always passing work and responsibilities down to the PIs.
- 
- 47 communication for refresher training is not accurate, I get a reminder for annual refresher biosafety training at least 3-4 times a year. reminders should be sent a month before needed and not at random times
- 
- 48 The frequency of renewals (annual) for each lab worker is excessive, particularly when the same questions are repeated.
- 
- 49 Biosafety compliance do not give clear information on what is required.
- 
- 50 Revisions or amendments routinely come back with questions pertaining to already approved, unmodified sections demonstrating a lack of consistency.
- 
- 51 Because I don't have a technical secretarial staff to assist me, I confine my research to topics and materials that do not have complex biosafety issues.
- 
- 52 I certainly understand what is required. Some of the requirements from HDOA are however unreasonable. A case in point is the requirements for importing microorganisms (see below).
- 
- 53 there are many rules from federal and state agencies plus UH rules... they are complex and seem to frequently change... some rules are vocalized but not written anywhere ( or else cannot be found) and interpretations vary depending on whom you consult
- 
- 54 Changes with changes in personnel, get one answer one day then another the next. One colleague got an approval, denial and then approval for the same IBC protocol all in one week recently. Need to replace leadership with qualified people who know Infectious Diseases, Epidemiology, Biosafety and proper Risk Assessment.
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## **BIOSAFETY Fulfilling federal requirements for training in biosafety**

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- 1 We do not know what is current. Had a visit from CDC and was told some sera that was 30 years old was a risk. Never been told that before despite many visits in the past. The conclusion that there was a risk was up to [REDACTED]. Who said to me in the past that well it is all about perception. I counter it should be about risk assessment. His response was to shrug his shoulders. Never had this kind of response from an RO. I ask CDC if there was a competency exam for University RO's or ARO's provided by CDC. The answer is none it's the UH's responsibility.
- 
- 2 I have a bit of trouble every year bringing in trainers from Manoa to train myself and students...it's not that easy to coordinate the time to have them conduct the training.
- 
- 3 Separate training for use of materials for an instructional/teaching lab class would be helpful.
- 
- 4 Why do we have to repeat everything on a yearly basis????
-

- 5 Because I don't have a technical secretarial staff to assist me, I confine my research to topics and materials that do not have complex biosafety issues.
- 6 No idea what that entails as the UH system seems to interpret this as they see fit, even in light of national/NIH standards.
- 7 Despite training and travel to receive training, the compliant office staff and directors are clueless about federal guidelines. These people should be fired as they are not qualified for the job.
- 8 the website for biosafety initial and refresher training is well organized-the dates and location of training sessions clearly listed. Initially finding the site is a little difficult because biosafety is no longer under Environmental Health and Safety Office.
- 9 We rely on the Office of Research Compliance to stay abreast of the current Federal regulations regarding Biosafety matters. This office hasn't always done so, or relayed to information to us in a timely way.
- 10 Just trying to schedule someone from UH-Manoa to give training. For basic biosafety, I propose that our own EHOS office at [REDACTED] could give the training instead.
- 11 Limited training
- 12 Biosafety training classes sessions should be advertised well in advance, and should be scheduled to be available to students (50 minute sessions? need to take 2 sessions?)
- 13 timing is problematic. Training is given at inconvenient intervals and places for investigators. Can't it all be done on line??
- 14 Getting undergraduate students trained; Needing environmental biosafety training rather than / or in addition to blood-borne pathogens training.
- 15 I have received requests telling me I should 'train', when I know I shouldn't. I have responded to that effect and then been 'cleared' because my training is (or was) current after all.
- 16 I can't always meet training times. When I did go, most of the information was not applicable to my research.
- 17 Who would know if we are fulfilling them or not? Im sure everything looks good on paper.
- 18 Not enough classes are offered for the face to face meetings.
- 19 Grateful that they allow our campus to do updates via online because of where it is located and difficulty getting to other campus' for trainings.
- 20 Recent training sessions for JABSOM were not easily registered for.
- 21 These requirements keep changing and the lab staff is the LAST to know. There is more confusion than clarity or solution in recent years. Our own responsible officials in the UH tend to be more fault finding and critical than proactive and helpful.
- 22 There is no hands-on training provided by Biosafety. It is left up to supervisors and Directors to provide staff training hands on. This does not happen consistently in all departments, making our practices inconsistent.
- 23 The initial training is probably OK for very basic research, but not sufficient for working with more risky organisms. Plus, PIs should have additional support and training to be able to run their labs safely.
- 24 Trying to get information from the Office of Research Compliance is difficult.
- 25 Unaware of federal requirements for training in biosafety!
- 26 No information re: what kind of training was offered and who was required to get the training.
- 27 training is easy; class and online
- 28 A lot of time required.
- 29 Biosafety Officers are ill-prepared and under educated with respect to preparing and integrating new and constantly changing Federal guidelines. They are sent to mainland meetings to be trained, but comes back with misleading information and renewed paranoia.
- 30 Sometimes it doesn't seem that the biosafety office really knows what they are doing.
- 31 There needs to be clarity for PI's that work with biologicals.
- 32 As above
- 33 See above suggestions.
- 34 Again, off-site /multiple locations can be problematic as every location has their own rules.
- 35 Training rarely offered.
- 36 The EHSO changed the policy for refresher course training from every two years to every year. This is unnecessary and time consuming. I think it should be returned to every two years.
- 37 the web-based system is mediocre in quality but easy to use.
- 38 I am told that for educational purposes, bringing ANY living tissue/ material/ organisms into labs or classrooms requires paperwork. That really isn't practical. Actually I'm not sure that's even true.
- 39 Takes time and is more bureaucracy without a measurable benefit
- 40 I have to organize and pay undergraduates to take hours of training that isn't relevant to their jobs. they don't handle biohazards or even chemicals, but have to sit through hours of training about it.
- 41 Each day I spend in compliance is a day lost on research productivity, and those days are continually stacking up

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42 Annual workshops available in [REDACTED], but if these conflict with classes, faculty have difficulty attending (ie., no choices in times).

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### **BIOSAFETY Establishing protocols to comply with federal and state requirements for handling biohazards**

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- 1 Protocols seemed to be 'one size fits all' and we are often forced to do ridiculous things that aren't relevant to the research we are doing. toxic waste training shouldn't apply to re-potting plants.
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- 2 The barriers and process for importing and/or acquiring microbial strains is prohibitive to productive research process.
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- 3 The importation of simple plasmid reagents and viruses is impeded by a lack of understanding of their complete safety.
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- 4 Need better biosecurity protocols for animal work in the field to prevent transmission of problems from farm to farm.
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- 5 Not clear what the requirements are.
- 
- 6 Not a problem once we know how to handle the material.
- 
- 7 Hawaii has some unique laws with regards to Dept of Ag.
- 
- 8 Just maintaining documentation, and determining what activities are significant/ hazardous enough to require formal protocols.
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- 9 See above suggestions.
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- 10 As above
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- 11 No specific resource for the program
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- 12 EHSO seems to have a hot or miss approach to this. If HIOSH got into things, I think they would see things a bit differently than EHSO
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- 13 State DOA approval takes forever
- 
- 14 For sharing facilities, it is a bit hard to track down all the materials used and activities.
- 
- 15 Lab inspections are a joke, because biosafety officers are not too knowledgeable and don't know what to look for. They cannot keep accurate record and often ask PI to have lab inspection again before approving the IBC applications, because another person in the compliant office did the inspection and did not enter this on their spreadsheet or entered it inaccurately. The right hand do not know what the left hand is doing. Likewise with training (biosafety and blood-borne pathogen training) they give, records are not kept in an online domain or readily available and IBC protocols are rejected because of non-recorded training by the Biosafety Office. I suggest the Biosafety office have an online system to enter all training for people at UH once they provide the training and IBC approvals, so PIs, ORS, IRB, IACUC and the biosafety office can look up to verify to approved protocols, grants, and integration to ensure compliant. [REDACTED] is not qualified for the job; he has little education and background to oversee the integration of even these two entity. His main goal is to once in a while teach PIs a lesson and make them squirm (in his words) by making trouble for their research. There is a culture of this from people not there to truly serve and help the research enterprise at UH.
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- 16 Again, time consuming.
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- 17 Some of the requirements for handling and transporting biological agents make no sense and the regulations should be modified. For example, if a biological agent such as a plant pathogen is found on Oahu in Manoa, and the same pathogen is found on the Big Island in Hilo. We are currently required to apply for and receive a permit to move the same pathogen from one island to the other, even though it is already found in both places and is the same organism. These types of intra-island permitting is really unnecessary for organisms found widely throughout the state.
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- 18 difficult for labs dealing with many diverse protocols but not particularly hazardous items (i.e. plant sciences vs medical sciences); can take a long time to develop proper comprehensive protocols.
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- 19 Have you tried to file an application?! Why can't there be simple instructions with examples for us to follow? Staff very helpful, but we should be able to file the application without so much back and forth and revisions.
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- 20 If there are changes to requirements, they don't become evident until we have inspections. Is there a way to get heads up on changes?
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- 21 UH does not have an expert on this subject. Each individual you talk to will have a different interpretation of the requirements.
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- 22 Differences in opinion on compliance
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- 23 IBC approvals were beyond confusing! I still do not know what was approved what was not. I have impression that people that handled my protocols either did not care or were not competent to review them. In addition, no help was provided to actually write protocols and manuals. Luckily, again, I could copy many things from my previous institution.
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- 24 I feel this isn't something that has been disseminated to most faculty -- that may be more a problem with the faculty than the protocols themselves.
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- 25 I am sure you have heard this, but HDoA requirements are beyond stringent
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- 26 Examples should be provided for each type of safety hazard.
  - 27 Only if the biohazard is caught and identified then yes we do everything to make sure it is handled properly but far too often it is not caught in the review period so it just gets overlooked until there is a problem.
  - 28 I was not informed there is a form for the emergency evacuation. I had to rewrite again.
  - 29 HI Dept of Ag requirements and regulations are nonsensical. Approval process for importing harmless microorganisms is prohibitive. I have not pursued potential research projects as a result.
  - 30 I was asked to provide a 'safety plan' for a small project that was to be reviewed by the IBC. I was told to include details of my lab's responses to natural disasters. Those natural disasters were not defined, but one would assume they include but are not limited to tsunami, hurricane, and perhaps earthquake. It seems no campus-wide response to such disasters exist! Why should I have to formulate a plan for my personnel in response to such disasters? Indeed, I should not be allowed to develop such a plan. I could write that my staff should work through an earthquake, ignore a tsunami! There should be a standard university document that I can incorporate into my lab's procedures. Instead, I ended up submitting 200 or so pages of complete nonsense, dealing with all kinds of stuff I just should have even been allowed to express an opinion on, such as what to do with a person in a wheelchair during a fire! The whole exercise was a farce, and I told the staff I shouldn't be doing it, that my project didn't need IBC approval, and that it was all a complete waste of time. A colleague on the IBC even agreed. However, I had to submit the 'plan'. I was subsequently told by the IBC that I didn't need their approval, or a permit, or something like that, and thank you. Yeah, thank you, too, for wasting my time.
  - 31 Limited training. Also definition of biohazards used by UH is too stringent (i.e., they consider any animal and plant material a biohazard). This creates inane requirements for movement of materials between labs even when the same materials are openly sold at stores and markets.
  - 32 "Proper" disposal of chemical hazards stuff has been a pain in the butt. Must take classes before I can have chemical waste removed from my lab.
  - 33 Disposal regs are difficult to know and therefore to follow.
  - 34 We rely on the Office of Research Compliance to stay abreast of the current State regulations regarding Biosafety matters, especially in regards to HDOA. This office hasn't always done so, or relayed to information to us in a timely way.
  - 35 The training sessions inform the attendee of what is required.
  - 36 People in the compliant office are clueless to be able to assist PIs and IBC members to appropriately evaluate IBC protocols. Often, advice from biosafety staff in the compliant office is vague and not helpful.
  - 37 Some of the Biosafety standards are not appropriate for all laboratories. They are excessive.
  - 38 There seems to be no consistency with this, so can write whatever.
  - 39 Because I don't have a technical secretarial staff to assist me, I confine my research to topics and materials that do not have complex biosafety issues.
  - 40 university does not provide resources to meet some requirements
  - 41 Requirements always changing and varies with who you ask in terms of Biosafety staff. IBC does not have adequate training. They can make some judgments in their areas of expertise but not in other areas. Often the personal issues, jealousy or competition interfere with approvals. Some people just like to talk at the reviews of protocols and no risk assessments are done on controversial protocols. Just a general lack of training, competency and experience with in the committee and support staff. No funding for training in decision making and up to date Federal rules. There is an annual ABSA Biosafety meeting with pre-conference courses available also in the distant past we could bring trainers out for the staff and IBC on a limited basis.
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### **Establishing protocols to comply with federal and state requirements for handling blood-borne pathogens**

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- 1 Rules are not made clear.
  - 2 Don't handle bodily fluids
  - 3 They may be good in the lab, but they are laughable in the field. They lack the expertise.
  - 4 State DOA approval takes forever - arbitrary opinions by Biosafety staff
  - 5 It went from ok to really bad when they fired ██████████, who used to run the whole compliant office by herself. Hopefully, things will improve and we do not constantly get on the news about CDC problems with UH JABSOM containment problems. Most of which are incompetency and inexperience from everyone in the Biosafety/compliant office. I like the news but never when it reflects badly about UH.
  - 6 Time requirements is not insignificant.
  - 7 Not relevant
  - 8 Everyone just pretends like they don't exist.
  - 9 VERY problematic when it comes to import regulations. Our lab has simply given up on important studies when, after 2
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or 3 years, we could not bring in relatively nonharmful materials. No one wants to be the one to say OKAY!

- 10 Templates provided.
  - 11 Because I don't have a technical secretarial staff to assist me, I confine my research to topics and materials that do not have complex biosafety issues.
  - 12 We have only one area in our department that collects and properly disposes biohazard material, it is sometimes difficult to coordinate a drop off time due to varying schedules and use of the lab. Also we are limited on funds to obtain our own access to dispose of biohazard materials.
  - 13 no agreement on what is and is not a blood borne pathogen
  - 14 On line training is verified by a simple 10 question examine. Bring out qualified trainers and offer two or three half day courses with hands on experience.
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### **BIOSAFETY Filing applications to comply with state requirements for the use of microorganisms**

- 1 People managing are not microbiologists, just bureaucrats who think in terms of ebola out breaks and do not understand infectious diseases and the human microbiome. they make up rules based on their perceive risk. and do not know the difference between commensal and pathogenic microorganisms. they assume the worst when making rules and with out the background to make decisions. Need training.
  - 2 there is no one currently working in UH Compliance who can assist people who need help and the state forms are confusing with minimal directions provided with them
  - 3 HDOA permit processing can take upwards of several months to a year. Many organisms are on the restricted list. For organisms not on either the restricted or the non-restricted list, they are treated as those on the restricted list. This is a huge problem. Also the PQ7 permit application documents are extremely cumbersome to prepare. This has significantly limited PIs' ability to conduct microbiological research.
  - 4 The system is broken, please fix it. [REDACTED] has alienated faculty, staff, and the DOA, resulting in a situation that is worse than it's ever been. Rather than fight the inept bureaucracy at UH, faculty have simply given up and not filed applications that take forever to get approved or are forgotten.
  - 5 Keep on doing the same thing every year.
  - 6 Because I don't have a technical secretarial staff to assist me, I confine my research to topics and materials that do not have complex biosafety issues.
  - 7 This changes so much, who knows.
  - 8 Requirement for annual reports for use of every organism in the entire laboratory over the year is excessive and burdensome. Some of the requirements are not logical or meaningful.
  - 9 Current Compliant Office Staff, as of yesterday, refused to communicate with Hawaii Department of Agriculture and send my strains collection representing our institution on my behalf. They don't want to be responsible for anything and want all PIs to directly send things to HDOA, which will create problems for UH. Previously, [REDACTED] has a good relationship with HDOA and did all annual inventory for all PIs at UH by communicating with HDOA on our behalves. New PIs will suffer significant importation delays because of this irresponsibility attitude by the Compliant Office and lack of relationship/communication with HDOA!!!
  - 10 Non starter. Applications for importation of microorganisms is a no go from the start.
  - 11 This whole process with getting permits from HDOA is a complete disaster. Much of it due to loss or lack of staffing at HDOA, and lack of understanding/communication within the UH. We need a better system for getting permits and understanding the requirements for permit holders.
  - 12 take too much time
  - 13 HDOA is a great impediment to biological research and reacts to unfounded hysteria instead of applying scientific principles.
  - 14 I've been lucky in that I'm using harmless lab strains but I've heard how difficult it is to import strains.
  - 15 In a number of instances, the State DOH did not reply to applications submitted to them to approve commercially available (and benign) biomaterials for shipment to Hawaii. They completely ignored the requests for months. The onus lies on DOH not EHSO and apparently there is not a thing that can be done to remedy that bottleneck. Absolutely incompetent.
  - 16 Very slow process with poor communication of progress, potential issues, and process for resolution from state to investigator.
  - 17 Persistent problem with the State of Hawaii requiring a very long process to get permission to culture microorganisms from its own offshore water. In some cases research is set back by 1-2 years because of problems getting permission to use organisms that are the primary model systems used everywhere else in the US.
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- 18 Not difficult, just time-consuming.
- 19 The whole Hawaii State procedure for importing microbes is a farce. Where else in the country can a board comprising members of the public (such as a pet shop owner) have any say in what a professional microbiologist can do? The whole import procedure is set up with the premise that microbiologists are deliberately going to import dangerous microbes for nefarious purposes. It is insulting. And then to respond to this premise, or some paranoia from people with no experience or training in microbiology, we have to jump through hoops for a decade to import a microbe that cannot survive out of the Petri plate! While the UH staff conform, one might say bend over backwards while we bend over forwards and take this nonsense, it's about time UH rose up and enlisted qualified counsel at the Federal level to overturn this medieval mentality and backward regulation. The entire import process has earned the derision of people around the world, and made Hawaii a laughing stock. The state's microbiologists, with centuries of experience among them, are beholden to people who have never even seen a microbe, including those in the UH EHSO, yet these people are able to pronounce on, regulate, and deny what the former (career microbiologists) can do. The Hawaii state import list of 'allowed' microbes dates back to 2001! Nothing named since then can be imported without a crushing bureaucratic process. Thus, nobody bothers. Yet we import Christmas trees every year, with little inspection, and every year some bizarre insect is found. I find live insects in my lettuce from the mainland in Costco. Tourists bring seeds on their shoes, pollen on their clothes, insects in their bags. All this is released around us. Yet we can't import a properly packaged microbe and work with it in a controlled space, i.e., a lab. This is a small summary of the grief the unqualified people in the HDOA have caused by their ignorance, which in turn stems from state regulations and the involvement of people who have no idea about microbiology. Knowledge of threats in microbiology is not learned from Hollywood movies about viruses!
- 20 Take responsibility away from Dept of Ag. Adopt guidelines similar to those implemented by other states. Create a list of bacteria that need to be regulated and consider the rest safe, rather than regarding them all as restricted unless they are on a list of approved organisms. No one can keep up with all known organisms, the vast majority of which are not a risk to human health.
- 21 I could not see why I need to submit the form to purchase E. coli competent cell every time. micro-organism ecosystem is already messed up in oahu island by tourists who can carry everything. I will follow the rule anyway, though.
- 22 Forms are incomprehensible.
- 23 HDOA again
- 24 Very cumbersome and takes a lot of time. It really hinders getting funded work done in a timely fashion. It actually deters me from ordering positive controls I need for my research.
- 25 I haven't had to do this myself, but I know our lab coordinator has had some issues.
- 26 Wait times were very long for approvals. CHanges in personnel and other issues at Compliance Office left many unsure of whom or where to call for advice.
- 27 problems on HDOA side. wait times for processing applications is completely unacceptable under [REDACTED]
- 28 Based on the time I was told it would take to get permission to import a microorganism, I decided not to pursue research with that organism.
- 29 Relationship between UH and HDOA is disastrous. The process for getting permits is like Kafka's Trial! I do not feel that UH support its researchers in ANY way to allow them to import organisms needed for research, even harmless ones, such as E.coli!!! UH Compliance Office should stand behind their researchers and advocate for approvals at HDOA. We are losing time and funding opportunities because of the laughable system in place. I am honest here - if I had known about this, I would have never come to Hawaii. If nothing gets done this spring, I will start looking for a new job because I cannot do my job here.
- 30 The State's approach to microorganisms is just nuts. Its a tremendous logjam trying to get standard organisms, cell lines, plasmids etc from ATCC or other vendors or other researchers.
- 31 Difficulty to complete some forms because I'm not quite sure of how to complete (I don't know if I am providing too much/ too little information). It would be nice to have a sample.
- 32 Filing the application is a major hurdle, but it is nothing compared to the long, long wait for approval. It's like throwing the application in a deep, dark hole because there's no feedback, and it could take years.
- 33 importing microorganisms is extremely difficult, takes way to long to obtain permits
- 34 The state official in charge of approving permits at HDOA is very overworked and it takes a long time to get permits approved. Many times the permits NEVER get worked on and the application dies at that office. State needs to hire another person to work on permit applications. Since researchers at UH are REQUIRED to have these permits in order to work on projects. How can we do our work if the required permits are never received?
- 35 In cases it excludes certain agents, complicated and lengthy approval process. In cases we had to drop parts of the research plan as it was taking too much time - this was with established cell lines.
- 36 [REDACTED] was the only one who knows much about select agent compliant and she is gone, so I am not sure what it will be like for UH in this respect in the future. My fingers crossed and I am praying for the best.
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- 37 There is a disconnect between the state(HDOA) and UH biosafety so that it is very difficult to get any approval.
  - 38 State DOA approval takes forever. burdensome and ever-changing arbitrary regs and intrusive inventory demands on materials not covered by Fed guidelines.
  - 39 Efforts need to be made to bridge the gap between UH and HDOA to facilitate approvals. Having approvals required by the Board of Agriculture causes tremendous delays.
  - 40 Tedious but not problematic
  - 41 Rules are not clear, or are inconsistent. Have had problems getting approval for working with lab strains of E. coli. (The same strains that can be acquired for use in high school laboratories!)
  - 42 Having good personnel to work with has made this requirement easy to address. However as of a few weeks ago these people have been “fired” and we anticipate huge problems developing.
  - 43 I’m an engineer, and a lot of my work deals with agricultural pathogens. Regulations related to transporting, handling, collecting, and maintaining microorganisms make me rely 100% on the small number of faculty colleagues willing to make this effort. If they were not here, I would have to rely 100% on colleagues outside of UH (which would significantly diminish our rate of progress and impact), or I would stop this line of research altogether.
  - 44 Inter-state, inter island shipping of non-toxic micro-algae is subjected to the same rules and regulations as importing new micro-algae into the State of Hawaii. This is problematic for UH working with industry on the different islands and within the UH system.
  - 45 We only work with local species or allowed imported species of microalgae but it is difficult to get a state permit (including for others in a similar position). Would be nice if UH could work a bit more closely with HDOA to allow for easier permitting.
  - 46 Many of the germs that are brought in for class and research are already in labs and nature... it is absurd to get approval for simple germs such as E. coli.
  - 47 The problems lie with the state regulations rather than anything on the UH side
  - 48 The UH forms for IBC protocol approval have some repetitive information. They could be simplified. The State DOA itself is terrible. It took over a year to review one of my organism import requests then they wanted to charge a large fee and hadn’t even guaranteed approval. How can you do research with this lack of accountability and inefficiency?
  - 49 We have had some difficulties in using potential pathogens.
  - 50 The barriers and process for importing and/or acquiring microbial strains is prohibitive to productive research process.
  - 51 The process in my experience could best be described as ‘glacial’ at best
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## BIOSAFETY Other

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- 1 Optional orientation on biosafety procedures that focuses on what PIs need to do and not just lists of regulations.
  - 2 ██████████ is excellent!
  - 3 Remove the paperwork required to import common, standard bacteria humans and nature already carry in this state.
  - 4 Underlying assumptions about the type of work done do not fit extension or field work.
  - 5 Really, no comments, because this training is A+++++
  - 6 The level of training provided is geared at a very low level of education and sometimes approaches the level of ‘common sense’. Undergraduate students may learn something useful here, but not the larger population of researchers and their associates. Focus is (perhaps understandably) on procedural issues, record keeping and enforcement, and thus gives the impression that this is another exercise designed to protect the university as on organization more than the individual P.I.
  - 7 With the exception of ██████████ who is terrific, the rest of the biosafety people don’t seem to have a clue.
  - 8 Fewer trainings. I had 4 in the past year and I find it excessive.
  - 9 These past accomplishment cannot continue with the absence of the personnel that are gone. It is a huge tragedy.
  - 10 not a good flow of info from safety officer to researchers
  - 11 Initial lab training and annual training quizzes are good, but lab inspections are weak and there is little communication.
  - 12 Biosafety training is given at the start of each year and is comprehensive.
  - 13 Brief regular updates/instruction and concise guidelines for each Health Science program
  - 14 Folks at Biosafety are very willing to help and provide information. Easy to renew training now that the tests are on line.
  - 15 More cops, not proactive or helpful. I get more help from Fort Detrick than from them.
  - 16 I feel that I learned all of my biosafety at other institutions. The biosafety program is unorganized, convoluted and has little value above general ‘common sense’.
  - 17 Several colleagues have expressed to me that the biosafety office is so difficult to work with, because there are too many characters to deal with in the Biosafety Office and uneducated and not helpful; to the point that many colleagues are complaining that it is getting too difficult to do research in Hawaii, and they are thinking to quitting research and focus on
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teaching. The Biosafety Office does not need more staff; they just need to hire/appoint more educated people appropriate for the job.

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- 18 The situation has gotten worse under [REDACTED]. There is now a veil of secrecy in that office, and staff are demoralized. There is little or no communication with faculty, although promises have been made to the contrary. Commitments have not been kept.
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- 19 I like the option to do the refresher certifications online
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- 20 People in Compliance office need some serious training in biosafety. I would also argue that they need to learn that they are our support not roadblocks. I think they are convinced that their role is just to police us and catch us when we are doing something wrong (even when they do not train us clearly what we need to do), rather than providing safe environment where it is possible to do excellent research. Safety is first, but not to the point that we should stop all research, so they have less work and responsibility. I know that this sounds harsh, but I have never encountered an office with more interpersonal and competence problems than that one!
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- 21 Hands on training as an initial requirement to start work would be helpful so all workers are on the same page from the start. Clear guidelines on what procedures are required for the different levels of biosafety would be helpful. I think the only way to ensure that all users are trained is to put their access to labs on hold until training is complete, otherwise, there is no way to ensure training is completed.
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- 22 Students should be trained beyond "Hazard" labeling to understand classes of hazards and how to use Merck index to look up each new compound to determine which compounds and classes of compounds are teratogenic, carcinogenic etc. Students should be trained to use activated charcoal and other approaches to decontaminate or reduce toxicity of certain agents.
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- 23 I honestly think at our campus the biosafety falls more on the lab coordinator than the faculty and this is useful, but I also think faculty should take more responsibility.
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- 24 The training was standard stuff. Sitting in a room with a person or looking at slides online is no different. You don't learn anything new by listening to a person. The in-person training is a waste of time. I would move it all online. Also, I found that I knew more than the person teaching the class.
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- 25 training on biosafety has extremely poorly organized
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- 26 My research has been delayed several times because the committee doesn't meet often and because a full review is required for everything. This has put things off for months. Not acceptable in the field of research.
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- 27 Get a new biosafety staff.
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- 28 Cleanse the current EHSO office. Bring in people who have an accredited education in the field they are 'regulating'. Even the current head of the EHSO doesn't have much idea of microbiology, although he seems to have been advertized as having some experience we should acknowledge. Unfortunately, his conduct and that of the current [REDACTED] [REDACTED] leave a lot to be desired. Really, does [REDACTED] actually know anything about microbiology? Beyond what he saw in a Hollywood movie, perhaps? The only person who had any real microbiology background was recently 'let go', I believe, while that person's duties were taken over by someone... who doesn't really know anything about microbiology, or perhaps took a course in microbiology decades ago. Or maybe he didn't. The point is, the current staff I have interacted with are way, way out of their depth in 21st century microbiology.
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- 29 The actual trainings are high quality, but getting the extra information specifically relevant to a specific research question is extremely difficult if the university has no direct experience with the question asked.
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- 30 Except for the importation of microorganisms the processes here at UH for biosafety are great.
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- 31 how about having a database or digital file keeping track of training certifications for each researcher, one that will set up automatic reminders when expirations are nearing? UH IT might have a solution or a programmer that could do this.
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- 32 The trainers need to understand the type of research done in each lab prior to regulating the actions and procedures. The attitude of "that's the law" without logical basis for regulation is not reasonable.
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- 33 This entity would benefit from standardized training from a national resource, as is required at most research institutions.
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- 34 Reduce requirements that are silly. Such as requirements for registering common foods (fruits and vegetables) acquired from grocery stores for demonstration materials in teaching laboratories.
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- 35 Biosafety training was very boring and lacked any sort of stimulation of interest.
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## LAB Understanding what is required and why

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- 1 As a new faculty member no one at any level has given me any information on lab safety and security. I have tasked a technician with trying to figure out what is required.
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- 2 Communication is erratic and bizarre.
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- 3 The lab safety training is so general as to be useless. I use a few substances that require special handling, but I am not a
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chemist. For folks like me, the most helpful thing would be a set of safe handling practices for commonly used chemicals. It would be helpful if lab inspections were more about finding efficient and easy to work with measures for safety and compliance, rather than getting dinged for minutiae.

- 4 Wasn't aware that there were Lab requirements. Would be a good idea to send an email to incoming faculty (or on a yearly basis to all faculty) with links to more info.
- 5 ITAR/EAR issues. It seems that our ITAR/EAR compliance office is new. But big universities on the mainland have had such offices for some time. Establish exactly how these research universities deal with this such as to minimize the burden placed on the PI, allowing us to skip any unnecessarily painful, and unproductive, learning curve.
- 6 The concerns about chemical waste are incredibly overblown.
- 7 Some rules are too rigid, and UH can't afford to fix every lab in time to comply.
- 8 Inconsistent information on requirements for inventory and storage of chemicals
- 9 Primarily ignorance; I'm not sure what is required. I do have a good idea what the hazards are in my lab and strive to make sure everyone knows.
- 10 Disposal of animals and animal organs that are preserved in 4% formalin in water
- 11 I've received conflicting info from vendors and UH safety about what the Hawaii state requirements are for various safety related issues. For example, the issue of whether fire proof cabinets need to have self closing doors.
- 12 Please see my comments about biosafety, same applies to this topic.
- 13 Some of the rules that apply to "research labs" have been applied to my "teaching lab" which has created some challenges when teaching with food products.
- 14 Many requirements seem to be "judgement calls" and results of inspections are uneven
- 15 Rules kept changing or their enforcement
- 16 See previous comments under biosecurity. Similar problems for general lab safety. Initial training and annual quizzes are good, but there is little enforcement.
- 17 Obtaining relevant information
- 18 Lab space can not be managed due to lack of staff. Laser equipment is used in unsafe manner. Clean rooms are managed by Department and access can not be managed properly as there is a general lack of space and staff to manage labs.
- 19 Fume Hood and Biological Safety cabinet certification is problematic. These are built into buildings yet UH Facilities hesitate to fix them. Then the expense often falls on the PI or they just don't get fixed. Then the lab lapses in this important safety requirement.
- 20 I understand, but only because I educate myself. Biosafety often pass their responsibilities down to the PIs when it comes to biohazard safety and security. They will not help or respond timely when there is biohazard bags are found in Spalding. They want PIs to carry our sterilized trash half way across campus to be dispose of.
- 21 Protocols that are available online need to be updated.
- 22 We need a consensus of the interpretation of the requirements among the lab users, compliance and support facilities staff.
- 23 We have a responsible person for each lab. Sometimes there are lapses in understanding and enforcing proper standards.
- 24 No easily accessed \*definitive\* source of info (not just a class!).
- 25 Too changes, too often. Some changes do not apply to the our lab and jet we have to follow and this interferes with the productivity in our lab. My suggestion is to stop 'umbrella' policies.
- 26 Labs in [REDACTED] were poorly designed where lab workers had to cross common spaces and were not not allowed to prop doors open or wear lab coats but are required to wear proper PPE in the lab. If a researcher is working in lab spaces in one wing or the other it does make it hard to get around.
- 27 Cannot receive timely assistance in getting permitting, engineering design, supporting staff, to comply with work and safety related infrastructure improvements to install new equipment and facility. Need more diligent and responsive staffing and management with timely updates accessible.
- 28 Again, dissemination of the information is mostly done by a lab coordinator, which is useful, but also hard on that person, vs. being something that faculty take responsibility for in working with the safety liasons.
- 29 expiration of one type of training for one person and we don't know until we go to renew an IBC or IACUC protocol
- 30 Door locks seem left to projects to specify and pay for. No guidelines. Computer security support at campus level is mixed; school level is better Hazmat requirements/support might be good for full biochemical laboratories, but not so for workshop-type labs.
- 31 In my work we handle ITAR materials. I believe that UH-[REDACTED] now handles this topic very well, but not all faculty are versed in ITAR, especially given the number of foreign faculty and students on campus. Also, when hiring new employees, we have to be able to specify US citizens or Green Card holders only; otherwise, the new employee will not be able to work for us. UH-[REDACTED] views this as discrimination but it is not.
- 32 I might say I have no clue what is required for biosafety. On the other hand, to me it's just common sense. So, sitting

through a training session teaches me nothing because it is all manifestly obvious. I am not trying to diminish the value or need for training, however, since there are people to whom none of biosafety is manifestly obvious! My point is that while I might say I don't know anything about it, it's quite clear that I do know something, at least of specific points, such as how to handle samples, microbes, chemicals, etc. What does frustrate me is the sheer volume of regulation that we are required to 'know', implement, and conform to. While not a problem on the one hand for EHSO, etc., because they don't make the rules, I often find myself bemused after listening to people from EHSO. Something might seem like a big deal, with a deadline and all that; it might even seem daunting as we 'prepare'. Then someone from EHSO comes to my 'space' and tells me I've passed, yet I can't believe that based on a brief walk-through and glance (if that) at my paperwork, I'm in compliance. This gives me the impression that the folks from EHSO, at least those at the bottom and doing the inspections, are nice people, but I still feel that something is missing, that I'm not complying. I feel only that an inspection from outside, such as by a federal inspector, would truly show whether I am in compliance or not. Unfortunately, I don't actually want a federal inspector near me in case I really don't know anything! Perhaps it's like not listening to your friends, or believing what they tell you, but you'll listen to an attorney or some other professional you've paid... all for exactly the same advice! Maybe our in-house 'bottom-rung' inspectors are too affable, too friendly, and I enjoy their company. On the other hand, those higher up strike me as unqualified, over-zealous, poorly informed people with a badge! Enough said. My suggestion might just be to have a top to bottom inspection of 'everything' by someone I have confidence in, or that I can believe. Sadly, I don't have the confidence in the current staff, although those I meet in the trenches are perfectly nice people.

- 
- 33 What is required for lab safety in labs that double as classrooms?
- 
- 34 Inadequate training re: current standards
- 
- 35 Life is complex, and it is getting more so, as more and more people interact. Unfortunately, more and better communication is the solution, and a different kind of problem in its own right.
- 
- 36 I have not yet been informed of any lab safety or security training that I should take in spite of starting a new lab at UH. I am applying lab safety and security principles that I have learned at previous institutions.
- 
- 37 Rules change frequently and are not communicated to PIs in a consistent and timely manner. Often we only learn after a red flag on an inspection.
- 
- 38 Difficult to find chapter and verse, all of the requirements.
- 
- 39 required by whom?
- 
- 40 for new faculty it may not be obvious that the CCs are under person, not under Manoa's lab safety officer.
- 
- 41 Same questions answered previously for biosafety apply here. The security requirements are not reasonable because excessive security is required for certain types of biologically safe research. Again, the regulators need to understand the biology of what is being regulated before they impose regulations. Some are highly unreasonable and biologically unnecessary.
- 
- 42 This is a relatively new activity in my research work. So I don't have much experience but will be learning more about it in the months ahead.
- 

## LAB General laboratory safety requirements

- 
- 1 Give clear expectations for labs and give help rather than threatening.
- 
- 2 buildings are not securable... no pest management program... biological waste is not secured... no centralized facility to receive hazardous substances so everything potentially gets delivered by shippers to secretaries and student workers
- 
- 3 Capricious in nature. Once they had us resurface all our laboratory chairs, after the building was newly built. Total waste of time and money.
- 
- 4 The main problem is that the regulators have a "one size fits all" mentality. Laboratories dealing with environmentally safe microbes should not be regulated to the same degree as laboratories working with highly infectious human diseases.
- 
- 5 [REDACTED], the safety officer for the [REDACTED] offers annual training sessions. Perhaps another person can be added to help with the demand of the training sessions and inspection of labs.
- 
- 6 As i said before, chem hazardous waste disposal is a problem for me. Documenting takes time - too much.
- 
- 7 The lab at my department is unclean, quite unsafe, and congested. Implementation is difficult.
- 
- 8 what are the differences for labs that double as classrooms?
- 
- 9 Having students comply with basic biosafety / lab safety practices (e.g. no food or drinks in the lab; wear closed-toe shoes, etc.) and having faculty enforce these requirements across the board can be a challenge.
- 
- 10 See my previous answer.
- 
- 11 First aid materials requirements? Up to projects to specify and provide. First aid training requirements? Facilities management seems disconnected from possible safety and security impacts (e.g. freezer failures and chemical odors)
-

- 
- 12 require students to wear labcoat in chemical lab exercises
  - 13 Some labs do not have compliant materials, again, mostly due to funding issues.
  - 14 Not often to get timely assistance in getting work order done. Should establish a central number for emergent access and assistance to receive timely information and updates of the status.
  - 15 lab safety includes inspection of biosafety hoods that are institutional resources. Individual PIs get can get cited for compliance issues when the hoods are not certified.
  - 16 No easily accessed \*definitive\* source of info (not just a class!).
  - 17 Some workshops (with basic power tools such a drill press, band saw, milling machine) are hard to monitor at all times. Ensuring proper training is a problem sometimes due to lack of personnel to provide the training.
  - 18 Safety requirements are more problematic because of the old infrastructure which makes lab work unsafe.
  - 19 It would be nice to standardize the names of courses and have them all listed (with descriptions). Names changed over time and makes it confusing to know if they are the same. An updated list and knowing which ones are required for different people would be helpful.
  - 20 difficult to stay current with any changes
  - 21 For sharing facilities, it is a bit hard to track down all the materials used and activities.
  - 22 Lab space can not be managed due to lack of staff. Laser equipment is used in unsafe manner. Clean rooms are managed by Department and access can not be managed properly as there is a general lack of space and staff to manage labs.
  - 23 See above
  - 24 Compliance is made difficult sometimes because proper storage is often not provided by UH and requests for acquiring these are difficult to get funded (cabinets, explosion-proof freezers).
  - 25 Getting students to properly store, label and dispose of photography chemistry.
  - 26 Safety equipment or recommendations for lab safety layout are not provided. Departments and P.I.s are left to themselves in providing this equipment.
  - 27 Lost key issues, break-ins, formaldehyde-counters.
  - 28 It's not clear how this question differs from the one above. However, it's not clear how to enforce lab safety requirements (e.g., no open toe shoes, no eat in the lab, etc). If lab tech, students, or postdocs don't follow the rules, how can you force them to?
  - 29 students are made aware of the requirements, if they do not comply they are asked to leave the lab
  - 30 Same as above; I pay attention to safety, but am not really aware of the requirements.
  - 31 Do we really need to treat alcohol or bleach differently than home folks discard of it at their homes????
  - 32 I don't know the requirements, so can't comment on the problems
  - 33 Students in Hawaii can't be convinced to wear appropriate clothing in the labs (e.g. shoes).
  - 34 My lab should have a eye wash installed. I cannot install an eyewash myself. I have asked to have one installed, but it has never happened. Is it my fault when I don't have an eyewash?
  - 35 a) UH Facilities does not adequately respond to safety issues (broken doors, locks) b) the UH electrical power grid is sub-standard and poses a serious safety risk to UH laboratories - even the chancellor stated that it is not UH's responsibility to provide stable power to researchers / laboratories - this attitude is quite a joke and any person with this attitude does not realize potential safety risks!
- 

## LAB Laboratory Inspections

- 
- 1 They solve nothing. We usually get sited for building compliance's which are beyond our control.
  - 2 Laboratory inspections for IACUC require large payments to fund transport of staff committees from Manoa to UH. The semi-annual inspections could be reduced to annual, because nothing changes so quickly, and the numbers of staff travelling and inspecting could be reduced to 1 with substantial cost savings.
  - 3 Attitude of the inspectors can be improved. Inspectors have developed a culture of "let's catch them doing something wrong". Assistance rather than punishment is needed.
  - 4 see above answer.
  - 5 Scheduled at the last minute and not clear what will be inspected ahead of time.
  - 6 UH does not provide adequate funding to maintain safe laboratories
  - 7 I'm not sure inspections are undertaken by anyone, and if they are, whether they are productive.
  - 8 See my previous answer.
  - 9 Fire inspections and requirements unclear
  - 10 Its a little problematic making meeting times match up between lab inspectors and myself.
  - 11 Should happen more often. Especially while work is being done.
-

- 12 In meeting protocols for CLIA waived tests
- 13 [REDACTED] is helpful during these inspections
- 14 Just had one recently and was great, I learned a lot and was very helpful in identifying problems.
- 15 Again, the problem is with the 'umbrella-like' policies. There used to be inspections that was clear and specific. For instance, the biosafety inspections covered general biosafety for the lab. However, Select Agents inspections used to be confined to Select Agents and the select agent restricted area of the lab. Recently, these inspections were combine to act as one. By combining both, not only the inspectors managed to confuse the lab personnel, all the lab staff are instructed to follow the same sets of rules as if they are all handling select agents even though they are working in the non restricted area of the lab and are not handling select agents. The non restricted part of the lab should not have to adhere to the same guidelines as the select agents guidelines. This makes non select agent work tedious and time consuming when you are working with non hazardous material.
- 16 shifting baselines - seems impossible to keep up with new requirements
- 17 No easily accessed \*definitive\* source of info (not just a class!).
- 18 We take lab inspections seriously and I'm not aware of any violations.
- 19 I had to push to get inspected when I opened my lab. It should be other way around.
- 20 Getting the checklist ahead of time would be helpful.
- 21 Biosafety Office inspectors are unknowledgeable in what they are looking for and asked students to tell them what to look for. They are simply not prepared or qualified for the job.
- 22 Inspections in the [REDACTED] labs is never a problem. Inspections in the [REDACTED] labs take a long time because it is clear that inspectors have little to no experience working in that type of lab. It is unnerving to have inspectors with little to no experience in charge of something they don't completely understand.
- 23 No funding to pay for safety inspection of the equipment as required by educational accreditation authority
- 24 We have a fume hood that is falling apart and presents a safety problem. Lack of action is due to FMO and not EHSO.
- 25 Our labs are never inspected.
- 26 Weak. Inconsistent rules. Lack of communication.
- 27 Inconsistent, and not much warning
- 28 sometimes down without prior notice
- 29 Uneven interpretations of "requirements" - tendency to focus on minutiae
- 30 same as above
- 31 In general, not a problem. But sometimes "safety inspectors" sneak around and aren't really personnel safety, rather they have an attitude that they aren't really there o help you be in compliant.
- 32 Safety inspections are often scheduled at times that are problematic, inconvenient, or impossible. A bottom-up approach would help.
- 33 The student labs do not seem to be evaluated as frequently as the research labs
- 34 There have been two types of inspections: fire safety and radiation. Radiation got pretty comical when they insisted on swab tests for a Xenon isotope. Fire inspections are normally a non-issue, but there was a surprise prohibition against storing stuff near the ceiling.
- 35 On some occasions there seems to have been a desire to find some problem, no matter how picayune, which generates subsequent paperwork.
- 36 Most inspections are done by people who know little except to look for certain usual violations such as an outlet strip on the floor, or a vacuum pump without a belt cover.
- 37 Unclear that they are safety inspections, and the communication is robotic. Better to come by and talk with PIs and help work through issues.
- 38 Each day I spend in compliance ia a day lost on research productivity, and those days are continually stacking up
- 39 Most of my research is field-based, so only need to deal with lab safety issues in a minor way.
- 40 In developing P&P regarding testing for CLIA-waived tests

### LAB Fulfilling federal requirements for training in laboratory safety and security

- 1 In developing P&P regarding testing for CLIA-waived tests
- 2 no designated LSO that I know of. I should be LSO
- 3 Not sure what the federal reqs are vs. state or local...
- 4 Again, not clear what these are. This question prompts me to look into this immediately...
- 5 See above
- 6 Ignorance again. Maybe because my lab has no spectacular dangers.

- 
- 7 Sometimes it seems some students (e.g. short time visitors to labs) for innocuous work needn't have this training but rather be required to work under a trained individuals presence should be enough.

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  - 8 see previous answer

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  - 9 Little information provided to new staff.

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  - 10 Funds to equip labs are from state.

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  - 11 So many trainers and each gives inconsistent information. Their interpretations of state and federal requirements are inconsistent and often based on paranoia, because they do not know enough about the issues.

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  - 12 What are the federal requirements? Unaware of these - always thought the requirements were from the university. This could be problematic.

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  - 13 More guidance is needed from the Office of Research Compliance. Again, too many interpretations of the requirements.

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  - 14 We take advantage of training provided by EHSO. We also provide additional training - first aid, CPR, fall protection.

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  - 15 No easily accessed \*definitive\* source of info (not just a class!).

---

  - 16 Unclear exactly who has to do this, emails announcing the training are not very clear

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  - 17 Security Issues along with Fire compliance issues do not always work together.

---

  - 18 The time to get students and staff trained is too long. Should have online system to train them in time as required.

---

  - 19 We have had some problems on access for foreign nationals even though our research is non-defense related and involves international collaboration. More reasonable and sensible application of export control regulations (comparable to other universities is required).

---

  - 20 Funding!

---

  - 21 Not sure what federal requirements are

---

  - 22 See above

---

  - 23 training session times don't often fit in my schedule

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  - 24 My staff and I do the courses or tests we're told to take. That's quite simple.

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  - 25 Federal agencies sometimes require extensive documentation of safety procedures that are not readily available.

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  - 26 I don't know of the federal requirements for training in laboratory safety.

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  - 27 do labs that double as classrooms have different rules?

---

  - 28 I don't know if anybody knows what those federal reqmnts are. Actually, I don;t think federal reqmnts are applicable here.

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  - 29 Training is too infrequent

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  - 30 Only with regard to chem waste.

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  - 31 what requirements?

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  - 32 annual training sessions are offered at ████CC.

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  - 33 Requirements for training in multiple areas are too frequent and too repetitive.

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  - 34 Every year the same exams. Why????

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  - 35 Lab safety training are not offered frequently enough for student to receive timely training at the beginning of an academic semester.

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## LAB Controls on access to computers and data/information

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- 1 Onerous campus-wide controls on access to particular software and Web sites are often detrimental to teaching and learning in the classrooms and labs.

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  - 2 We certainly waste a lot of time nowadays on computer security, and indeed our ITS person says we are getting banded on continuously. ITS certainly has a tough job, but when we have had problems in our own net, I think they have not been properly responsive, nor competent.

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  - 3 With the majority of our funding being soft money with highly time dependent milestones, implementing proper controls on access is problematic when it was not considered in the original proposal budget and brought up after the project is initiated.

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  - 4 All machines in Department run linux/unix but campus has no support. Safety of data/information is the burden of the faculty.

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  - 5 Problems up until a few months ago, but this area is getting better.

---

  - 6 Unsure what this is, so it could be a problem.

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  - 7 Main concern has been ensuring deadlock bolts on lab doors. Have been able to obtain this, but in one case had to pay out of grant funds to obtain this. Should be installed as a matter of course.

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  - 8 We have controls in place for ITAR sensitive information.

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- 
- 9 Screen saver removed from my office computer without my permission. Office files unlocked and left unlocked again without my permission.
  - 10 Should have a simple access with information up to date.
  - 11 Need for constant upgrades
  - 12 We do not have enough computer support staff at UH-█████ to deal with computer issues in a timely fashion. Security breaches, infections, etc. are very likely. I put in request for computer assistance in September; it is now almost February and no one has come to help me with virus/spyware protection.
  - 13 I can't say I've ever heard a discussion on this in the workplace
  - 14 We have not had sufficient staffing or ITS support to implement controls on computer access and data that we have desired for more than a decade.
  - 15 Up to the PI to specify and provide for the most part. Phishing attacks not adequately broadcast at campus level, very good at (my) school level. ITS staff don't seem concerned enough with the human element of computer security.
  - 16 We had to create our own server system to control ITAR.
  - 17 Not sure which computers and information you're referring to, really... I would like to see a standard UH document that could be a uniform Emergency Response document. Then I wouldn't have to listen to someone from the IBC telling me to develop my own document outlining how my lab will respond to a hurricane, tsunami, etc. I could append a standard UH file to any permit application I make. New staff could do that, too, saving them the hassle of re-inventing the wheel. That reinvention may not always be round, as in not in agreement with what UH or even the federal authorities would like us to have in our safety manuals...
  - 18 No passwords required on classroom computers...?
  - 19 The online training was a little problematic on the Laulima site.
  - 20 Nasty computer virus attacked lab computers, appears that UH has little in the way of active protection.
  - 21 many of the faculty/staff do not understand basic computer security and safe practices with respect to using computers connected to the Internet.
  - 22 Very little UH oversight to this.
  - 23 no information on how to do this
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### **LAB Controls on access to facilities, equipment and/or supplies**

- 
- 1 buildings are often open at night and weekends... door locks are easy to circumvent
  - 2 Need more locked cabinets in my research space
  - 3 University facilities management personnel have had problems repairing door locks. Now doors have been repaired, but keys have not been given to faculty so it is impossible to enter some doors on weekends. One must walk around to the other side of the building to find a lock that opens.
  - 4 ██████ CC has an agreement with ██████ Hospital to a few rooms for research and store supplies and equipment. It would be good for the investigators to have easy access to the storage area (there is one key that is in the department chair's office).
  - 5 Card key access and front lobby security is an issue when dealing with some aspect of the the universities teaching mission.
  - 6 Depends on situation, sometimes it's not clear what we are supposed to do,
  - 7 Having to submit new POs to the ██████ Stockroom each month is an administrative problem, and we frequently do not have a PO in place when we need supplies. A PO shouldn't need to be thrown out at the end of every month.
  - 8 The design of my building makes controlling access to these resources next to impossible. There seems to be very little appreciation of the possible dangers though at the facility level.
  - 9 Facilities outside the main UH ██████ campus do not have electronic locks.
  - 10 Equipment and materials disappear from the lab from year to year! It's sometimes hard to find them.
  - 11 The UH employs keys to lock doors such as those to my lab. UG students always lose the keys because UH will not require a deposit. As a result, we lack keys and I no longer give keys to UG students. I even have problems finding keys for RA students and Post Docs because we have so few remaining. UH will not permit me to cut additional keys and facilities refuses to cut additional keys. If the problem gets worse, I will have keys cut illegally so my paid staff can do their work. Welcome to UH!
  - 12 Export controls are now being enforced on many pieces of equipment. These are not ITAR issues, but still can be inconvenient.
  - 13 These rules seem to change quite a lot...not sure why, but it makes life complicated. My suspicion is that the rules are maximized, and occasionally one is relaxed but only because it has gotten to be troublesome for the administering ser-
-

vice...never because it is a burden on the investigator!

- 14 Not all faculty in the department are willing to keep doors to labs locked when there is no class in session. This presents a security issue.
- 15 See earlier comments re locks. Building locks have been persistent problem over years.
- 16 We have experienced problems with facilities personnel entering our lab without our permission or notice, and conducting work that puts sensitive equipment at risk and has the potential to interfere with research.
- 17 need locking cabinets for chemicals
- 18 We changed key access to our laboratory to prevent theft during non-work hours. Would like to do a scan card to limit access more and remove people when they graduate or leave, but was told it was too expensive.
- 19 Do not know what and where to make complaints. Do we have any mechanism for control?
- 20 installation of locks on doors took an extraordinarily long time before the work order was fulfilled
- 21 No easily accessed \*definitive\* source of info (not just a class!).
- 22 Some labs require more access control. The level of access control varies with time, as some judgement is applied to allow necessary work to be accomplished.
- 23 We are in a very old building, so doors are locked sometimes, but now always. Having ID cards to access the building would be much safer and easier.
- 24 See above.
- 25 Off-hour construction by contractors in buildings requiring offices and labs to be open; security seems to be lacking. It seems that anyone may walk in and take equipment, supplies, etc.
- 26 locked doors when no one is in the lab- is this what this means? If so, this isn't a problem.
- 27 Some buildings are so old and lack security systems, cameras, and intruder detection system. Security guards are not seen there often and should be assigned focused locations on campus where there are more security requirements identified.
- 28 housekeeping does not maintain physical security - does not relock doors upon exit.
- 29 It varies from building to building. Like the elevators in the building, there's no consistency.
- 30 Project on [REDACTED] are managed by collaborations that do not have enough funds to keep facility in good shape.
- 31 Procurement is problematic, because we end up with quantities that exceed what we need given that vendors have minimum orders and shipping costs often double or even triple the cost of supplies, etc...
- 32 It is very hard to find available space to store equipment in my campus.
- 33 Labs and studios in the [REDACTED] building are available to faculty, staff and students enrolled in classes. Sometimes we have individuals who do not exercise proper care of securing the facilities.
- 34 Will be asking for eyewash stations in the labs.
- 35 Sometimes, the security access is cumbersome and overkill.
- 36 funding for supplies limited
- 37 Again, this question is a bit unclear, but I read it as being able to control access to my lab. I've had a difficult time getting UH facilities to change the lock on my laboratory door (it's a combination lock whose combination can't be changed, and everyone seems to have the combination). It has been 5 years and counting since I first requested the change.
- 38 [REDACTED] are open to the public 24/7. The doors are rarely or never locked because employees have not been provided keys. These buildings need lockable doors on all hallways that lead to research labs.
- 39 Student researchers should be allowed access to labs during off-hours without a mentor being present... yet UH policy dictates that this is not allowed so undergraduate research suffers.
- 40 The limitations on access to our building ([REDACTED]) are inappropriate, expensive, and onerous.
- 41 Support at UH for these issues is such a disaster that it's comical. For example, it took several years of nagging on my side to get my lab re-keyed when I first moved in. The key I was given was the same as the one that the lab occupants before me used, so I had no idea who had access to my lab. Moreover, I only had 1 key, and at one point had 5+ people (students/techs) accessing the lab. We shared the key using a real-estate agent lock box. Only after several pieces of equipment went missing from my lab did I finally get it re-keyed, but again - this took months of nagging and persistence on my part. I asked for a combination lock to help with access for multiple users. Instead I got 2 keys cut.
- 42 Locks on cabinets meant to control access to equipment and supplies are non-functional and require remediation.
- 43 Basically, there are no controls. Several of the doors to my lab don't lock, or we don't have keys. They stay open.
- 44 power issues - see above
- 45 Need more research space in general.
- 46 Mainly related to limited facilities access due to remodeling/maintenance of [REDACTED] infrastructure.

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## LAB Personnel issues related to laboratory security

- 1 one of my postdocs had to leave the country and re-enter because the College office failed to complete his Visa renewal in a timely fashion. They acknowledged it was their fault, but of course, there were no accountability -for them. I now avoid accepting foreign nationals except under unusual circumstances.
  - 2 Foreign nationals are a problem?
  - 3 Our main problem has been with the system enforcing export controls. Also I am not allowed to pay one of my best grad students from [REDACTED] grant, which is for totally unclassified work. These are not UH problems but falling upon us from the Federal government. Yes, the Chinese are stealing us blind, but the Federal response does not prevent this (I can cite examples), and only serves to hurt the US by preventing us from getting and keeping the best grad students and post-docs.
  - 4 It has been difficult to get approval from our very slow building manager/security apparatus for access changes and access cards.
  - 5 One of my international workers kept sneaking food into the lab. It took several stern warnings to get compliance.
  - 6 We are always worried that foreign nationals, no matter how nice and open they may appear, will take research findings of others back to their countries of origin following leaving the university. This is not in reference to confidential work, but more just with respect to general research.
  - 7 Labs and studios in the [REDACTED] building are available to faculty, staff and students enrolled in classes. Sometimes we have individuals who do not exercise proper care of securing the facilities, equipment and/or supplies.
  - 8 In support of world-class research, we need to be able to hire the best talent available. Recently, selective enforcement has been extremely problematic.
  - 9 hasn't been a problem for me, but conceivably it could be (i.e., I don't think our work really crosses into areas critical for national security, but would diminish our competitiveness if I were not allowed to hire a foreign national to work on such projects if they were the most qualified)
  - 10 I do not understand the question.
  - 11 Students wanting access to laboratory or machine shops need to be trained and UH [REDACTED] would require a manager for the site. There are no funds to provide this.
  - 12 In a case - unknown to us for years - we had a [REDACTED] individual in the lab who was accessing computers at night, using, abusing, and distorting information so obtained, used lab portals to try to break into protected computer networks (the supercomputer) and was found by the FBI to attempt collection of secret data for the [REDACTED] government.
  - 13 It would be helpful to have a checklist of what needs to be done when there is a visitor to the lab (a day visitor, vs. week visitor, etc). It could be impossible to have a one week visitor do all training - so it would be helpful to know what to do.
  - 14 I have no experience with this
  - 15 I am hiring foreign nationals, but I still do not know what UH does to make sure that they are suitable to work in the lab. I have to rely on my judgement and US embassies on this.
  - 16 We have controls in place for ITAR sensitive information.
  - 17 No easily accessed \*definitive\* source of info (not just a class!).
  - 18 No training and information on what compliance and how to be done properly.
  - 19 Have had some problems with export controls for foreign nationals. It should be noted that our research is non-defense related and involves international collaboration. More reasonable and sensible application of export control regulations (comparable to other universities is required).
  - 20 A few graduate students do not have lab safety trainings
  - 21 Too strict. I had a [REDACTED] colleague visit and the security would not let him in because he only had a [REDACTED] license. Also, when a visitor comes and the security calls and gets my approval to let him/her enter they should allow them to come to my lab or office instead of me having to go and get them at the reception area every time.
  - 22 Some colleagues seem ignorant of possible issues, others protest federal requirements
  - 23 See above
  - 24 Most graduate students are foreign. This can be a problem if they can't use the equipment they need to do their research.
  - 25 Deal with Import-export technology, so need to monitor this
  - 26 there should be training
-

## LAB SAFETY Other

- 1 The ORC should not treat information and reports re: laboratory safety/security as top secret that cannot be shared. Since we are asked to file the reports and are responsible for our labs, how can we improve if we are not told what the reports contain? Could it be that ORC is simply protecting itself from being exposed to not doing its job? Under [REDACTED] there has been more unnecessary secrecy and reprimanding of good staff than at any time since I have been at UH.
- 2 Always web based exams that are meaningless. It has become a game amongst our people on how to beat the system.
- 3 Regulators could be encouraged to review all regulations and to make them appropriate for the type of research being conducted in each laboratory. Researchers could be consulted as to the appropriateness of some of the regulations before blanket regulations are applied to all laboratories regardless of the actual biological hazards in question.
- 4 If UH provides PI training on these matters, there should perhaps be a "triage" step for new hires that determines what training should be required for them. I am unaware of specific UH training courses I should take to understand the UH requirements.
- 5 Increase frequency of training
- 6 EHSO should provide training with the use of fire extinguishers, working with the fire dept. Perhaps a fire drill should be conducted during a specified time each year.
- 7 There is no training offered for classroom equipment safety or rules.
- 8 I am not familiar with web based training programs or whether they exist for this kind of compliance. They should be available for all users of laboratories.
- 9 As I said above, we need to be able to hire effectively, and that means specifying applicants who can meet the minimum requirements of certain US Government programs.
- 10 Training as been done by an outside lab
- 11 Some other way of getting info to faculty than just having to figure it out on our own. Perhaps when we are hired?
- 12 There is no full understanding of what compliances, procedures, and information center for access to any of the above questions. Need to have a centralized information hub for responses.
- 13 No easily accessed \*definitive\* source of info (not just a class!).
- 14 It would be good if there could be more support for developing safety plans and ITAR control plans.
- 15 I am not aware of any security training. It should exist.
- 16 i have never had any class, training or information given to me about security
- 17 I have major problems with hazardous materials shipping. There needs to be on campus training readily available to researchers, faculty and staff. People in my department have routine needs for shipping chemicals oversees, with [REDACTED] etc. We require our own certification, rather than using UH EHSO, because we often have to ship from distant locations back to our home campus.
- 18 If UH and our campus, UH [REDACTED] wants to develop their research arm, more funds need to be available for each Department that requires additional support.
- 19 online refreshers should be sufficient in lieu of annual certifications, depending on the level of safety or security required for each individual lab.
- 20 The level of training provided is geared at a very low level of education and sometimes approaches the level of 'common sense'. Undergraduate students may learn something useful here, but not the larger population of researchers and their associates. Focus is (perhaps understandably) on procedural issues, record keeping and enforcement, and thus gives the impression that this is another exercise designed to protect the university as on organization more than the individual P.I.
- 21 Below average so far. But ITAR training is provided this month, which is a good thing.
- 22 The biggest problem with the bureaucracy at UH (and many places) is that functionaries see their only mission as staying out of trouble. Doing the job swiftly and facilitating research gets them nothing. Consequently thee is little or no motivation to be efficient... just to stay out of trouble. Motivating the staff to be efficient and helpful to researchers is a challenge to our UH managers. OK, this goes well beyond lab safety and such...
- 23 I put not available on the last 2 questions, but it could well be available. I just don't know about it.
- 24 I struggle with the concept of both safety and security mentioned in the same breath. I have no issues with the safety aspects but the 'security' issues seem to be vague at best.
- 25 relevance is lacking. We don't all work with flammable or toxic substances
- 26 Optional orientation.

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## General chemical safety/security responsibilities

- 1 Not a problem due to my extensive industry experience, so I know what to do
- 2 Each day I spend in compliance is a day lost on research productivity, and those days are continually stacking up
- 3 As a new faculty member I have not received any information on chemical safety and security procedures. I have tasked a technician with trying to figure out what is required.
- 4 I am never sure what to do about waste. It isn't picked up and nobody seems to know how to deal with it.
- 5 a) the collection of chemical waste by EHSO takes sometimes weeks - excessive solvent waste in laboratories provide safety issues. b) electrical power issues - see above
- 6 as stated above, overgreat concern about volatiles, labeling, putative carcinogens, etc. etc.
- 7 The big problem is the university delayed repair of chemical fume hoods that are needed to work with the chemicals in a safe manner. Also, we got cited for improper shelving (UH supplied) so at our expense we needed to fix the UH shelves. UH takes a large 36% chunk of indirect costs from the grants. Yet the faculty member is on the hook for all responsibility for problems, and if the research progress is slowed, which is was especially with defective fume hoods, it adversely affects the progress reports submitted to the grant agency.
- 8 dealing with pesticides can be a bit problematic, particularly transportation among islands
- 9 Again, treating the discard of simple chemicals like bleach and alcohol differently at UH when compared to home is just a waste of time.
- 10 I have gone through the training here. It is not publicized well.
- 11 Cant get safety office to arrange for chemical disposal.
- 12 Again, I teach ██████████ and some of the laboratories involve the use of food products. The chemical hygiene procedures can be a challenge at times, but not insurmountable.
- 13 rules keep changing
- 14 Obtaining information
- 15 We have annual inspections from EHSO and have worked to take care of any safety violations.
- 16 Many users in shared labs do not report their chemicals to EHSO in inventory, some do not know of the requirements for proper labeling, handling, storage and disposal
- 17 No institutional support for cleanup of problems left by OTHER researchers (e.g., researchers who leave or retire). If I bring up a problem, \*I\* get stuck with the cleanup(!) and so these problems are left to fester.
- 18 Do not have necessary infrastructure to meet needs and compliances. Need capital improvements.
- 19 lots of chemical hazards in protocols are overlooked and not handled properly because of it. No one did the initial research so they did not realize it was a safety issue.
- 20 If I didn't have a technician that I assign to be responsible, I would not even know what the requirements are and how they have changed
- 21 Training required for disposal of obsolete chemicals when I last encountered this problem. The disposal should be available without questions asked - I inherited chemicals left behind by a former user of the lab but was burdened with getting training for chemicals that I have no use for.
- 22 I only learned chemical safety from other universities, not UH, since I am not housed in a chemistry laboratory.
- 23 College of ██████████ lab facilities not up-to-date. Restricts ██████████ activities.
- 24 Making sure comply - takes some effort.
- 25 Changing stanards. Inadequate support for waste disposal
- 26 As mentioned previously.
- 27 I have not yet been informed of chemical safety / security training that I should take in spite of starting a new lab at UH. I am applying chemical safety and security principles that I have learned at previous institutions.
- 28 Again the quality of instruction varies as does the clarity iof procedures
- 29 Researchers are not provided with the proper cabinets and storage facilities. Must purchase out of grant funds.
- 30 no fume hood in my laboratory

## Chemical cataloging and inventory management

- 1 all depends on me, and I'm stretched thin on time
- 2 Difficult to maintain an accurate inventory due to time for manual entry into a database. Also, the requirement for a paper copy of the inventory is ridiculous in this day and age. It would be great if a system could be developed in which purchasing logs could be transferred to an inventory system automatically.

- 
- 3 Not very demanding in my case.
  - 4 Would be helpful if individual lab list were part of a central list
  - 5 There is no support for this administrative function - individual PIs are left to find ways to comply with this necessity. Because of personnel turnover and breaks in service it is very difficult to ascertain that records are complete and up-to-date.
  - 6 Inventory of donated goods, and keeping the MSDS up to date with the donations.
  - 7 just a little tedious and time consuming; to be honest it would be very difficult to determine if chemicals went missing- and if it were detected it most likely would not be immediately after it went missing.
  - 8 Given funding levels, it is difficult to maintain permanent staff, so the inventory management depends on student assistants, which are often short term.
  - 9 Moving toward the new OSHA labeling standards, I would like to see UH come up with a standard template for everyone to use/follow. I fear that I will be making new compliant labels then later having UH dictate their own standard and having to redo the work.
  - 10 We eliminated the problem by getting rid of most of our chemicals.
  - 11 facilities are old
  - 12 Are there templates that are suggested to keep chemical inventory? We have chemicals, but probably don't update inventory regularly.
  - 13 Waste pick up is very slow. We are waiting for months now for somebody to come in and pick it up.
  - 14 We have annual inspections from EHSO and have worked to take care of any safety violations.
  - 15 Many users in shared labs do not report their chemicals to EHSO in inventory, some do not know of the requirements for proper labeling, handling, storage and disposal
  - 16 Not easy to keep tracking on items accurately. Need better inventory interface and staffing to handle these tasks.
  - 17 I've never done that but don't have that many chemicals in my lab anyway.
  - 18 Not a problem only because of project technical support
  - 19 Far too complicated. No system in place to manage inventory. Little to no idea which chemical goes on which shelf... Of course I could 'Google it', but we have hundreds of bottles, so who is going to do it? And what do we Google, anyway? "What shelf does Xxxx go on?" All that Group 1, Group 2, Group 3, etc... we have no idea what belongs in which group, or even if those groups exist anymore.
  - 20 Inheriting left-behind chemicals. Should be a process for clearing a lab of obsolete chemicals when a lab changes hands.
  - 21 A standardized online tool would help with this.
  - 22 Difficult to know exactly what is required for chemical inventory.
  - 23 What inventory is necessary for multiple-use rooms?
  - 24 College of [REDACTED] lab facilities not up-to-date. Restricts [REDACTED] activities.
  - 25 Have to do it - takes time
  - 26 Inadequate training
  - 27 Don't do as good a job as I should, because of time requirement
  - 28 Not a problem at present since I have yet to stock chemicals in my lab, but I am unaware of the UH rules.
  - 29 there should be a uniform system for labs across campus to use
  - 30 All the UH policies and information seem to deal with a situation where a laboratory is under the control of a sole researcher. What I have is a mixed use lab (instruction + teaching) that is used by several faculty with no one person in charge.
  - 31 There is no way to get around the physical inventory of chemicals (unfortunately). But it is definitely a time-consuming and tedious task.
  - 32 Excessive recording is required.
  - 33 With the new chemical labeling (GHS), we are told that everything needs to be labelled by June 2015. But we should have been given a template by the system, rather than start from scratch. My largest fear is that we label our stock room, then UH come down with their own template they want all of us to use.
  - 34 Necessary but bureaucratic paperwork hassle.
  - 35 no vented chemical storage areas... chemicals must share space with other supplies in a closed area.
-

## Fulfilling federal requirements for training in chemical safety

- 1 what requirements?
- 2 Not a problem at present since I have yet to stock chemicals in my lab, but I have not been notified of chemical safety training requirements.
- 3 As mentioned previously.
- 4 Not frequent enough
- 5 Science [REDACTED] faculty not included in any UH [REDACTED] training.
- 6 What training is necessary for multiple-use spaces?
- 7 Getting undergraduate students trained in chemical safety can be a challenge.
- 8 We do the courses we're told to do.
- 9 As a PI, I don't know what the federal requirements are except insofar as particular labs share information
- 10 Timing and scheduling is an issue. On line system might be able to provide the needed services.
- 11 Where is the online source of DEFINITIVE, COMPLETE info??
- 12 I think the only way to ensure that all users are trained is to put their access to labs on hold until training is complete, otherwise, there is no way to ensure training.
- 13 We have annual inspections from EHSO and have worked to take care of any safety violations.
- 14 I don't think they are a problem, but not sure of federal requirements.
- 15 Times available for training are not always convenient, and not always scheduled very frequently
- 16 Again, mostly ignorance here.
- 17 Don't know what the requirements are.
- 18 Not sure even where to get training without major hassle.

## CHEMICAL SAFETY Other

- 1 Provide optional orientation.
- 2 More proactive approach to helping PIs meet requirements.
- 3 We do not use many chemicals, so not a big deal.
- 4 It's a bit silly asking for an average when I have not had experience with enough institutions to satisfy any statistics whatsoever. Any answer I give is meaningless.
- 5 the safety/handling information comes from the supplier, not UH
- 6 Go to the workshops as much as possible to improve or keep food safe
- 7 Our safety officer is pretty passive and never follows up with anything. That might be good since we are basically unregulated
- 8 same as lab safety and security. annual in person recertifications seem excessive unless highly risky work.
- 9 Install vent hood in lab space
- 10 Storage is an issue especially for large items like gas cylinders. EHSO pushes us to comply but the infrastructure and organization on campus is lacking. Therefore, we end up paying far too much in delivery costs for the gas cylinders we use.
- 11 As noted on the prior page, there is a major gap in hazardous materials shipping. We need on campus training and certification for shipping dangerous goods. This usually only will involve 1-2 items for any particular research group (e.g., for me it is shipping ETOH).
- 12 We police ourselves
- 13 [REDACTED] is not service oriented - will be dismissive or laugh when presented with a problem by PI requesting assistance, pushing it back on PI
- 14 Waste should be picked up more frequently.
- 15 The training did not really provide enough detail about how chemicals should be stored.
- 16 I believe for the most part, chemical safety is very good at UH. It would be nice however to have a chemical waste collection come by once in a while for the basic (Acid only, base only, flammables) chemicals.
- 17 A booklet on how to store and catalog chemicals. Someone to look in my steel cabinet and tell me what's wrong... if anything! I can't believe it's right.
- 18 As before - online training would be helpful.
- 19 Safety training presented through teaching [REDACTED] safety standards. No budget to purchase lab supplies by [REDACTED] faculty. Preservice [REDACTED] need to learn safety protocols through science coursework.
- 20 Training
- 21 If UH provides PI training on these matters, there should perhaps be a "triage" step for new hires that determines what

training should be required for them. I am unaware of specific UH training courses I should take to understand the UH requirements.

- 22 Provide [REDACTED] with more resources.
- 23 Appears that UH has done a pretty good job of dealing with Chemical safety after the citations came to the University several years back.
- 24 Most of the personnel auditing are not familiar with chemistry and in the past have routinely used internet search engines as their source of information. Hiring a chemist might be a good first step.

### Fulfilling federal requirements for training in radiation safety

- 1 [REDACTED] radiation safety is solely my responsibility. I take it seriously.
- 2 Very expensive to have the radiation inspections performed. Extra funding would be helpful!
- 3 The irradiation work is being conducted off- campus.
- 4 Some teaching labs expose students and faculty to low dose of radiation.
- 5 Past experience - we no longer use radioactive labeling material
- 6 I have no idea. I took radiaiton safety training. I hope that meets federal standards.
- 7 Not sure if there is any training class on campus. Has been self-training within the lab.

### Dealing with federal requirements for handling radioisotopes

- 1 The federal rules are a little over the top for radioactive sources... but we deal with it.
- 2 Transferring radionuclides between sites is really difficult to do.
- 3 There is no official place to keep radioactive sources except in their original box.

### Ensuring security of machines and radioisotopes, including personnel procedures

- 1 The radionuclides I work with are remarkably nonhazardous, so security isn't really a problem.
- 2 There is no official place to keep radioactive sources except in their original box. Other equipment is next to vendor box.
- 3 UH seems to love to build shared spaces/labs. Yet using radioisotopes in a shared lab space is problematic. It can create problems with having all students and PI's trained, even though only one PI may use isotopes. I've seen this cause a rift between PI's sharing space.

### Dealing with federal requirements for X-ray machines and other radiation-producing equipment

- 1 No X-ray machines but Thorium source is housed in vendor box. Have not had any problems yet.
- 2 Need professional assistance in securing compliance and safety practices.

### RADIATION SAFETY Other

- 1 The Rad Safety staff have been very helpful and informative in helping our program to maintain compliance with DOH.
- 2 My graduate student, [REDACTED], works at the [REDACTED] radiation facility in [REDACTED]. All requirements and regulations are handled by them. He has been trained to use the facility with supervision.
- 3 This is a minor part of my research. I have one detector on an analytical instrument that produces a very small amount of radiation. It is easily contained. I am probably not representative of faculty who require radiation safety oversight.
- 4 Please provide some training by professional staff on UV, laser equipment handling and operation safety training.
- 5 Generally good interactions and responses from [REDACTED] et al. I think the quality and quantity of radiation safety training could be improved.
- 6 Very easy group to work with.

## Understanding what is required and why

- 1 Committee is much to worried that the university might suffer reputation. Trivial things (done elsewhere with ease) require prolonged negotiation. There is mission creep. Instead of just worrying about ethics they get into design, which makes for worse research since they don't know the area.
- 2 As a new faculty member I have not received any information on ethical issues. I have tasked a technician with trying to figure out what is required.
- 3 Forms for COI are too long and all on paper.
- 4 I was once not recommended for an administrative position because, I learned later, my division chair had told the search committee I wouldn't be interested because I had [REDACTED] Sexist. I didn't even get a shot because of him.
- 5 I say somewhat problematic because ethical issues in research don't have black and white answers. There is a lot of grey area and it would be really good to have a "community of researchers" here at UH where we could openly discuss ethical issues with our colleagues. I understand that we can create these research communities on our own, but if there were institutional structures that helped to support this community building it would be great.
- 6 UH attorneys obviously are important to the function of UH. But my experience is that many opportunities for innovation and leadership are lost when the UH attorneys get involved in review of contracts. We need to work more like a business, and allow more flexibility in contract negotiations with vendors.
- 7 some UH administrators have different (i.e. very low) ethical 'standards'
- 8 I found out about some requirements only after issues were raised in my home department that triggered training sessions. We do get the annual little booklets on some of the issues but nothing comprehensive is pushed out proactively.
- 9 [REDACTED]
- 10 All folks in my department were required to do that RCR training program. I think this is all that is required?
- 11 I'm referring to ethical issues as they are known to academics in the humanities, and especially to ethicists. That may be a very different thing from what the survey is referring to here, of course.
- 12 Sometimes I become privy to information from a student and am unclear about my responsibilities in conveying that information to the [REDACTED] administration.
- 13 I am not aware of any ethical issues requirements for faculty at UH (besides "being ethical" ). I know that students have to take an ethical issues Focus course, so it seems like there should be some ethical issues training for staff and faculty.
- 14 Clarifying what's ethical and what's not per campus
- 15 it is highly unethical to ask illiterate non-English speaking peoples to sign a written consent form they do not understand.
- 16 We are learned individuals with degrees, we should not require ethics, violence, sexual discrimination... training.
- 17 As indicated earlier, inherent conflict between maintenance of subject protection and confidentiality vs UH [REDACTED] and HI state requirement for subject filling out tax forms (with name, address, and social security numbers) for small subject participation incentives. If UH [REDACTED] could move to have these tax forms ONLY for large subject participation incentives such as those over \$200 like other universities, then subject confidentiality can be protected for most research studies, except long term medical research that require large amounts of time and perhaps invasive procedures--mandating large participant incentives.
- 18 We are required to provide bloodborne pathogens training to our student worker staff yearly, but this seems to fall under the UH system responsibility (for all staff/faculty from any program that might come into contact with BB pathogens). We train the staff ourselves, but when it comes to questions around whose responsibility it is if there is a workplace exposure, the responsibility of the department vs the system becomes murky. It would be good to have health and safety streamlined and defined so we could get an overview training and directives from an identified UH entity set up to provide yearly updates/overviews who would also provide specific information to our students on how to follow up.
- 19 Hard to remember details without regular use.
- 20 Don't know what the requirements are.
- 21 There is a problem with bullying which extends to faculty and administrators. Suggestion for fixing the problem: first, bring it to light. second, provide explicit discussion of this within the Workplace Violence policy. Right now if one reports bullying, an investigation ensues and generally what comes out of the "fact finding" is that the actions did not rise to the level of workplace violence. Bullying, however, has an insidious effect on workplace morale and impacts the health and

- security of those who experience bullying.
- 22 I learned not to use just any cleaner in the lab; hire a professional company like Ecolab to suggest the best product needed
  - 23 Colleagues engaged in unethical practices are not addressed.
  - 24 Lack of transparency. Unequal access to information. Patronizing of women. Stolen chair election.
  - 25 Requirements are not well defined. Some training is required for some sponsors (e.g. NSF) but recommended for others (e.g. NIH) but different departments seem to interpret the “recommended” items differently.
  - 26 Faculty at my unit get no training regarding compliance with the Americans with Disabilities Act, with FERPA, or with any employment discrimination issues other than sexual harassment.
  - 27 Please see my responses to the human subjects section. I have generally not found the UH IRB to be a problem, but have found the Department of Education approval process very cumbersome and difficult to navigate.
  - 28 Students are required to fulfill RCR training, but they are not familiar with the majority of the issues that are covered.
  - 29 UH [REDACTED] could do a better job drafting ethical standards.
  - 30 Research partners from outside the university have different research ethics concerns that are more geared towards community level concerns. They find that current IRB ethics concerns are very individualistic and form-centered.
  - 31 As non-permanent staff and a [REDACTED] I have experienced academic bullying and have been deprived of basic safety information (e.g. I was accidentally removed from UH-Alert emails, despite having a current university email address. When I made this issue aware to the departmental chair, I was basically told it wasn’t his/her problem because I wasn’t really staff (because I am on contract). I have previously worked/lived in three countries, including the U.S.A, and I have never been treated horribly until I came to UH [REDACTED]).
  - 32 I believe I understand what is required and why, but would like to be more confident!
  - 33 I can’t say; I’m a little scared details could identify me to my superiors.
  - 34 Responsible conduct of research training is required by NSF.
  - 35 UH IRB website (last time I looked) did not differentiate between legal and ethical, which is a needed distinction for social science research in education conducted with adults.
  - 36 Usually has to do with student projects and to what extent students must clear their projects for ethical standards.
  - 37 Students must be repeatedly reminded of ethical and legal requirements
  - 38 Explanation for initial training was ridiculously inadequate. It was not clear what needed to be done and why. I have only gone through this training once so I do not know if it has improved.
  - 39 Reporting of domestic violence or other issues that occur off-campus but are disclosed to faculty/staff by students. I don’t know what the solution is. (I don’t think this necessarily fits the institutional definition of an ethical issue.) We have received unclear guidelines for reporting.
  - 40 No clear information provided. [REDACTED] office is not clear.
  - 41 I think I know what is required through NSF guidelines and the like. Internal information does not seem to be well publicized: I would not even know where to look at the moment.
  - 42 Senior faculty frequently try to get overload while on an 11-month position because exceptions were granted in the past. They often times are not doing the actual work on the grant and are instead unloading it onto staff as “other duties as assigned” when they should be handling it themselves. Additionally, there are faculty who receive consultant fees for their work on grant projects under the table (i.e. not through UH’s Human Resources) so these do not get counted toward their work load. In the end, junior faculty suffer because they aren’t able to get the release time or overload in the same manner senior faculty are by bending the rules.
  - 43 I didn’t know of any ‘ethical training’ program
  - 44 have had some strange IRB responses to participant reimbursement.
  - 45 Unsure what this statement is in reference to. I may THINK I am doing things correctly, but may not be aware of a place I can look for quick reference (checklists would be nice)
  - 46 Is this different than IRB? If it is then my understanding of ethical issues at UH is quite problematic because I wasn’t even aware that this was its own entity.
  - 47 Leadership at the IRB is junior and unfamiliar with different types of research and unable to really help.
  - 48 I received training and attended numerous classes in scientific conduct elsewhere, but I still do not see where I can get this kind of training at UH.
  - 49 Not aware of any issues.
  - 50 mostly in purchasing with uneven applications of purchasing rules by different fiscal officers. Redoing purchasing paperwork has caused some funding to be lost due to lack of timely feedback from FO’s.
  - 51 There needs to be an indigenous Faculty review board for those cases where indigenous communities are being sought by Faculty who belong to the same community. Asking outsiders for permission in these cases is a little absurd in the twenty first century.

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- 52 No training.
- 53 Often the UH bureaucracy is the biggest hurdle to progress. The fiscal policies at ██████ CC are about as ridiculous as one can imagine - my ██████ is an accountant for ██████ and when I share the purchasing requirements even he is astounded by their draconian nature.
- 54 I have taken trainings on this at OTHER campus' -- are they required here? What kind of ethical training?
- 55 Just what is considered unethical by the State Ethics Commission seems rather random. For example, accepting compensation for giving a student a good grade (ie. a bribe) is clearly unethical, and should be so. However, providing compensation (such as good grades, meals, and gifts) to students for good evaluations of instruction (ie. a bribe) is not considered unethical. This does not make sense to me.
- 56 As acting chair several years ago, I had to deal with some thorny confidential ethical issues. I did not know how to start to handle these but got help from my
- 57 Training in ethical research procedures in my discipline is part of the research methods courses I teach. Faculty in my discipline regularly address ethical issues of empirical research in courses. Ethical issues in the social sciences are to some extent discipline-specific, to some extent related to particular styles of research. As teachers and supervisors of student research, it is faculty's responsibility to guide students in how to observe ethical standards at all steps in the research process. It is not possible for university-wide guidelines to address discipline-specific problems, yet it is these problems that we face in our research. Acknowledge that expertise and experience rests within the disciplines, respect the faculty, consult with us, stop telling us what to do.
- 58 I have no idea who I talk to about ethics issues
- 59 not much information or training available at UH
- 60 I don't actually know what the requirements are at UH. Generally in our field, ethical issues are addressed through IRB reviews, at the level of federal grants agencies that often require some kind of statement about it, and through the guidelines listed by professional associations.
- 61 Questionable ethical behavior of UH management and faculty leaves me wondering if anything is being monitored.
- 62 I am familiar with ethical issues as an avenue of inquiry but have no idea what you are trying to figure out by these ill conceived/defined questions.
- 63 Is there a code of research ethics at UH? If so, it's not encouraged that people consult it.
- 64 It's a question of interpretation. I didn't believe I should write a permit application, complete with all that emergency response stuff I referred to earlier, while someone associated with the IBC believed I did have to. I protested, to no avail. I wrote the permit application. The IBC's response was that I don't need a permit. Enough said.
- 65 I worked with an illiterate group to study ██████. I was asked to have them sign IRB forms. How can this be possible when the people have never held an pen?
- 66 This is an extremely broad topic and issues could certainly arise that have not been covered in any training.
- 67 Counselors in the system have unclear professional boundaries when it comes to standards of practices based on counselor ethical guidelines
- 68 Online information through UH was helpful
- 69 I don't see the school promoting ethical behavior in the classroom, in the lab or just generally. Leadership comes from the top.
- 70 Keeping up with changing laws, changing societal views. I think that the Gender Equity office is doing a good job of providing workshops to learn these things.
- 71 Inadequate training confusion exists
- 72 Need constant reminders and consistent behavior throughout the entire system
- 73 No advice or information provided on the cultural specificity of compliance needs, ethical standards or institutional commitments to research from ██████ perspectives.
- 74 I frequently include modules on research ethics in my courses
- 75 In my field ethics are governed by an oversight board that provides very clear guidelines regarding research ethics. However, here at UH ██████, there is another layer of ethical guidelines and interpretations entirely, and these guidelines are poorly understood and even more poorly implemented. Questions of ethics seem to come down to faculty and staff covering their assets and passing the buck rather than coming to consensus about what constitutes ethical research behavior.
- 76 I have not yet been informed of ethical training that I should take at UH. I am applying principles that I have learned at previous institutions.
- 77 Obvious violations are no problem within the PI's immediate lab. However, if there are issues the university does not handle them. They prefer we don't bring it up and no one does anything about it anyway. UH pays lip service only to ethical breaches in just about every aspect of university life. Apparently, there is no political will, certainly no one with the backbone and follow through.
- 78 Our rules are too strict for my type of research.
-

- 79 People are aware of ethics but lack the morals to do the right thing. Requires better leadership to focus activities on making things better for students.
- 80 There is a difference between ethical issues requirements and legal requirements and this office seems to confuse those. Ethical requirements are far broader and more complex than legal, and ambiguities are not always dealt with thoroughly in training. This is also often true in ethical issues classes, where General Education Focus stresses filling out rubrics rather than actually thinking.
- 81 Researching on the campus of [REDACTED] is made exceptionally difficult. The faculty who are tenured here are exceptionally protective of their so called "territory", by which the general understanding is program, and will not let new and innovative ideas flourish. The STEM department especially is a problematic area and someone with new ideas, that do not conform to their existing way of working, will be condemned and discouraged even let go. This has happened to many in the past few years and continues. The level of mathematics required in the coursework offered in STEM is dismal and hinders research. Moreover UH [REDACTED] has not understood what it takes to conduct a successful 4 year degree program. Physics also suffers from the same lack of depth and I know some good efforts are being made by the new faculty to build this up. Work in the other programs, Sustainability especially, is lacking depth and the course curricula is weak too. This is not ethical as students are being robbed out of an education. The business program in IT suffers from lack of depth too. There is little if not any emphasis on research and anyone to the contrary is condemned. I think this is an ethical question at the campus. It is indeed the prerogative of the faculty to maintain an academically free environment full of welcoming new ideas and research, which UH [REDACTED] has failed exceptionally to fulfill.
- 82 AVAW is a bit sketchy - if something happens to students on a campus partner, are we required to complete a CSA on that. My interpretation is that it should be reported but this needs to be clarified.
- 83 Don't recall seeing any guidance documents from UH [REDACTED] on this
- 84 can be a bit confusing in general
- 85 I have a thorough understanding of ethics in research through study, working research groups, and 25 years experience. I take ethics seriously--but do so as an ethnographer/advisor which demands nuanced understanding of ongoing ethical dilemmas and risks.
- 86 Faculty/staff were exposed to environmental hazards. Staff and administration were unaware of the safety hazards the workplace posed.
- 87 I have read the online the university's policy statements concerning ethical standards in research but I have limited experience with UH [REDACTED] since I have only been here for under 2 years.
- 88 Quite problematic because I don't know what's required or expected.
- 89 IRB approvals needed for collaborative research (ie between UH [REDACTED] and [REDACTED] or [REDACTED]) are very ambiguous. In 2012, I spent 6 months trying to get a project approved because the UH [REDACTED] IRB office didn't know how to work with [REDACTED]. Since we do not have a university hospital, it is CRITICAL for UH [REDACTED] to have a well-established procedure in place to get the necessary approvals for collaborative research.

## Fulfilling requirements for training

- 1 There is training?
- 2 Helpful to have more training sessions on neighbor islands.
- 3 Each day I spend in compliance is a day lost on research productivity, and those days are continually stacking up
- 4 Again, I know that a computer-based training is less expensive than face-to-face trainings - but perhaps it could be a blended experience (online and face-to-face). This might help to build a "community of researchers" at UH who are used to collaborating with others on finding solutions to issues (both ethical and practical) that they are having with their research. It would also be good to learn about ethical issues through case studies, inquiry, and dialogue/discussion with peers or more experienced researchers.
- 5 [REDACTED] recently lost a long-term contract with [REDACTED] due to UH [REDACTED]
- 6 Organized by my unit.
- 7 There's training?
- 8 The RCR interactive sessions are few and far between. Very difficult to get in.
- 9 the web-based certification process is annoying and should not be required annually.
- 10 see comment above
- 11 At first I had trouble seeing all the steps of the process but I got useful feedback from the office.
- 12 never seen a training session for ethical issues
- 13 All of the trainings, including ethical, biosafety, chemical, lab, etc... actually take much time away from teaching and research. The biosafety training and refresher frequency can be reduced by half. The ethical training can be once in 10

years. Training = UH is interested in covering their butt and placing all responsibility on the faculty. To do research, faculty need to write grants and compete for funds, and once funded they need to recruit good people, run their labs, train students, comply with restrictive purchasing rules, and then comply with an increasing burden of training and rules.

- 14 I have never encountered options for ethics training
- 15 A complete waste of everyone's time.
- 16 We are required to provide bloodborne pathogens training to our student worker staff yearly, but this seems to fall under the UH system responsibility (for all staff/faculty from any program that might come into contact with BB pathogens). We train the staff ourselves, but when it comes to questions around whose responsibility it is if there is a workplace exposure, the responsibility of the department vs the system becomes murky. It would be good to have health and safety streamlined and defined so we could get an overview training and directives from an identified UH entity set up to provide yearly updates/overviews who would also provide specific information to our students on how to follow up.
- 17 Online course seems to not work, and it's difficult to get students to do it. It would be better to have courses on our campus.
- 18 I've taken the RCR course. No particular problem, though not particularly enlightening.
- 19 Some of these so called "trainings" are ridiculous. For the sexual harrasment/workplace violence training, i was put in a room and shown a grainy video with bad audio that lasted almost 2 hours. for an online training it was possible to simply go to the end and print the certificate. We all know it is just about administration covering its backend. suggestions for solutions: construct a genuinely meaningful training session. but then if administration took responsibility for the workplace, there would be less need for this kind of backend covering.
- 20 Same comment on the standardized online training discussed earlier.
- 21 Needs for free training.
- 22 It is unclear and not a catalogue of all courses available at [REDACTED] is publicly available
- 23 Not sure what these are, outside of IRB..?
- 24 As above, requirements are not well defined. Some training is required for some sponsors (e.g. NSF) but recommended for others (e.g. NIH) but different departments seem to interpret the "recommended" items differently.
- 25 As mentioned above, the CITI testing is totally lacking in value for my research, requiring attention to much that has no relevance and so where my research students could not behave unethically since we don't engage in that sort of research activity, but leaving totally unaddressed the many ways in which our research could be harmful to individuals and communities as we do fieldwork. Fortunately, our field places great emphasis on and pride in ethical research behavior.
- 26 Make clear what CITI modules are required for what types of projects, and minimize the number of modules that one has to complete.
- 27 Very little training is offered. At a minimum, all faculty should receive training in teaching and otherwise working with students who are blind or vision impaired, deaf or hearing impaired, or who have other disabilities that might require classroom accommodation.
- 28 Training availability was not clear.
- 29 Was not aware that UH had any ethics training
- 30 Limited availability for the required face-to-face training.
- 31 The CITI training is too long and tedious and is not relevant for community issues.even when they managed to complete it, they don't come out of it with an increased knowledge in research ethics.
- 32 Responsible conduct of research training is not offered regularly
- 33 Fulfilling the requirements is not a problem; quality of the training was a problem.
- 34 Is there a training?
- 35 The lecture session was a waste of time. Once the on-line material needed was clearly identified it was useful and provided adequate training.
- 36 The ethical research practices training for students working on NSF projects is not offered nearly as frequently as it should be. One time within a semester is inadequate with student course and travel schedules. It is also not offered at all on other islands.
- 37 it is hard to get very short term workers to comply with training requirements. I think there should be a minimum time of service/support on federal funds for compliance on this training type.
- 38 No consistency.
- 39 ORS is adding unnecessary layers of bureaucracy to processing grants, contracts and other types of awards. Their staff is overburdened due to the extra requirements of myGRANT for every little post-award action. Although myGRANT was pitched to be simple and sync with Kualii, it does not. It adds so much time and administrative burden to already complex projects. What's the incentive for getting involved? ORS's staff either needs to take this burden on themselves, or ORS should lessen the amount the field is required to do.
- 40 I didn't know of any 'ethical training' program

- 
- 41 To be honest, I'm not sure I've had training on this.
  - 42 new people into the lab require training, but classes are not always available. Make sure to have frequent training sessions at the start of the semester. (or offer online)
  - 43 Wait, are these separate from our IRB training?
  - 44 Again - is this different than IRB?
  - 45 See previous comment on having UH IRB support in having University staff/admin comply with federal granting agency human subjects training requirements.
  - 46 I do not know what office is responsible for this and where to find this information.
  - 47 Staff especially are VERY overworked with little or no time for training.
  - 48 Hiring instructors for non-credit training is very challenging. The bureaucracy is ridiculous.
  - 49 Not sure what training is available or required?
  - 50 difficult to understand which CITI courses are required
  - 51 See above.
  - 52 The training is unsuitable for research in my discipline and a waste of time.
  - 53 Did not realize there were requirements for training. More communication from admin regarding training is necessary.
  - 54 Time consuming but necessary.
  - 55 timing
  - 56 You mean there's training for ethics! You're joking, right? How come i don't know about it?
  - 57 Online training should be available for any required training.
  - 58 See comment above
  - 59 I'm not sure what the training requirements are.
  - 60 Sometimes students do not capture the subtle elements of ethics.
  - 61 Budget issues do not allow for faculty to attend trainings
  - 62 It is time consuming!
  - 63 I think finding time for training, and being fairly compensated, are two big issues.
  - 64 time consuming
  - 65 Training not addressed
  - 66 Mostly involves lack of time
  - 67 Again, can be confusing which training is required under biomedical vs social & behavioral.
  - 68 Not sure what training is involved. I see emails and info re: ethical issues.
  - 69 No such training.
  - 70 I have not been notified of specific ethics training requirements at UH.
  - 71 what requirements?
  - 72 Time.
  - 73 Isolated campus prevents easy access to training.
  - 74 What ethics training is this referring to?
  - 75 Again, it was a huge waste of time for me, as a [REDACTED] researcher, to have to learn about, and pass quizzes on, protocols for studying human subjects in settings (e.g., hospitals, schools) in which I never have, and never will, conduct inquiry.
  - 76 same as above
  - 77 No training provided?
  - 78 See above. We need experts in social sciences who advise rather than set unreasonable & inapplicable requirements. We need highly qualified experts in ethnics who support rather than regulate research.
  - 79 I have read the online the university's policy statements concerning ethical standards in research but I have limited experience with UH [REDACTED] since I have only been here for under 2 years.
  - 80 Is there a formal training program for ethical issues?
  - 81 Is there training available, and for what?
- 

### Filing conflict of interest forms

- 1 It seems wasteful of time, effort, and paper for everyone to file the forms every year. Where do the forms go? Why not have only those with conflict fill the forms?
  - 2 I have read the online the university's policy statements concerning ethical standards in research but I have limited experience with UH [REDACTED] since I have only been here for under 2 years.
  - 3 Form is old and redundant
  - 4 Again, the criteria are different according to fields.
-

- 5 Filling out the conflict of interest forms in sections related to spouses/family can be difficult to navigate. More examples might be helpful.
- 6 saa
- 7 This seems like a hassle and likely isn't going to stop someone who is interested in exploiting a conflict of interest
- 8 Do not recall if there was any face to face training on conflict of interest.
- 9 who owns the right to work created while employed by university
- 10 It would be nice to know the implications of checking a box that requires a PI to relinquish copyright on research before submitting the grant.
- 11 Bureaucratic nonsense. Simplify.
- 12 Not sure what is required to report
- 13 Form is unclear. Instructions for the form are also unclear and have not been updated in over a decade.
- 14 My unit does not apply COI restrictions uniformly to its staff. COI filing is perceived to be a "stick" which is used against staff which are perceived not to be supportive of the director. Many examples exist of clear COI violations that seem to be tolerated, and other issues that receive COI punishment that don't align with this units "official" priorities.
- 15 Takes a lot of time. We are encouraged by Administration to pursue public-private partnerships but are hassled when we are involved with the private party.
- 16 A bit time-consuming
- 17 There is a grey area between volunteerism with stipends and hiring workers. The forms don't necessarily deal with this area and I'm not sure they should. But if it could be clearer where this area stands in the forms, that might be helpful. Clearer explanations for what constitutes working with one of our students outside of academia, for instance.
- 18 Confusion regarding what does and does not constitute a conflict of interest under multiple contexts
- 19 Budget issues do not allow for faculty to attend trainings
- 20 Again, see problem above.
- 21 I can read. The forms seem quite simple. We complete the same form every year, right...
- 22 Repetitive and time consuming.
- 23 Not clear what is the time period--school year or calendar year
- 24 annoying to fill out the forms every year.
- 25 The forms are redundant
- 26 Waste of time for me because it is not relevant.
- 27 Didn't know there were these...
- 28 The forms ask for reporting of things considered conflicts. This has led to individual faculty with companies saying they have no conflicts. It would be better to ask for all other compensation and then ask for their opinion about conflicts. BTW, I own nothing, so the forms are easy for me.
- 29 Forms are intimidating. UH needs professors to work with business and industry to better prepare their students for the real world. This involves doing contract work and working on project teams with various vendors on occasion, or starting their own company. Fortunately my supervisors have been supportive over the years, and our students have benefited greatly from the opportunities stemming from my connections with business/industry. But the forms can only be interpreted as a means to discourage faculty from these types of synergistic relationships.
- 30 Too much information is now required.
- 31 Wording is ambiguous and do not reflect staff that do outside consulting.
- 32 I do not know even that they exist! Where should I find them?
- 33 Once told to alter conflict of interest forms so that I could indicate that conflict of interest might exist when in fact clearly none existed. Case involved hiring [REDACTED] There was no space in COI form for indicating such a situation, but staff was so concerned about covering all possible UH rules, including those that did not actually exist, that they thought it was safer to alter form in order to be able to state that conflict might exist. Was not IRB in particular that made this request.
- 34 Constant complaints from faculty and staff about having to fill in these forms. A lot of times because "subordinates" are responsible for collecting these, faculty and staff may tend to ignore or cast aside. Would appreciate stronger language from those in executive positions on cooperation with these annual forms.
- 35 The technical language is confusing - thus I assume I have no conflict on the form because I don't understand what I am being asked.
- 36 If I know of a conflict of interest situation, where do I get the form and who do I file it with?
- 37 They are too long but not difficult. There should be a short form for those with mostly N/A.
- 38 [REDACTED] has their own COI forms in addition to ORS - why do we need two sets of these? It is wasteful & difficult to keep track of, and ultimately there's only one federal law. If in doubt (and [REDACTED] needs more detailed disclosures), why can ORS not accept those more stringent ones?

- 
- 39 I will say that while the form is easy to fill out, I do not for a minute understand why we are still doing this on paper. Why can't there be a form on the web?
- 
- 40 PI's for non-research projects should not have to answer research compliance questionnaires.
- 
- 41 No training for Department Chairs on COI, yet they have to certify that faculty/staff in their units are not having conflicts. Putting it on the DC is unfair.
- 
- 42 they are a waste of paper and redundant and last year it wasn't clear what form to fill
- 
- 43 Needed: examples of tricky situations that are still common; a flow chart.
- 
- 44 The process in my college (██████) is very well done and makes it easy to stay in compliance.
- 
- 45 Should develop a online version.
- 
- 46 Again, I am concerned that, broadly, conflicts are inadequately understood.
- 
- 47 We are trying to commercialize research from our lab, and have formed a company so there are some ethical grey areas. I (and my colleagues) report these issues in our COI forms, and I personally feel like our research and commercial activities are highly synergistic and beneficial for both institutions and the granting agencies involved. Even so, it feels like kind of a grey area...
- 
- 48 It is abundantly obvious that many of my colleagues do a great deal of paid outside work, leaving others of us carrying more of the administrative and mentoring load than we otherwise would. This is very, very demoralizing, and problematic from an EEO perspective, as women tend to be the ones who pick up the load.
- 
- 49 N/A
- 
- 50 Not always clear who needs to file and when.
- 
- 51 Especially on the initial forms, instructions were not clear and/or did not account for some of the particular nuances with ████████ faculty compensation.
- 
- 52 Again, it would be helpful to have this laid out clearly on the ORS/IRB website
- 
- 53 Odd requirement that our primary clinical work has to be listed as a potential conflict of interest at UH. Not self evident.
- 
- 54 Easy enough, but really repetitive. Those things just don't change very often.
- 
- 55 overly legalistic, not appropriate content for average reader
- 
- 56 Can these be online, so we just have to click a button? (Has anything changed since last year - Y or N?.) Electronic signature via out UH user id?
- 
- 57 The general conflict of interest form needs to be revised - its difficult to figure out what time periods it covers and what is/is not a conflict.
- 
- 58 Detailed guidelines/examples would be very helpful, as would a "certified" point of contact. Lots of grey zones where I'm unclear what to answer, and different "higher-ups" advise different things. The RCR sessions didn't help with filling out conflict of interest forms.
- 
- 59 A little bit scary for those of us who do contract work on the side. Fortunately my supervisors so far have seen the synergy that is created when our educational leaders do contract work with business/industry on occasion. Many opportunities we have had over the years resulted from connections made from when our faculty did contract work.
- 
- 60 Forms should be simplified and put online for quick data entry.
- 
- 61 It used to be a simple form. Now it's become much more time consuming like many other forms at the University over time. With the advent of increased technology, faculty are being asked ot do more and more of the paperwork that used to be done by others.
- 

## Reporting an ethical issue

- 
- 1 No one really cares so it is not only a waste of time to report an ethical issue but it can create more problems for the whistle blower. Tons of research backs me up on this. I reported in my first semester; I'll never report again.
- 
- 2 Trivial things are blown up into large problems.
- 
- 3 Some departments appear corrupt.
- 
- 4 Hierarchy unfortunately trumps the pursue of ethics.
- 
- 5 I've learned to pick my battles. You can't fight every dragon that comes your way.
- 
- 6 Administrators themselves are not ethical! Read the papers lately?
- 
- 7 useless to comment - UH covered it up anyway.
- 
- 8 Administration responses to reporting of ethical issues are slow and reactive.
- 
- 9 This was a concern with a prior ████████ who no longer works at UH - requiring filing of an Office of Information Practices request, which was handled in a poor, non-transparent and non-reponsive manner
- 
- 10 It's always difficult to know when to call it. Ethical issues happen all over the place, but most are small enough to be overlooked. Or maybe they shouldn't be overlooked. But then we'd never get any work done...
-

- 
- 11 The only kind of ethical issues that I've encountered, in my role as department chair, concern potential conflicts of interest and fraud. When these have arisen, I've simply referred the matter to upper administration.
- 
- 12 See answer above.
- 
- 13 Is it anonymous?
- 
- 14 The campus is very political and the impression is that 'cover ups' are rampant. That is an image, true or not, shared by many faculty on campus. I would say more than less. And this is especially true at [REDACTED]. Specific cases have transpired within [REDACTED] that are clearly ethically challenged but overlooked at best but I would say encouraged by those allowing these incidents to occur time after time. These include the Dean and former [REDACTED] director. Examples include repeatedly poaching into faculty expertise and taking credit for projects as their own initiatives, writing in faculty into grants without informing them so taking credit again for other's work without their approval, preventing faculty to work in the area of expertise so they can push forward the faculty of their choice without much expertise, delaying/refusing the 'signing off' on MyGrants based on reasons such as need to know the 'exact \$\$' the college would get in indirect when a PI would not know this until they are awarded and actual budget approved by funding agency, trying to implement separate RTRF percentages for targeted individuals such as 50% more but not requiring any RTRF for most. This management style places undue pressure on those who try to bring in grants and is at minimum unfair. In some cases negotiating a lower RTRF with outside colleges (e.g. indirect at 5%) thus having the [REDACTED] faculty who bring in RTRF to 'carry' other College faculty fiscal support, e.g. grants of certain [REDACTED] faculty cannot be approved unless they bring in full RTRF but only 5% is charged by former [REDACTED] director as the 'PI' of grants for colleges outside of [REDACTED] etc. I suppose it makes the College look as though they are bringing in more funds. However, while doing this, they penalize/excessively target potential grants that may have substantial RTRF by making it very difficult so they can capture as much RTRF for the Dean's office and [REDACTED]. This is a situation that is demoralizing but also unethical. RTRF in [REDACTED] is advantageous for those who do not bring in funds because one could get more back from [REDACTED] travel funds and start up funds through the College than through the returns. If a \$100K was brought into the University and \$50K was brought into the [REDACTED] then the PI only gets \$6-7K as all of the rest gets usurped into [REDACTED] travel funds, etc. And interestingly [REDACTED] does NOT provide fiscal support. It only reviews and approves what has been prepared by the projects. A number of us who are in the College that used to bring in competitive grants have discussed this and feel the research environment is discouraging if not punitive at [REDACTED].
- 
- 15 To whom would I report an ethical issue?
- 
- 16 Because the issue is still being investigated and confidential, it is hard to capture the exact problem: It had to do with the treatment of a child by an adult worker and the issue was taken to the Dean. It is not clear how these instances get processed and it seems as if there are no clear guidelines.
- 
- 17 When administrators are more interested in suppressing problems than in dealing with them, we have a problem. Solution for fixing the problem: discipline administrators.
- 
- 18 I don't know where to report it. Of course, the IRB director, but that's all I know.
- 
- 19 Not sure if issue should be reported or not.
- 
- 20 Still unclear about the reporting structure
- 
- 21 The survival instinct is quite high in Hawaii, i.e. protecting my job is paramount. While I've had many issues come up over the years, particularly with contractors, I've always felt that going through official channels to report possible issues would lead to a strike against myself, as opposed to the contractor. With the majority of positions on soft money, nobody wants to risk being a whistleblower.
- 
- 22 Dean of College will retaliate.
- 
- 23 Faculty often fear potential repercussions when considering whether to report ethical issues on campus, especially when they lack tenure. Since our campus is so small, confidentiality is hard to maintain.
- 
- 24 Indifference on the part of the school's leadership to the problem described immediately above.
- 
- 25 I don't know who to call and fear retaliation,
- 
- 26 As an untenured faculty, I would have a very hard time reporting. If you don't play along in my campus, you get cut.
- 
- 27 The network of conflicting interests that can be involved in an ethic situation means that everyone has to adhere to the same ethical standards. Experience suggests that this can be difficult because of the "politics" involved.
- 
- 28 I assume I would have to report it in the same way I report any other type of issue, to department chair.
- 
- 29 To report a conflict at UH [REDACTED] opens the possibility that, ultimately, blame will fall on the whistle-blower's shoulders, especially when a powerful person may have committed an infraction. Such a practice puts undue risk on whistleblowers.
- 
- 30 Sometimes this is subjective.
- 
- 31 Expertise and Credibility of administration is lacking.
- 
- 32 Where/who to report?
- 
- 33 I can't say; again, we've had some problems and I'm not sure that describing them won't reveal who I am.
- 
- 34 Never had to do it. But, I don't know who I would report it to if I needed to do so.
- 
- 35 While the issue of sexual harassment reporting has improved over the past couple of years, the options for a member
-

of the UH academic community to discuss in confidence, and report if necessary, discrimination, workplace disputes, ethical issues, unprofessional conduct, etc., are limited or non-existent at all administrative levels. Ombudspersons are needed.

- 36 Cheating and plagiarism - addressed with student , revising academic contract, document all incidences, bring in counselors
- 37 don't know who to report it to.
- 38 Reporting of domestic violence or other issues that occur off-campus but are disclosed to faculty/staff by students. I don't know what the solution is. (I don't think this necessarily fits the institutional definition of an ethical issue.) We have received unclear guidelines for reporting.
- 39 we deal directly with the agencies
- 40 Although HR requires mandatory ethics trainings, it is tenured faculty and administrators who have breached ethical issues. If the [REDACTED] does not address it either, then what recourse is there other than going above established channels and reporting it directly to the state? This doesn't help our reputation or efforts to secure future funding from the state or feds, so ultimately what is the right process for reporting ethical issues?
- 41 Not sure I know how to do this outside of the areas of sexual harassment and workplace violence.
- 42 Don't know who to report the situation to, especially if it is confidential.
- 43 Not sure where to go to report an ethical issue.
- 44 Better information dissemination on where/how/who to report ethical issues to.
- 45 Only uncertainty is with which agency to first file a report. This is in the nature of reporting and is not unique to this system, nor does it demonstrate a lack of training.
- 46 Where should I report? What office is in charge? No clue.
- 47 I am not aware of any ethical problems, but I feel there needs to be more training in this area.
- 48 For one student this started a firestorm of inappropriate scrutiny. No ethical violation was reported, but a query was made. Please get rid of [REDACTED]
- 49 There is still an atmosphere of "finking" on peers and losing research opportunities.
- 50 Not always clear who one should report to.
- 51 Not sure immediately where to seek help.
- 52 Only in the sense that Hawaii is small and secrets are hard to keep. I have seen my share of unethical actions over the years, but nothing compared to what my [REDACTED] experiences in the corporate world. Mostly what irks me is the hiring policies being engineered for prescriptive outcomes, more often than not precluding the best person from being hired. Hawaii, and UH in particular, need more people who can see beyond their nose and understand that it is to the benefit of our state to attract the best people, and not to be threatened by excellence. We want people who are better at what we do! We want to be challenged! Diversity should include inviting people who do what we do best but get under our skin because they do not conform to our values.
- 53 There have been ethical issues at my unit and there is not an independent office where you can file reports. Reports are made to the [REDACTED] office, who chooses whether it is worth pursuing. The last [REDACTED] told us that he was unlikely to pursue an investigation (presumably [REDACTED] would pressure against it).
- 54 Not sure how to do this or when to do it.
- 55 See above comment. Just what is actually considered unethical and not merely unprofessional is sometimes confusing.
- 56 Worrying about retaliation, I'm afraid to report that there is a major ethical issue related to a major conflict of interest by [REDACTED] faculty who serve at the [REDACTED] for many years and getting the support of [REDACTED] Deans. Many know of the problem but everyone is avoiding fixing it. As I was told by my superiors at UH: "Pick your fights." However, the conflict of interest by the [REDACTED] faculty and Deans discourage other UH faculty to turn in grant proposal and to some others, to stop serving in [REDACTED]. This has been going in UH for over 20 years!
- 57 See above.
- 58 Consequences for keeping data secure and confidential are often ignored. Funds are misused. But, no one wants to be the "snitch."
- 59 who? where?
- 60 Although I have not had to report an ethical issue, it's not clear what the procedure is to do so.
- 61 Again, I am not sure to whom at UH I would report a problem with ethical issues. I would probably contact my national professional association.
- 62 NOTHING IS CONFIDENTIAL OR ANONYMOUS AT THIS INSTITUTION.
- 63 There are times when people have reported ethical issues and the backlash and treatment from others on campus, while unethical, is tolerated. It makes it so that people are unwilling to report due to the way you'll be treated for reporting. Campus culture needs to change - admin needs to see unethical behavior and stop it or address it rather than allowing it



- 7 See above
- 8 I did face issues in terms of building up a research portfolio here at UH [REDACTED]. I know that the upper division faculty need to do research to help them progress in the field and also to teach the most updated developments in the field. Specifically, I was approached by an outside organization for discussing new idea and I responded (mainly at my own time and during summer). Working hard I successfully received their attention and interest in considering a proposal from UH [REDACTED]. Upon further deliberations I found out that UH [REDACTED] administration was upset that such a dialogue happened and to my shock was disappointed in me. I was amazed that my hardwork will result in disappointment. I later learned that the administration wanted to have certain procedures followed in outreach and asked me not to discuss research ideas with non-campus professional without explicit permission. I think this stifles research and academic freedom and should not have been put in place. A solution would be to allow faculty to reach out and discuss with anyone about anything freely and only discuss procedure when something formal is proposed in writing within each organizations. The reaction by the administration was out of proportion and unethical for a faculty who is aiming to expand the horizons of the campus.
- 9 what procedures?
- 10 For the above reasons
- 11 Lack of following up on several issues. Administrators need to be mandated to take the ethic training they mandate others to take.
- 12 Don't know how to submit.
- 13 I haven't made a report so I don't actually know if it is a problem or not
- 14 Reporting is not a problem. Response is. I filed [REDACTED] and was told by some, they would handle it, that is, not to file (!) and by others to file. [REDACTED] does not get taken seriously enough at UH.
- 15 If the director has done some things that are unethical, what is the reporting chain. And, if your director is a person with a lot of influence on campus how safe is your employment.
- 16 Not familiar with who to report to.
- 17 Inconsistent application of ethics violation complaints seem to be the norm here.
- 18 See above
- 19 In short, the UH does not give a shit about E-issues. H.R. simply wants to white wash problematic cases and go back to sleep. I had to contact [REDACTED] for a measure of justice. If the criminal act goes to [REDACTED] you might hear about, maybe not. Nobody but me seems to care but me.
- 20 Only problematic in that if a case arises, hopefully it is an isolated incident. But the procedures for dealing with it and the aftermath might not be revisited again for many years, so we must re-educate ourselves on what to do, especially if procedures might have changed. Don't really have a way to fix that....seems inherent.
- 21 See above.
- 22 Idem: Problematic when it is about a "Boss"
- 23 [REDACTED]
- 24 N/A
- 25 I know the procedures. [REDACTED].
- 26 Faculty Senate did not take action on the issue.
- 27 Fear of the other shoe falling.
- 28 Not sure where to go to report a fellow researcher's breach of ethics.
- 29 I do not have any faith that I would be supported by UH in reporting ethical issues.
- 30 Unclear who we report issues to - issues do not get addressed by administration. Those that raise issues are seen as "trouble makers." Campus culture again needs to change, starting with the leadership.
- 31 ALL SENSITIVE INFORMATION FINDS ITS WAY TO THE PUBLIC. Whos is to blame for this?
- 32 Procedures for reporting are not clearly available nor is there an annual training
- 33 Although I have not had to report an ethical issue, it's not clear what the procedure is to do so.
- 34 See above.
- 35 Worrying about retaliation, I'm afraid to report that there is a major ethical issue related to a major conflict of interest by [REDACTED] faculty who serve at the [REDACTED] for many years and getting the support of [REDACTED] Deans. Many know of the problem but everyone is avoiding fixing it. As I was told by my superiors at UH: "Pick your fights." However, the conflict of interest by the [REDACTED] faculty and Deans discourage other UH faculty to turn in grant proposal and to some others, to stop serving in [REDACTED]. This has been going in UH for over 20 years!
- 36 It is not so clear where to report things. I recently found out that we have an office of research integrity.
- 37 N/A

- 
- 38 No clear guideline.
- 39 Procedures are not clear.
- 40 See above.
- 41 We do not have established procedures for reporting ethical problems. We plan to work on this.
- 42 Again, I am not properly informed about this.
- 43 Not transparent.
- 44 Better information dissemination on where/how/who to report ethical issues to.
- 45 Not sure of the procedures.
- 46 Will the procedures protect me if the matter is confidential?
- 47 Same as above
- 48 In the event an ethical problem was reported, it was not appropriately addressed.
- 49 Vague, not clear
- 50 Procedures are unclear.
- 51 See previous comment.
- 52 How do you do it and with whom do you file? Afterwards, how do you not get fired?
- 53 See previous comment.
- 54 It can be very difficult for a junior faculty to bring a case against a senior faculty member. The Office of Research Integrity may indeed seem to be part of the problem.
- 55 Same as above.
- 56 See above.
- 57 No one follows up.
- 58 College is highly political
- 59 See previous answer.
- 60 Sometimes, uncertain of what procedures to follow.
- 61 Fact finding is often assigned to a less than competent administrator or to someone whose interest is in maintaining what they perceive to be a positive relationship with those who appoint them. They end up providing a report that gives the administrator what they think he/she wants to hear. suggestion for fixing the problem: Hire administrators who have some moral courage.
- 62 Don't know what the procedures are
- 63 Not sure there is an outline of the procedures?
- 64 Defining what's ethical and what's not or what's borderline
- 65 see comment above
- 66 Depends if it involves the Dean's 'favorite' faculty or department. Climate of reporting an unethical issue is discouraged and frowned upon and many [REDACTED] faculty feel that the Dean's office is very retaliatory.
- 67 I [REDACTED] so have experience. But, I think most of my colleagues in the physical sciences know little about this area (and generally do not need to know much).
- 68 Leaving confidential information in publically accessible offices, coding to avoid revealing identifiable information, electronically storing information
- 69 Problematic when it concerns a "boss"
- 70 I think I know procedures re. sexual harassment (from the brochure) but not re. other ethical issues. I'd probably talk to my head or associate dean, but I know from the sexual harassment side that these folks may be required to take action on some level. Again, would be good to have a "certified" point of contact.
- 71 [REDACTED]
- 72 As above. The UH administration was viewed as obstructionist
- 73 useless to comment - UH covered it up anyway.
- 74 The ethical issues are a little bit upside-down from what people normally think. The lack of ethics actually stems from the draconian, onerous regulations that prevent faculty and administrators from being proactive and innovative.
-

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- 75 I had a faculty member who was wrongfully accused, and that was not fun, but it all worked out in the end. However, he went through a whole lot of hassle in the meantime. Perhaps reports could be triangulated a bit before putting people through a big hassle?
- 
- 76 Not clear on who is required to report
- 
- 77 See previous comments.
- 

## ETHICAL ISSUES Other

- 
- 1 (same as above)
- 
- 2 Again - it would be nice to have education related examples for our students. We especially have problems with their masters and doctoral projects. The Department of Education required review has made it nearly impossible for them to do studies in schools. It is really a shame.
- 
- 3 All faculty, whether tenured, tenure-track, instructor, lecturers or teaching assistants should go through a training upon arrival at UH, which they can not opt out of, on ethical issues, discrimination on the basis of gender, race, physical disability, sexual orientation, etc. etc. We should be trained on what is legal, what is not legal or ethical, how to report, what the response will be from the university to those affected, and resources are available (for counseling, etc.). We should be trained how to handle these allegations when our students bring them to us, so we can help our students as well.
- 
- 4 All I remember is having to take some kind of required research ethics workshop hosted by [REDACTED]. [REDACTED] I actually had some research ethics questions that I was going through and hoping that I could address them at the seminar, but then we spent the entire workshop playing dress-up and role-playing various ethical scenarios. I'm sure [REDACTED] thought that she was being cool and fun and entertaining, but it was a complete waste of time for anyone who was actually hoping to get actual questions answered.
- 
- 5 Allow it to be voluntary since nearly no one needs it.
- 
- 6 Apart from what I received on the online program, I am unaware of any other sources, so my answer "not available" may not be accurate.
- 
- 7 As I read through this page, I feel I do not understand what you mean by "ethical issues." Do you mean everything mentioned in the previous pages (e.g., human subjects, etc.)? Do you mean Conflict of Interest forms only? Do you mean FERPA? Do you mean sexual harassment issues? The fact that I have to ask all these questions means my responses to this part of the survey are probably not useful to you.
- 
- 8 As I recall we received one two or three hour training session on ethical issues a few years ago. The training and examples focused on contrived situations that would occur only on TV and were completely irrelevant to my experience with research and education at UH and [REDACTED]. Training should focus on the real world, not the imaginary world.
- 
- 9 As support staff, I do not engage in ethics training or compliance, however, it might be important for staff to understand the ethical issues PIs need to comply with and how we might be able to assist.
- 
- 10 Aside from annually filling out conflict of interest declaration forms, ethical issues compliance doesn't typically arise in my department.
- 
- 11 Be clear on who to call and protect against retaliation.
- 
- 12 Better help when trying to find information. The staff at [REDACTED] in general are not helpful and seem incompetent with their work. I found it's easier to figure things out on my own than rely on what information the staff provides.
- 
- 13 Better training either in person workshops or online tutorials--and publicize these widely.
- 
- 14 CITI is fine.
- 
- 15 Classes on research misconduct policies might be helpful. A number of graduate students have complained about faculty plagiarizing their research but will not report this when the faculty member is the committee chair. [REDACTED]. [REDACTED]. These ethical issues need to be addressed.
- 
- 16 Departmental information meeting was a joke. [REDACTED] knows nothing of social sciences and seemed utterly uncaring about what we do. Why don't you hire someone who has skill, training and a broad-based understanding of university research, or simply release those of us who only do sporadic interviews with citizens from the clutches of this IRB.
- 
- 17 Do not recall having to attend training on ethical issues.
- 
- 18 Does UH have ethics training available? Never heard about any. Never seen any announcements about training.
- 
- 19 Enough said above.
- 
- 20 Ethical issues covers a wide variety of things. IT could refer to the treatment of students. We have some training to make sure we're in compliance with the Americans with Disability act. It could also mean following fair hiring practices. I've had some training in this, but many issues and questions remain. It could also refer to how we deal with our colleagues or when we should be a bell blower.
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- 21 Ethics can be tricky when it is a matter of opinion, but perhaps with proper training AND enforcement, it can enhance the campus.
- 22 Having a training would be a great thing on each campus for regulatory issues. I have heard through word of mouth from another teacher, but would have liked some type of in-service on what we are supposed to do. I have been approached to use my students as part of a study from another university...do we have to go through the UH Board for that or just research we do on our own campus? What constitutes research? Can I send a survey to my students or whole student body or does that need to go through the Board?
- 23 Human Subjects and research ethics are the only areas really relevant to my part of the humanities, and they don't impinge on my own research at all; but our grad students may conduct interviews with artists, curators, and other public figures. It's often difficult to articulate to them when and why they need IRB approval for such interviews, especially as most of them are with people who spend a lot of time acting and speaking in public anyhow. In general IRB procedures are not a good fit for humanities projects overall, and while I understand why that is, it might be useful to develop some guidelines for supporting ethical student research when human subjects interviews are concerned.
- 24 I am a scholar in Humanities; yet [REDACTED], for example. required all tenured faculty to be familiar with the above mentioned items (including ethical one) through online training. We all serve university-level grants committees and read proposals.
- 25 I am new here. All my training was provided by previous institution. "Not available" answer refers to "no experience"
- 26 I am very familiar with code of ethical conduct for my profession. I don't remember receiving specific training on ethics for the university or state. Maybe a short web-based information would help. Would want to know where to find the code, where to find procedures if I feel ethics violation has been committed.
- 27 I am very unclear about what constitutes a conflict of interest for faculty, and what the guidelines are for faculty in outside consulting/work etc. This information is hard to get. Should be clearer guidelines and an easily accessible site where the standard practices and expectations are posted.
- 28 I cannot recall any ethical training in all my years here. I suspect it is presumed that faculty are always ethical ...a rather dubious assumption- like all other assumptions
- 29 I do not know what this section is referring to, specifically.
- 30 I don't even know what the survey means by "ethical issues"
- 31 i don't invent things that could be commercialized and don't 'treat' subjects of research so this is generally not applicable to me.
- 32 I don't know what trainings are even available? I have taken ethics courses for researchers at other campus' but didn't realize this was available here. Would be interested to find out more...
- 33 I don't like the online RCR sessions. Too simple. Ethics are tricky, with so many factors playing in. The sessions don't get to this at all.
- 34 I have an ethical issue with the IRB. [REDACTED] called and talked to other IRB directors and interfered with my ability to obtain approval with joint IRBs. I know this for a fact. Of course this happened with [REDACTED] and not the present director, but really, how do you prevent this from happening again? I had a protocol approved by the leading research institution in the United States.
- 35 I have filled out the conflict of interest form in my Department [REDACTED] regularly. The other questions do not seem to really apply to my position as a [REDACTED] instructor.
- 36 I have never been provided with ethical training at UH, except for the optional online sexual harassment training I once completed--although I suspect few of my colleagues did.
- 37 I have not been notified of ethics training requirements at UH.
- 38 I have read the online the university's policy statements concerning ethical standards in research but I have limited experience with UH [REDACTED] since I have only been here for under 2 years.
- 39 I observed and heard from others that trainers inject their personal views into their comments regarding ethical personal conduct, rather than sticking to University rules. That seems inappropriate.
- 40 I only received training during the second [REDACTED] grant when it was required, but never since.
- 41 I put NA because I don't recall a memo on complying. Is there a yearly memo or something? Maybe they could send us one like they do with the election compliance and the substance abuse compliance. Maybe they could make a poster?
- 42 I rated this average because the CITI training is standardized. The ethical training here is as good as anywhere else.
- 43 I received ethical training as part of my graduate studies at another university, made available through the National Science Foundation. As far as I can tell (only been here 6 mo) the UH is sadly lacking in this area.
- 44 I say above average because our trainer is not on this island but he is available if we have questions.
- 45 I studied at [REDACTED] and at another research university where I was required to apply for IRB approval. Since working at [REDACTED] CC and UH [REDACTED], I've been confused about whether and when I am supposed to apply to the IRB at Manoa.
- 46 I teach an E focus course. The information provided for instructors of these courses has been very useful in both my teaching and research.
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- 47 I think there is a fine line between those of the institution and those of the individual PI's who really need to be responsible and insure they are treating their students, colleagues and stakeholders properly.
- 48 If I indeed received ethical issues training when I was hired 7 months ago, I'm not remembering it, which is problematic that it didn't stand out for me because I believe that I'm a very ethical person.
- 49 if the training and info. is there, i don't know about it. thus my confusion on these questions
- 50 Interactive training. Flow charts. Examples of common situations that are not black and white.
- 51 Is this different than IRB? I wasn't aware this was a separate entity with distinct training at UH
- 52 Is this the sexual harassment training? It was fine.
- 53 It is clear that there have been terrible problems within the Cancer Center and JABSOM, though UHM in general is not without sins. I think a major cleanup campaign is in order.
- 54 It is good to keep faculty informed across various fields (including arts and humanities) - please keep circulating brief information about on-going issues.
- 55 it would be nice to get feedback from the conflict-of-interest forms. It would be even better to have a box on the front of the conflict-of-interest form that says "no change from last year", and then we don't have to fill out the form again every year (and if you provide us with our old form, then it is easier to verify that everything still applies).
- 56 Mandatory training
- 57 maybe a quick, one time online course for researchers would be helpful that would introduce them to the ethics issues and resources available. I didn't know there were items until I searched for it on the Manoa site.
- 58 More information/training
- 59 More interactive sessions
- 60 More training and may be someone who we can contact to ask for advise.
- 61 Most of my training in ethics predates my time at UH
- 62 MS [redacted] / PHD [redacted] program provided excellent training.
- 63 My field involves a great deal more training in ethics than I have received from UH. I am comfortable with how I integrate ethics into my courses.
- 64 Never received any training.
- 65 No training. That could be considered problematic.
- 66 Not aware of training opportunities at UH.
- 67 Perhaps I don't know about this because it doesn't apply to my work? I don't remember any training for this subject.
- 68 Provide basic training and scenarios.
- 69 Provide urrent laws in email attachments
- 70 Providing effective information sessions about ethic issues and what we can do when we become a victim
- 71 reduce bureaucracy, increase competitiveness, encourage innovation, enable faculty and administrators to transcend mediocrity and inertia
- 72 Research/education ethical issues should be introduced to beginning faculty and research- and teaching assistants. To my knowledge, there is only a very basic introduction for TA's.
- 73 Same as before - because I don't enroll human subjects for study, many of the potential ethical issues and complications are not relevant to my work, which mostly involves secondary analysis of datasets. There are still some issues, of course (mostly surrounding disclosure and keeping the secondary data secure), but much of the training is not directly relevant.
- 74 Same comment on the standardized online training.
- 75 see above
- 76 Tell your H.R. directors that "just be nice" is not an appropriate response to criminal acts of privacy violations. I don't take the UH ethics bullshit very seriously. The UH failure to follow it's own policy on ethics, in my case, tells me I'm on my own when it comes to hard issue and all the balless wonders in administrative position can kiss my \_\_\_!
- 77 Thanks, [redacted]!
- 78 That administrators model ethical life on campus. Some live it otherwise and they become talk of the campus community. It is quite disturbing.
- 79 The "ethics" courses mandated at UH [redacted] are too often taught by faculty with too little knowledge and esperience. We whould increase attention to these courses, possibly by faculty developement programs.
- 80 The campus needs to have a academically free and research focused environment. People should not be curtailed in reaching out to professionals in the field to discuss ideas. This is essential to build a research portfolio. Procedures for formal communication should not be confused with informal communications. No where does it say that a faculty cannot reach out to industry professionals for research and collaboration discussions and this should be respected.
- 81 The CITI modules on ethics are insultingly mindless
- 82 The material on line was (eventually) clear. The in-person training was less useful because, again, the person conducting the training did not know anything about political science research.
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- 83 The NIH training modules are much better than that currently used by UH. Please add the NIH IRB training option.
- 84 The online training regimen was pretty good but nearly all of it was irrelevant to my field.
- 85 The only ethics training I've received at UH has been in regards to Title IX and mandatory reporting, and that was more about legal compliance than ethics per se.
- 86 The only ethics training received at UH is related to conflict of interest forms signed as an employee. Research ethics related to data integrity and proper research methods and fairness were covered through mentoring and NSF-required research ethics class offered by my professional association of my discipline, not by UH.
- 87 The problem is to get administration to act upon and according to ethical regulations. No filed complaint ever brought any results.
- 88 The questions in this section are too vague, especially considering the lack on training on ethical issues beyond specific issues involved in the CITI training modules for human and animal work make it impossible to answer these questions. I believe it would be wise to introduce a mandatory comprehensive training for all faculty on ethical issues related to research and the processes in place for addressing issues when they arise.
- 89 The training is great, but I am sometimes confused as to what the IRB is actually doing.
- 90 There could be more system training on ethics per Department and more support for that.
- 91 There is no training for faculty
- 92 There seems to be an imbalance: an over-abundance of ways and people to report / monitor the "wrong", and little guidance on what is / how to do the "right"
- 93 There should be a mandatory training for all PI's involved; nobody should be allowed to be a PI without the appropriate training on ethics, myGRANT, Quali, RCUH, etc. If this is too much to ask of a PI, then perhaps they do not have the time, commitment, knowledge, and skills required to fulfill their obligation.
- 94 There should be classes for faculty and administrators to understand the negative implications of what is considered unacceptable by the federal government with regard to research practices ie plagiarism, misrepresentation of expertise, fabrication of data, misappropriating funds, etc. In case, the Dean and director are extremely cavalier. Awareness of the role of the Research Integrity Office in enforcing these practices is important so it is understood that the practices are strictly prohibited. The process of intimidating/suppressing/oppressing/ignoring/trivializing these issues to come forward will ultimately damage the UH reputation. It can also negatively affect future funding opportunities for all of the UH.
- 95 These issues flow forth from the top. If leadership is lacking in ethical stature, this will be felt down the ranks. And there you have it.
- 96 This one is a bit confusing since it isn't about IRB approval. I assume this relates to the conflict of interest forms we sign each year, but there hasn't been any training associated with that to my knowledge.
- 97 This survey is painful
- 98 To me, ethical standards are obvious. To others, no amount of training will make them ethical. It's like comedy... you can't teach someone to be funny. Ethics or comedy, you can teach the rules, but you either have it or you don't.
- 99 Training
- 100 Training that goes beyond harassment issues.
- 101 Training was not through RMATRIX They do not provide any assistance
- 102 UH in general does NOT have any kind of welcome aboard package. A large amount of time is taken trying to find resources or fighting rules that are unevenly applied on purchasing, etc. There needs to be a web portal that is provided to new and existing employees that collect campus resources (CIS, credit union, OHR, ITS, parking, etc) into a single location. Too often it's assumed that you know this information or that someone remembers to show you where it is.
- 103 UH should make sure that no one can serve in the same committee for more than 2 - 3 years and direct the money to his and his close friends pocket for more than 20 years (see case above)
- 104 We fill in more and more forms to say that we don't have conflicts or ethnic violations, but faculty who violate rules have no problem signing these. The only answer is to somehow punish violators. This is common practice. The police give out tickets for a month to curb speeding and the IRS do audits to ensure compliance.
- 105 We get the training (although it is conducted at about a sixth grade level and is inordinately redundant and excessively time consuming, especially since it never matters in practice.
- 106 We talk in the department about the ethics of research--it is big part of my work at a conceptual level.
- 107 What little ethical training I received was not applicable to anything I needed to know. I've been in multiple general training sessions on sexual harassment, worked through online training certification, etc., but never had any training on lying, cheating, mis-treatment of colleagues, etc.,
- 108 When the administrator spoke to us, on the "lost" of the personnel, He mentioned that the financial losses were incurred by the office because of some University programs that had run a deficit. While administrators have the responsibility for these decisions, this did not seem "fair".
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### Add any other areas not listed here that are relevant to your work.

- 1 I do mostly [REDACTED]...analytical work. One of the PRIMARY reasons I do analytical work rather than human subject behavioral research is BECAUSE of all these rules and regs. I'm much more content with my pad and pencil.
- 2 material transfer (biological and genetic specimens)
- 3 Such odd questions that don't have any relevance to me and my classes. Why am I getting this survey?
- 4 Compliance with the Hawai'i State Department of Education research procedures, approval, and protocol.
- 5 DAR Special Activities Permits (scientific collection permits): the slow down in this process stalled research of many faculty in 2014
- 6 FERPA - familiar with and relevant to my work
- 7 Shipping of hazardous materials
- 8 I have found the Department of Education protocols to be cumbersome. I don't know that I need additional training, but I wish they would streamline and increase the timeliness of their process.
- 9 (FYI, some of the "not applicable" boxes above would be more accurately summarized by "not familiar with", but this option was not available
- 10 Ships, airplanes and helicopters....
- 11 There was no option for "not familiar with, possibly relevant". I would have chosen this for: - currency movement between countries - NEPA - UAV
- 12 FERPA. I am very familiar with the regulations, but most other faculty I know are not. This is a problem.
- 13 Customs
- 14 Family Education Rights and Privacy Act
- 15 I wasn't given the option to select not familiar - regardless of it being applicable to my work. I would have chosen 'not familiar- for 11/12 for these
- 16 FERPA
- 17 again, no easy to find resource for finding regulations, updates, support for any of these subjects.
- 18 Hiring workers and working with colleagues in other countries
- 19 Ordinary people talking about ordinary things in their daily lives?
- 20 USDA grants require knowledge of flood zones. I'm unable to find this info for Hawaii
- 21 JUst a question--HIPPA or HIPAA?
- 22 Chapter 343 requirements.
- 23 A good, consolidated list of current (and upcoming) rules relating to interisland transport relevant to moving live animals, plants, soils, fungus, microorganisms, etc. between collaborators between islands would be helpful. We currently use the most cautious approach of only non-viable organisms moving between islands without inspection, but have been met with blank stares from HDOA officials when requesting inspection of materials that may or may not be restricted when transporting material for collaborators outside our field of expertise.
- 24 I test [REDACTED] and have a [REDACTED] License from Hawaii Dept. of Ag.
- 25 Physical health and safety issues concerning performers in performance and rehearsal situations Cultural safety issues Cultural intellectual property rights Sexual, racial, religious and other forms of discrimination
- 26 I have worked with RCUH to handle monies collected from students for a Faculty-led summer study in [REDACTED] program.
- 27 None of the questions asked have been applicable to me. I am inundated with forms and questionnaires at UH. Can you please send them to people to whom they apply?!
- 28 Work at sea on research vessels and in manned submersibles
- 29 State permits/exemptions for collecting plants or animals for instructional classroom use.

### OTHER COMMENTS

- 1 Create two compliance tracks: one for instructional/classroom use and one for research.
- 2 UH campuses need to assert their academic freedom policy and faculty should be free to do their research and outreach without fear of intimidation.
- 3 This is confusing. It says, "select most important" and then "all that apply."
- 4 The several trainings that I attended on ethical matters or research were provided by unqualified staff. Several trainers made statements that were either incorrect or offensive. If anything is done to improve compliance issues, training must be provided by competent expert who have a first hand understanding of the issues discussed. The issue of confidentiality and protection of personal information is an ongoing issue and because such threats are not spectacular like terrorist

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- attacks, most people view them as not serious.
- 5 None
  - 6 I don't really deal with regulatory requirements in any way, so I don't think I can answer what would best help those who deal with these issues.
  - 7 The issues raised in this survey are so irrelevant to what I do that most of the time I didn't understand what I was answering.
  - 8 I think an orientation training required for ALL new faculty would be very helpful. But this should be part of their campus orientation, not something they find out they need to take from the lab coordinator!!
  - 9 ORS should focus more on providing service to the field, especially when it comes to compliance. Too many times they've commented that they do not have enough staffing or receive enough indirect costs to justify their assistance to the field. They seem to pick and choose which campuses and PI's get the most service. The fact that ORS does not have any support staff solely dedicated to the community colleges should send a loud and clear message where the priorities lie; not with the two-year institutions. If that is the case, we should not have to pay indirect costs for services we do not receive.
  - 10 Provide training in evenings or weekends so that faculty does not have to take class time away from their main function of teaching. Many times class time conflicts with informational sessions.
  - 11 I may not be the best to ask these questions of. I only interview historical subjects who are still living, or persons familiar with historical subjects or issues.
  - 12 Many of the required tasks are not discussed prior to them being due or past due - I think that information about the requirements for a certain position should be made very clear.
  - 13 Between compliance and inefficient purchasing and travel documents... UH creates layers of wasted time and money for everyone.
  - 14 As requirements change, training should be for both existing and new researchers/instructors.
  - 15 All are important and need to be improved. Training is a real issue at UH [REDACTED]
  - 16 Instead of producing a plethora of documents for researchers and teachers to follow, please provide support by hiring professional and experienced staff to train and enable research at UH instead of hampering and disabling research at UH.
  - 17 The main issue is that we are over regulated due to a system desire to CYA and not real need. Often staff in ORS and ORC don't have a clue to about requirements or at least can't convey to users. Need to hire better qualified people for these jobs. Also some assistance in correcting issues would be helpful rather than just kicking forms back with minimal guidance. Often we just have to make wild guess as how to answer questions or fill out forms. IACUC is particularly bad. We need financial support for compliance and this should not fall to the individual unit or PI to take care of.
  - 18 But I would HATE training.
  - 19 Provide more funding and resources for IRB office.
  - 20 Reorganize the OCR and start over, including replacing the [REDACTED] and [REDACTED]. Make the office more service oriented and transparent. It now operates as an enforcer of regulations and the keeper of information, and is not willing to collaborate with others. All decisions must come from the top and anyone who dissents are purged.
  - 21 see above
  - 22 I would ask that tenured faculty, especially full professors, who have been around for decades be obliged to review sexual assault and harassment policies, but also policies on bias of any kind (racial, gender, age, etc). Some of our older faculty need to be reminded that today's generation will not put up with othering of any kind.
  - 23 Cannot assume that all faculty and staff are fully knowledgeable about ethical and compliance protocols. Assistance for filing compliance applications and documents would be great!
  - 24 Enable research.
  - 25 There is an urgent need to assist young investigators in obtaining permits in a timely fashion. UH could focus more on facilitating compliance to reasonable, well-documented regulations, rather than arbitrary rules and "one size fits all" regulations. Over-regulation particularly in the microbial acquisition and use area is a serious problem. Permits are not provided in a timely fashion and the review system is cumbersome, designed to fail. The reporting system is particularly cumbersome. When young researchers cannot obtain permits to do reasonable research in a timely fashion, the entire University of Hawaii suffers. Some give up, others leave. UH does NOT have a good national reputation in this regard, and such impediments foster discontent and difficulty in recruiting new faculty.
  - 26 Three people [REDACTED] in the compliant office don't really know or care enough to be biosafety officers and director in the compliant office. These people should be reassigned to other duties. Perhaps, [REDACTED] should appoint other PhD researchers at UH (a new ongoing task force to receive ongoing complaints) to be directors and oversee all this, with some power to these people to fire or reassign incompetent staff from the compliant office; this will ensure longterm oversight and maintain efficiency for UH researchers. Or maybe the IBC can be assigned such power, but we have to make sure that [REDACTED] does not manipulate stock the IBC with many of his friends. My worry about the current task force and survey is that once all this quiets down and nothing drastic is done, we will go back to

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and be left with the same crap in the compliant office. We need something ongoing as oversight to put continuous pressure on the compliant office to improve; IBC member can only suggest to ██████████ of important issues relevant to UH researchers, but ██████ does nothing most of the time and does not even show-up to the IBC meetings anyway, and the IBC only meets once a month with limited time to complain about issues important to researchers to deaf ears... Some drastic changes are needed!!!

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- 27 Cut down the nonsense. Don't hire any more people to create or process unnecessary paper or electronic forms.
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- 28 Stop telling faculty and PI s that we're the problem when it's the disjointed, poorly organized and often incoherent system that is the heart of the problem, I have wasted so much time on the stupid forms including totally dumb stuff like being told to submit an electronic form when it isn't form fixable and actually has to be submitted in hard copy. Or not having any one who actually knows disposal rules for toxic substances and tells me to look it up on some other univer-sit's website. When zi do they say it's fine even though they don't know. Or they don' approve it even though they don't know. Good grief.
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- 29 IRB procedure should emphatically protect human participants. At same time, the IRB and office should not impede safe research process at UH. The IRB should facilitate and help the university community to protect human participants and recognize that researchers have deadlines and are coordinating numerous aspects of work. Having a more service ori-entation towards researchers and their work and recognizing we are all part of the university would be beneficial. Being asked to divide our modifications to submit over several months to not overwhelm them with changes, rather than to understand that at particular phases of research, more modifications are expected, does not show an understanding of our research needs nor a service orientation to the research community of UH. That comment showed that researchers are supposed to shape their research for the IRB's sake, while we have grant requirements and timelines. Some projects generate more paperwork and materials to be reviewed, yet we have received comments about the quantity of pages we submit and that reviewers don't want to read that much. We have received comments and questions that suggest that staff or reviewers may not have read or are not familiar with a project. One fix is at other universities, a researcher may be present at an IRB meeting discussion to answer questions that the IRB have. Some issues would be immediately re-solved by this type of communication. Training or information on the website of how to present the applications to help the IRB while still meeting the needs of the research project could be useful.
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- 30 Less surveys. More time for research and teaching. Thank you.
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- 31 More (other) hands is nearly always the best answer.
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- 32 A few years ago the link between UH & Department of Education (DOE) was seamless. Now it is seriously broken. I know that the problem is in the DOE, but the time frame for approvals has made it nearly impossible for student in the DOE to do relevant research. I hope that our UH unit would reach out more and try to help solve this devastating problem!
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- 33 the Information re: research compliance mandates and requirements should be easy to find on all hawaii.edu web pages.
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- 34 UH needs an Ombudsman to deal with a range of issues regarding compliance.
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- 35 Where environmental documents are required, there is no assistance in getting those done or in submission. At one point, I had a VP Administration refuse to sign an EA that I had prepared for a project. And the same VP refused to sign a required air emissions permit (for Hawaii DOH) for a project. Unhelpful to say the least. The biggest problem I have had is in non-responsiveness of Office of General Counsel. I have to obtain Rights of Entry to conduct field surveys and it can take months to get a response and, in one case, it's been 18 months waiting for a determination and no likelihood that I will get a response. The funds for that work are long since expended on other field research sites.
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- 36 Give up. Disband the current office, or at least get rid of the upper echelons. Get in young, PhD level professionals with backgrounds and qualifications in the field. I have no conflict of interest in saying that because I don't know any PhD level professionals like that. However, the people in the office now don't inspire me at all. They're not qualified to be in the office.
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- 37 Name and phone number of person who can answer questions.
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- 38 Not sure how effective ORS and ORC would be working together.
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- 39 ORC and PAM are practically non-existent. I cannot think of one thing they have done to help research, the institution or the UH reputation. They are never present at anything except parties and that seems to be what they spend most of their time doing. Planning parties and trying to fix things that arent broken, instead of tackling the problems.
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- 40 I believe all faculty need regular updates on changes in the compliance regulations that are relevant to work performed at UH
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- 41 More training is needed and more support on open data sharing.
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- 42 Devolve requirements and training so that both are relevant do the researcher's discipline and research tradition.
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- 43 The issues that I and some of my colleagues run into at UH ██████ involve working in foreign countries. We hire people to drive us, to provide manual labor on our projects, to cook for our crews, etc. Sometimes we have students who pay fees in order to participate in the projects, and those fees are used for the students' basic support (food and lodging, etc.). These transactions are conducted in cash, and while we get receipts for everything, we consistently run into enormous

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frustrations when dealing with RCUH and the bureaucracy at the university. Obtaining a cash advance from a grant to pay expenses that are part of that grant budget and common in our field should not be the near impossible task that it is. And being asked, year after year, for the US tax ID numbers of indigenous villagers working with us in foreign countries is ridiculous. I realize of course that the way our projects work is unusual at UH but it has been going on here for decades. The bureaucracy's inability to deal with different situations is so frustrating that I am personally unwilling to apply for federal grants if they have to be processed through RCUH.

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- 44 perhaps most helpful would be a central repository of training records for all training so that we could use the web to just look up and see who needs what training when. It could also have our IBC and IACUC protocol exp. dates as well
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- 45 Place a limitation of 2-3 years limit to BOD and Committee Membership on all UH and UH related activity to avoid conflict of interest and corruption that benefit and being controlled to this day by professors and emeritus professor at UH. ██████ and ██████ are examples of a continuous problem in this regard.
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- 46 assistance by knowledgeable people, not bad user interfaces. Have user interfaces evaluated and approved by Human Computer Interaction researchers BEFORE forcing faculty to use them.
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- 47 As someone, who works in the humanities, I've never even heard of all these regulations.
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- 48 I would say that there is a culture of "pre-emptive compliance" at UH, which often involves carrying out draconian compliance procedures that are not required by the Federal government or Federal agencies just in case.....
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- 49 All of this should be standard and already in place...
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- 50 We used to have personnel in the Office of Research and Compliance System (ORCS) who were helpful, proactive and most of all they offered a research friendly atmosphere. Furthermore, ORCS personnel showed respect and valued the experience and the knowledge of the PTs and their staff had, with relevant to their work. For one reason or another, there has been a drastic turnover of personnel in the ORCS. Some of the proactive personnel of that office were either fired or terminated. As a result the current atmosphere in the ORCS is far from research friendly. Their current approach seem to be over-regulation and/or micromanagement and dismissal of the years of experience, knowledge and the skill sets that the the PI s and the staff have working in their labs on campus. If this type of 'not people-friendly' not-proactive types of practices continues, our PIs will have a hard time getting research grants from funding agencies to do challenging frontier type research that will put this university on the map of excellence. The personnel on the ORCS needs to validate and respect the knowledge and experience that the PI s and the staff have instead of make the PI s and the staff feel that they don't know what they are doing in their own labs.
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- 51 Classify the labs into different categories according to their safety risk and inspect them in different time schedules.
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- 52 I am not sure that the ORC is sufficiently in tune with Faculty needs. There seems to be a "police" attitude rather than a facilitating attitude, this should change. Many of the infractions that probably occur in compliance are through ignorance, not intention. Training workshops for these things tend to be too lengthy for faculty to attend or only at limited times. Perhaps some canned presentations that are served out on the web and can be viewed at any time might help participation.
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- 53 Unless you're a specialist, these forms are impossible to accurately fill out and the lack of online help makes guessing rampant.
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- 54 It has been my experience that while staff are very concerned about compliance, it is not always a priority for PIs and/or the leadership. It would be great to know and to reassure staff that while we get the brunt of the push back on compliance, there might be a position/place higher up where we can voice our compliance concerns without fear of retribution. Staff underneath PIs are constantly in an awkward position to enforce compliance.
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- 55 Please don't waste faculty and graduate student time on orientations that are completely meaningless. For those of us in the non-experimental, non-medical, non-animal fields of inquiry, no longer try to interfere with irrelevant information, protocols, and meetings.
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- 56 I am afraid that the whole mentality would have to change, so that people in compliance office understand their role at UH. They should provide training and support for researches, not just being another obstacle, sometimes impossible to overcome. Being strict does not mean being nebulous and unreasonable and stopping people from working just because you do not understand it or you do not want to make any effort to solve problems. They should take responsibility of our safety and that means training us FIRST and THEN making sure we are doing everything right. My impression is that their actions (this is mostly for biosafety) are erratic and ineffective, most importantly - UNSAFE at the end because we are confused and do not have enough support from people that should provide it. With few exceptions, I do not have any confidence in competency and good will of our biosafety people. They need to reorganize their system from the very bottom to the top.
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- 57 More funding and support from the top would surely help these important and vital programs thrive. It would be great if that was the outcome of this survey.
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- 58 none at this time
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- 59 While the new research compliance website is pretty, it hasn't made itself very visible in searches. The idea to do more

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things online (BSP2) form is great, but the current execution has made the process more cumbersome. More information is being asked, and the final is a printout of the webpage, which is not “pretty” and longer in length. The move should be to make things simpler, not more difficult.

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- 60 microorganism permitting system is broken
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- 61 If at all possible reduce the administrative burden to deal with numerous procedures, approvals, protocols, their renewals, training, and retraining. In a larger lab, a PI absolutely needs a dedicated person - it better be a skilled post-doc - just to keep up with all these - paid, of course, from scarce research project funding. The overall time required for these processes is enormous - yet we are expected to seamlessly fit these efforts into our research time and use research funds to pay for time spent on these procedures.
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- 62 ORS is painful and difficult. Don't mix ORS and compliance. The compliance office is generally small enough to be well run. Don't mess with it.
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- 63 Hires people who cares and are willing to help PIs.
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- 64 Have an annual “compliance day” when all in a unit get training completed. Those from other cultures need more awareness of our “culture of safety”.
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- 65 A change in attitude -- it seems that many of the compliance offices are more concerned about keeping UH in compliance than helping the PI's be in compliance. A few exceptions -- radiation safety and IACUC are actually quite facilitative. UH MUST sort out cost sharing between UHM and other UH institutions. UHM pays for most regulatory compliance and supplies the staff yet the system institutions benefit without paying their fair share.
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- 66 This survey did not contain any questions about emerging areas related to data management, public access to research data, long term data archiving and data security, with the exception of HIPPA. A data management plan is a required element of all NSF proposals and NIH is adopting new requirements for contributing data to national archives and/or appending research data to publications. Many institutions are taking steps to creating institutional archives of data or developing methods to tag data with digital object identifiers (DOIs). Guidelines about access to computational or research instrumentation by foreign nationals would be an important aspect of training.
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- 67 Assisting? What a novel idea.
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- 68 an integrated electronic system would appear to be easiest to tailor to the needs of a range of faculty.
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- 69 The staff I have had contact with are patient and dedicated individuals, always willing to help. I suspect that they and their office, like a lot of entities at UH, is underfunded and overworked, and that is why things haven't always been as good as they could be (with the recent institution of online training, “CITI”, being the most obvious example. I believe staff are working to improve matters. Probably the most useful suggestion the Faculty Survey could give would be to hire more people, and then after that, hire a person with an interpretive social science background as well.
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- 70 Having the training at orientation would be helpful, perhaps, to identify areas that need certifications or requirements, but it is unlikely that a new faculty member would know at the time. Are grants/proposals read for potential issues in compliance? If so, is the PI contacted in these cases? And further, is there assistance available to explain what is needed? Perhaps what is needed here is additional personnel to assist PI's with this.
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- 71 Better training. Not a boring lecture.
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- 72 One tends to learn these requirement from others practicing in the field. And if they have learned it in a similar manner, there is a high probability that some details are being lost in the process. Why isn't there better training for faculty across the board?
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- 73 I research ombudsman to help faculty deal with unreasonable IRB requirements.
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- 74 It would be wonderful if the IRB (CHS) met more often, and if we were able to submit forms online (rather than printing, photocopying and mailing hard copies).
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- 75 Our current system is fragmented. Other institutions FACILITATE regulatory requirements for researchers with the implicit understanding that this leads to more productive research by streamlining the process of fulfilling requirements, and streamlining the access of information. Many also streamline the information itself to highlight what is relevant for particular areas of research. That message has not reached the UH offices in charge of regulatory issues.
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- 76 Training/programs for postdocs.
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- 77 An integrated electronics system for compiling application and training information would be very helpful for storing relevant documents.
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- 78 Why doesn't UH do all of these things?
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- 79 Make sure to minimize the time and effort required by a faculty member to comply with regulations. Most administrators never consider that every minute spent on fulfilling rules and forms means less productive time spent on research.
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- 80 The leadership at the Animal Colony at ██████████ does not understand that a particular mouse mutation pertaining to HIV can not be transmitted to humans and creates unnecessary extra costs for scientists trying to conduct research. In addition, they make it nearly impossible to import mice from other mainland research institutions that are required to conduct certain experiments. Part of the issues are lack of knowledge about these animals leading

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to unnecessary fear and too many precautions. They may need some remedial training so they have more reasonable concerns, not ones that are imaginary. And despite documentation demonstrating the safe use of these animals, they refuse to believe, are inflexible and persist on their own beliefs. This makes it difficult for scientist at the [REDACTED] to conduct their research at the [REDACTED] Campus. Please create a survey about that, specifically for the [REDACTED] scientists.

- 81 IACUC applications/requirements have become conflated with other lab safety/risk exposure requirements - this is a mistake - IACUC is already too complicated without adding other levels of complexity. Recent memo from [REDACTED] regarding consequences that might result from future accidental fish deaths was aggressive, misplaced, inappropriate and displayed no sense of support for UH faculty. This person should be retrained or replaced. Dive safety - The Dive Safety Office (DSO) has taken on a life of its own. Training requirements for dive certification are way too extensive and onerous and have more to do with validating the role of the DSO than ensuring safety of UH personnel.
- 82 Be very clear re who to call and how to contact them. Those employed by multiple entities need to know who to report to and which requirements take precedence in particular situations.
- 83 On line recertification process for many of the compliance documents is a blessing.
- 84 Increased staffing / responsiveness from IRB staff
- 85 I do want to emphasize how helpful the particular IRB person whom I most often deal with has been. She discusses my questions professionally and courteously and has always followed up promptly by v-mail or e-mail. I really appreciate the aloha.
- 86 There should be an online IRB university course coupled with e-updates to ALL faculty, staff, and students. I've been here 15 years and never heard of any IRB changes in policy or procedure. It's easy to do. However, I really do APPRECIATE the emails letting me know that my application is in need of renewal. THANK YOU so much for these. The current IRB staff is much better than [REDACTED] and I do thank whoever made that possible. It's more professional and less buddy oriented.
- 87 A personal visit annually from someone familiar with both a wide range of requirements (and associated training opportunities) and how experimental work is actually done might just convince me that the University actually cares about the requirements and help me figure out which are actually necessary and how to most easily satisfy them.
- 88 Thank you.
- 89 Please straighten out inherent conflict between maintenance of subject confidentiality and UH [REDACTED] fiscal mandate to collect tax forms for any subject incentives. Other universities only require these forms when the subject incentives rises above a certain threshold and there are guidelines that these forms be held in investigators locked file and not submitted to fiscal in department, college and university systems.
- 90 Interaction and collaboration with the DOE, which has their own compliance procedures. Would be nice to complete ONE set of regulations.
- 91 Reduce the amount of repeated trainings (please!). Have staff fill out the forms. Speed up the Dept of Ag.
- 92 UH needs to understand that not all human research is the same, and thus there should be allowance to variation in requirements more than there is or else they will be ignored or compliance will be faked.
- 93 More competent staff at UH CHS would benefit research here.
- 94 In general, problems with compliance procedures are not easy to correct at UH. It might be useful to have an ombudsman who could distinguish the quite silly, common, issues from the true concerns and arrange corrective action.
- 95 If compliance offices merely act as police (e.g. "no, you can't do that, you need to go away and fill out a large number of forms") the incentive for taking on certain types of project is diminished. Ideally compliance offices will be problem solvers (e.g. "leave it with me, don't worry, I'll sort it out"), insulating the PI from these issues, allowing UH PIs to focus on writing proposals, getting money, and doing work.
- 96 As far as I know, there are no research compliance issues related to the research that I do or my students do. Perhaps I am wrong, in which case that would be a compliance problem.
- 97 Anything to reduce costs in faculty time.
- 98 I repeat earlier comment that our biggest problems are with functionaries whose only concern is staying out of trouble, not getting the job done expeditiously and with the interests of researchers and UH success in mind. The system needs to push everyone on the service side to be mindful of their service being not just lawful, but to make the system run efficiently, particularly being timely and helpful to the research tasks, and hence to the larger issues of success for UH research endeavors.
- 99 A public Laulima site could be used well for this work.
- 100 Glad to see progress on this! Thank you to the members of the RCTF.
- 101 ORS should not require compliance at the proposal stage, but only to release the funds. We put in many, many proposals that are not funded and regulatory compliance is an enormous hurdle for every single proposal. It discourages faculty from applying because of the paperwork burden.
- 102 Work on building the infrastructure for a "community of researchers" at UH who can work together to conduct research and resolve practical and ethical issues that they are facing in their work.

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- 103 I would recommend fostering a better attitude toward PIs regarding compliance issues. Staff should see their roles as assistants and professionals rather than as gatekeepers.
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- 104 Work to lessen, not increase, the paperwork burden on faculty. The advent of systems like Quali and MyGrant have significantly increased paperwork workloads. If Compliance could actually give faculty more help, this would be a refreshing and welcome change!
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- 105 most are not applicable to my work, but i have checked what seems to be most helpful were I to need to apply for permits and permissions under any of the various regulatory requirements covered herein.
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- 106 Put USABLE info online.
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