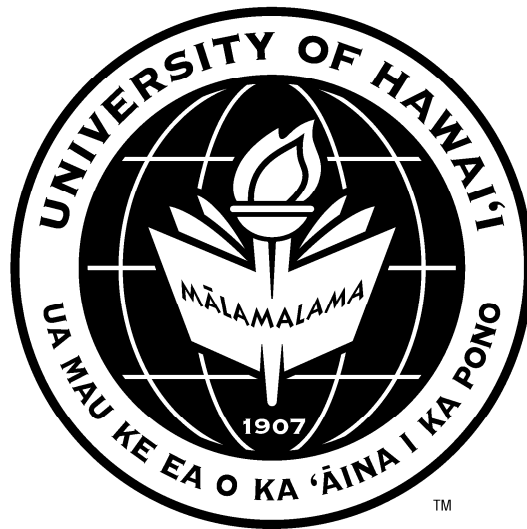


UNIVERSITY OF HAWAI‘I SYSTEM REPORT



REPORT TO THE 2018 LEGISLATURE

Report on
Technology Transfer Activities
2017

Act 38, Session Laws of Hawai‘i 2017

December 2017

REPORT TO THE LEGISLATURE ON TECHNOLOGY TRANSFER ACTIVITIES
PURSUANT TO SECTION 3, ACT 38, SESSION LAWS OF HAWAII 2017

Act 38, Session Laws of Hawaii 2017 confers upon the University of Hawai‘i (UH) the responsibility to ensure the ethical use¹ of its resources in technology transfer activities sponsored by UH. Prior to Act 38, the State Ethics Commission applied and interpreted the general provisions of the State Ethics Code to determine whether technology transfer activities conducted by any state agency -- including UH -- were permissible. Under Act 38, technology transfer activities and transactions sponsored by the University of Hawai‘i are subject to its managerial oversight, and its technology transfer activities must comply with the compliance framework, procedures and policies approved by UH. Act 38 sunsets on June 30, 2022. This report is submitted pursuant to Section 3 of Act 38.

I. Background

By clarifying that the ethics principles set forth in the State Ethics Code will be applied and interpreted by UH to technology transfer activities its sponsors, Act 38 advances its stated purposes to (1) facilitate UH’s contribution to economic development and employment diversification for the State; (2) maintain UH’s ability to compete for extramural funding to conduct applied research; (3) attract entrepreneurial faculty, researchers and students; and (4) draw upon UH’s existing compliance infrastructure and experience managing financial conflicts of interest in connection with federal research funding to develop a compliance program for UH-generated technology transfers that is tailored to the unique aspects of a public university.

Technology transfer is defined in Act 38 as “the process of transferring scientific findings from the public sector to the private sector for the purpose of commercial development and application for personal or financial gain.” Technology transfers constitute a relatively infrequent, but strategically critical, phase of the overall research enterprise at UH. Most products of university research are freely disseminated and shared among the academic, research and teaching communities, subject to copyright protection for the author. Comparatively fewer research products have potential commercial value. Even a smaller portion of those products may actually be feasible to manufacture on a commercial scale, may be financially viable because a market is there, may fit the investment profile of third parties with investment funds, and may attract the entrepreneurs to build a successful business. The early stages of a startup company built around a university discovery are high risk.

II. Technology Transfer Activities of the University of Hawai‘i.

¹ The phrase “ethical use” of University resources in technology transfer activities as used in this legislative report concerns conflicts of financial or organizational interests, conflicts of time commitments, or conflicts between public purposes and private benefits that may occur when University resources are used in concert with private resources to promote the commercial returns to University-generated inventions. The University does have oversight programs, policies and research protocols to assure that laboratory animals used in research are ethically and humanely treated, and that human participants in research projects are protected and fully informed of the risks and options to participation. This Report does not address those kinds of ethical issues involving University research.

Technology transfer activities at universities are often described as phases in a cycle: 1) faculty who are conducting research discover a potentially patentable invention; 2) the invention is disclosed to university administrators; 3) if the university believes that the invention has commercial promise, it will spend university resources to apply for patent protection; 4) if a patent is awarded, university staff will engage in marketing efforts to “transfer” the intellectual property rights to an interested business entity; 5) under the negotiated license, the business may pay the university a periodic “maintenance fee” for the continuing right to exploit the patent, the business may pay the university a portion of any revenues generated by the patent as royalties, and the business may give the university a negotiated number of equity shares in the company. Any revenues received by the university pursuant to the license of the patent are then reinvested into the research phase of the technology transfer cycle to support further discoveries.

In recent years, the University of Hawai‘i made a strategic decision to more actively pursue commercialization of its research products. One of the four strategic directions for 2015-2021 is the Hawai‘i Innovation Initiative. A specific set of tactics was developed to advance innovation and entrepreneurship within UH and the community. In particular, UH is committed to introduce new approaches to commercialization and technology acceleration through more flexible licensing, implementing a proof-of-concept accelerator to nurture UH-generated discoveries, and engage in greater community outreach and internal awareness and promotion.

Active support includes, for example: providing hands-on entrepreneurial training and mentoring to startup companies that are built around the UH invention and that rely on UH affiliated personnel, e.g. faculty, research staff, as “key personnel” in the startup. In selected cases, the University of Hawai‘i may directly invest in a company that holds UH-generated intellectual property.

Through the Office of the Vice President of Research and Innovation, UH reached the following milestones in its technology transfer program:

1. A structural reorganization, effective July 1, 2017, created the Office of Innovation and Commercialization (OIC) within the system-level Office of the Vice President for Research and Innovation. The OIC will assume responsibility for the revamped technology transfer program and expanded economic development program, which was handled by the former entity known as the Office of Technology Transfer and Economic Development. Under OIC, one subunit (Office of Technology Transfer) will be tasked with patents and licensing and the second (UH Ventures) will handle economic development and commercial investments.
2. In August 2017, the UH Board of Regents authorized the appointment of new director for the Office of Innovation and Commercialization, who is scheduled to join UH in March 2018. The incoming director has extensive technology transfer

experience based on prior employment in technology transfer programs at both Stanford University and the City University of Hong Kong.

3. The University of Hawai‘i formed a Hawai‘i Limited Liability Corporation named “UH Ventures, LLC” and duly registered the LLC with the Department of Commerce and Consumer Affairs on September 1, 2017. This limited liability company is controlled solely by UH and is a useful corporate form to insulate the University from risks inherent in startup ventures. The newly formed corporate entities and subsidiaries will also be used to support accountability and the mitigation or management of potential conflicts of interest.
 - a. UH Ventures, LLC will replace the Research Corporation of the University of Hawai‘i as a partner in an existing Limited Partnership that provides venture capital funding for start-up companies accepted into the University’s XLR8UH accelerator program.
 - b. UH Ventures, LLC will also enter into a management contract with a third party to help operate the XLR8UH program and provide other consulting services.
 - c. UH Ventures, LLC may create special purpose subsidiaries to compartmentalize specific investment decisions.
4. The University of Hawai‘i entered into a collaborative agreement with Arizona Technology Enterprises (AzTE), an organization conducting technology transfer activities of Arizona State University. This collaboration enables UH to utilize AzTE’s much broader and developed marketing reach to promote selected inventions and discoveries in its research portfolio.
5. The new Office of Technology Transfer (OTT) expanded its educational outreach on UH’s technology transfer program to faculty and researchers on every campus (UH Mānoa, UH Hilo, West O‘ahu and the UH Community Colleges).
6. The OTT hosted two showcases of UH technologies for the Honolulu business and innovation community. The technologies included MRI correction technology; blood volume assessment; Miracle lettuce; secure bi-directional data transmission; Inflammatory Bowel Disease treatment; a radar-based occupancy sensor; and Alzheimer’s treatment from corn silk extract. Several of these technologies are held by startups that have made it through UH’s XLR8UH program.
7. The OTT implemented a new online disclosure form for UH faculty and researchers to provide a more convenient and efficient way for inventions to be submitted and tracked.
8. Notable licenses issued this past year include:

- a license for a bioreactor for microbial gas fermentation to an Italian biotechnology company specializing in renewable resources.
 - a license to Apple, Inc. for software that can simulate battery degradation.
9. In 2016-2017 approximately 50 inventions were disclosed, approximately 11 U.S. patents were issued and four license agreements made. The number of U.S. non-provisional patent applications filed also increased from the previous year. The inventions were generated by different units at UH: College of Engineering, College of Social Sciences, Shidler College of Business, College of Natural Sciences, College of Tropical Agriculture and Human Resources, School of Ocean and Earth Sciences and Technology, Daniel K. Inouye College of Pharmacy, and the College of Agriculture, Forestry and Natural Resource Management.
10. In November 2017, UH’s startup accelerator, XLR8UH, was named as one of only twenty national winners of the U.S. Small Business Association’s (SBA) Growth Accelerator Fund competition. This marks the third year in a row that the accelerator has won the award and builds upon the national recognition garnered by XLR8UH in 2017, which also includes being named one of the top 30 accelerators in the country by *Forbes*. Launched in 2014 as a public-private partnership between UH and Sultan Ventures, XLR8UH has mentored and trained five cohorts consisting of 24 companies.

III. Development of the regulatory framework and research compliance program for technology transfer activities at the University of Hawai‘i

As noted above, Act 38 does not exempt technology transfer activities from all ethical oversight; it shifts the responsibility for that oversight from the State Ethics Commission to the University of Hawai‘i and requires it to develop a “compliance infrastructure” and apply ethical principles and policies for UH-sponsored technology transfer.

In developing its own compliance framework, UH will draw upon and blend principles and conceptual frameworks from two sources: the State Ethics Code; and relevant federal conflict of interest and organizational conflict regulations.

A. State Ethics Code, HRS Chapter 84. Although University of Hawai‘i technology transfer activities are now nominally exempted from the scope of certain sections of the State Ethics Code, UH will apply several underlying ethical principles in the State Ethics Code to analyze circumstances and structure management plans where public resources are used to produce both public and private benefits.

As explained in an Advisory Opinion issued by the State Ethics Commission in 1992 (Advisory Opinion 92-2) the State Ethics Code does not *per se* prohibit technology

transfer arrangements that involve some degree of conflict of interest or private financial gain so long as the State's interest are adequately protected.

The University of Hawai'i intends to enforce State Ethics Code principles, including the following:

- To justify the use of University resources--such as faculty time, laboratory facilities, administrative support and funds -- the proposed technology transfer activity must potentially generate sufficient benefit to the State or to the University of Hawai'i. In other words, UH resources may not be used where the sole beneficiary is a for-profit entity and where neither the State nor the University has any financial interest in the entity, nor is there any advancement to UH's mission as Hawai'i's only institution of public higher education.
- To adequately protect the interest of the State or the University, any "new value" created by the technology transfer activity must be allocated among the participating interests—the inventor, UH, the general public, any third party participant -- through "arm's length" negotiations free from conflicts of financial interest and loyalties.
- Where conflict of financial interest, time commitments, or fiduciary loyalty cannot be avoided entirely because of the nature or structure of the underlying business undertaking, the conflicts must be actively managed by a mitigation plan.

B. Federal regulations on personal financial conflicts of interest, and organizational conflicts of interest.

Since the 1980s, UH has used and updated an internal set of its executive policies and administrative procedures that implement the federal regulations on research integrity or conflicts of interest, 43 CFR, Part 50, Subpart F (Revised in 2011) (commonly known as the Financial Conflict of Interest regulations). These federal regulations are intended to promote objectivity in research supported by federal Public Health Services (including NIH) funds by ensuring that the design, conduct and reporting of research will be free from bias resulting from the researcher's financial conflicts of interests.

A federal source for guidance in developing a university framework to identify and resolve organization conflicts of interest is subpart 9.5 of the Federal Acquisitions Regulation (FAR) as implemented by various federal agencies. For example, NASA's guidance on organizational conflicts of interest (March 2010, as supplemented) defines the essence of organizational conflict of interest as divided loyalty between the best interest of a person making a decision on behalf of the government and the best interest of the government. As acknowledged by NASA, given the increasing complexity of the interface between the private sector and actors, and the government sector and actors, "no single method of resolution exists to address all organizational conflicts of interests and, instead, the particular facts of the conflict may require a "hand crafted" resolution.

(NASA Guidelines, at 5). NASA identified the three basic approaches to deal with organizational conflicts: avoiding the creation of a conflict; neutralizing the conflict through specific action; and where conflicts are unavoidable, reducing the impact to an acceptable level of risk.

C. University Compliance Programs

To implement federal requirements that accompany federal research funding, UH has established its own executive policies and administrative procedures. See, e.g., Executive Policy 12.214 on Conflicts of Interests and Commitment, and related Administrative Procedures A 5.504 Procedures for Disclosing and Addressing Conflicts of Interest and Commitment” and Administrative Procedure A8.956 “Financial Conflicts of Interest for Public Health Services Grants Cooperative Agreements and Contracts.

Compliance activities are housed in the Office of Compliance, within the UH Office of the Vice President for Research and Innovation. Key achievements in the past year include:

The Office of Research Services launched a new myGRANT Conflicts of Interest Module to streamline and focus on new information pertaining to possible conflicts of interest in November 2016 and the module was just updated in October 2017.

Researchers must disclose the following information:

- Significant financial interests (as defined in federal regulations) of the researcher or immediate family that relate to the researcher’s institutional responsibilities;
- The nature and amount of any significant financial interests held and how the interests are related to sponsored research activities;
- Whether or not the research has a financial interest in any contract or purchasing negotiation, or any other financial transaction with the non-UH entity that may create a potential conflict of interest;

The Office of Research Compliance has created a website that links to pertinent resources in the area of conflicts of interest. <http://www.ors.hawaii.edu/index.php/fcoi-information>

These resources include a template for a conflicts of interest management plan (revised in August 2017) and instructions for developing and using the management plan.

http://www.ors.hawaii.edu/files/compliance/COI_Management_plan.pdf

http://www.ors.hawaii.edu/files/UH_Guidelines_Mngmt%20Plan.pdf

The University of Hawai'i is adapting the existing federal framework that focuses on the research phase of technology transfer to more explicitly apply to the proof-of-concept and early stage development of business that use UH-generated intellectual property. An area of focus for the upcoming year is on conflicts of financial interest and conflicts of commitment -- when UH faculty are also employed by or hold a substantial equity interest in a for-profit business that has licensed a University patent, and additionally wants to sponsor follow-up research by UH to refine or further improve on its specific invention.