



UNIVERSITY OF HAWAII SYSTEM

Legislative Testimony

Testimony Presented Before the
Senate Committee on Ways and Means
February 26, 2021 at 9:30 a.m.

by

David Lassner
President
University of Hawai'i

Michael Bruno
Provost
University of Hawai'i at Mānoa

SB 589 SD1 – RELATING TO THE UNIVERSITY OF HAWAII

Chair Dela Cruz, Vice Chair Keith-Agaran, and members of the Committee:

Thank you for this opportunity to provide testimony in strong opposition to SB 589 SD1, which proposes to legislate several matters relating to the internal structure and management of the University of Hawai'i (UH) relating to the UH Cancer Center (UHCC) and the John A. Burns School of Medicine (JABSOM).

This bill would replace the judgment and decision of the Board of Regents, which established the Cancer Center in 1981 as a freestanding Organized Research Unit (ORU) of the University of Hawai'i at Mānoa, by imposing a structure created by the Legislature and by imposing new restrictions on the use of certain funds by both the UHCC and JABSOM.

We oppose this bill for three reasons:

The UH Cancer Center is now an extraordinarily successful unit. The National Cancer Institute (NCI) of the National Institutes of Health has awarded formal cancer center designation to only 71 NCI-designated cancer centers in the nation and the UHCC. This is a critical designation for which we have worked diligently and in which the university and State have invested significant resources. The UHCC is not in need of a management "fix" by the Legislature that would tie the hands of the university from making future changes.

Neither is a legislative mandate with new restrictions on uses of funds necessary or appropriate to achieve synergies and efficiencies among the Cancer Center and other UH units, which include but are not limited to JABSOM.

Third, while the Legislature has reserved to itself the right to legislate matters of statewide concern, it is neither appropriate nor necessary for the legislature to substitute its opinions on specific matters of internal structure and management for the reasoned views of the UH, which is ultimately responsible to maximize the ability of the Cancer Center to reduce the burden of cancer on the people of Hawai'i.

Success of the UHCC

Each year the University of Hawai'i Cancer Center is assessed by our External Advisory Committee (EAC), which is sometimes referred to as the External Advisory Board or EAB. The EAC is composed of a group of Cancer Center directors and leaders from around the country who visit each year to provide unbiased input and guidance to advance our program and help ensure our compliance with the NCI P30 guidelines.

The EAC could hardly have been more positive over these past years regarding the turnaround at the UH Cancer Center under the leadership of Dr. Randy Holcombe, our esteemed, accomplished and experienced Cancer Center director. I have appended the latest Executive Summary of their report to this testimony so that you can see just how well Dr. Holcombe and his team have addressed what were longstanding and widely recognized challenges. This report is from their 2020 visit – we have not yet received the 2021 report from their more recent (virtual) review but the verbal debriefing we received was extremely positive as well.

The primary mission of the UH Cancer is distinct from that of JABSOM. A legislative “fix” such as proposed in this Bill would embed a legislatively developed structure in statute and likely tie the hands of the University and Board of Regents from making future structural changes, which might be even more sweeping than what is proposed in this legislation.

Achieving Synergies

It is important also to note that modern cancer research reaches across the entire University, including but not limited to our medical school. There are many opportunities for synergies at our Kaka'ako campus, and it is important also to note that modern cancer research reaches across the entire University. Major synergies and efficiencies have already been achieved through collaboration with JABSOM and other critical parts of UH.

It is notable that **26 full and associate members** of the Cancer Center are based in UH units other than the Cancer Center as are **21 collaborating members**.

Some specific academic examples of synergies and efficiencies include:

- Dean of JABSOM participates as a member of the Hawai'i Cancer Consortium which was created by UHCC and includes the CEOs and other representatives of the major hospital systems (Queens, HPH, Adventist Health Castle, Kuakini) and the UH President and UHM Provost to coordinate efforts in Hawai'i to reduce the burden of cancer and enhance the quality of cancer care for our state.
- UHCC moved ownership of the NMR (more than \$1M in value) to Chemistry to better support their work as their NMR was less capable and eventually non-functional. The NMR also remains housed in JABSOM.
- The R25 CREATE grant (\$1.3M) which is designed to give the undergraduate students summer instruction has PIs from both the UH Cancer Center

(Maskarinec & Ramos) and the Department of Native Hawaiian Health at JABSOM (Kaholokula).

- UHCC has one of its Faculty (Ramos) working as multi-PI with JABSOM (Kaholokula & Gerschenson) and Engineering (Francis) PIs to submit a large Proposal called 'Akahi which is designed to provide funds to recruit Native Hawaiian and Pacific Islanders into Faculty positions across UH STEM programs and create a culture of Inclusive Excellence at UH Mānoa.
- Support of two First year Graduate students in JABSOM's Cell and Molecular Biology Program.
- Support of two graduate students per year in Public Health (School of Social Work) or Nutrition (CTAHR)
- JABSOM and UH Cancer Center share access and expenses of running the vivarium at Kakaako with members from both on its Space Allocation Committee.
- UHCC collaborated with Outreach College to create the highly successful and oversubscribed Clinical Research Professional Certificate Program in Fall 2020. This was an intense program taught by faculty from UHCC to fill the great need in Hawai'i of Clinical Research Associates to help run clinical research in the hospitals. Several have already obtained positions.
- UHCC works with hospitals in the Hawai'i Cancer Consortium to recruit much needed Cancer Specialists to Hawai'i. This includes providing a research/clinical trials outlet for them which is an expectation of these Clinicians.
- UHCC is working with Life Sciences to identify areas where its faculty can work to help teach undergraduates there in lecture formats (they already coordinate to identify students for research training).
- Joint faculty appointment with Nursing (July 1, 2018)
- Participation in the Colleges of Health Sciences which includes not only JABSOM but Nursing & Dental Hygiene, Social Work & Public Health, and Pharmacy (UH Hilo)
- All Cancer Biology faculty provide course direction and teaching in the JABSOM CMB department
- Cancer Center participation in JABSOM-created UHP faculty practice plan
- Support of Kaka'ako wide Genomics and Bioinformatics Shared Resource (joint venture between UH Cancer Center and JABSOM)
- Support of Chemical Biology Core leader, who is Chemistry faculty
- UH Cancer Center NMR facility is housed in JABSOM
- Cancer Center endowed chair awarded to a Chemistry faculty member
- JABSOM faculty member (Palafox) heads Cancer Center effort on a research partnership with Guam
- Cancer Center faculty participate in innumerable graduate committees for programs in other units, particularly Cell and Molecular Biology (JABSOM), Molecular Biosciences & Biotechnology (CTAHR), Public Health (Social Work)
- UH Cancer Center faculty participate as members of the JABSOM recruitment and curriculum committees for Cell and Molecular Biology

- Multiple UH Cancer Center clinically oriented faculty hold joint appointments in JABSOM (Medicine, OBGYN, Pediatrics, Pathology)
- UHCC and JABSOM merged phone systems to improve efficiencies
- UHCC and JABSOM share common area maintenance charges
- UHCC and JABSOM coordinate on achieving parking solutions for Kaka'ako campus
- Several of the large COBRE grants include UHCC faculty either currently or previously.
- Clinical Faculty at UHCC practice through the University Health Partners of Hawai'i Practice Plan.
- Cancer Center Director serves as chair of IFA search committee
- Standing meetings between Cancer Center and JABSOM administrative directors
- Cancer Center supports 2 months of salary for a JABSOM researcher
- Significant amount Cancer Center pilot research funds have been awarded to JABSOM faculty (>\$150,000 over the last 3 years)
- Nomination of JABSOM faculty researchers for grant mechanisms restricted to Cancer Centers
- UHCC Director serves as a Board member of University Health Partners
- UHCC Director serves as a Steering Committee Member Ola Hawai'i
- UHCC Director serves as a Board member for the Hawai'i Journal of Health and Social Welfare with JABSOM, Nursing, Social Work, Pharmacy Schools
- UHCC member Morita serves as Contributing editor, Journal of Health and Social Welfare
- UHCC Director serves as Internal Advisory Committee member for Marla Berry-led COBRE project, Pacific Biosciences Research Center
- UHCC member Braun-Inglis holds a secondary appointment in School of Nursing, developing advance practice training program for cancer APPs with Assoc. Dean of Nursing Qureshi.
- UHCC and JABSOM Facilities/Admin collaborated on lease arrangement for Disney for Doogie Kamealoha
- UHCC has established 3 advisory boards to enhance collaborations in the community: Community Advisory Board, Patient Advocacy Committee, Native Hawaiian Cancer Research Advisory Board (Cathy has membership of each).
- UHCC member Shepherd collaborates actively with the Hawai'i Data Science Institute

We fully realize that our work to create and expand synergies in Kaka'ako is not done. But it is clear that an ongoing effort to identify further synergies and efficiencies in the areas of research, education, clinical practice and administration within Kaka'ako and beyond does not require the legislative imposition of a draconian change that would gravely threaten our NCI designation and compromise the ability of our UH Cancer

Center to serve the people of Hawai'i as the sole NCI-designated cancer center in the Pacific.

University Governance

Article X, Section 6 of the Constitution of the State of Hawai'i charges the Regents with "exclusive jurisdiction over the internal structure, management, and operation of the university," with the legislature reserving to itself laws of statewide concern. Imposing this change in internal structure and management via statute, with disregard for the university's consultative shared governance and management processes, would overrule the judgments of those who are responsible for the internal structure and management of the university under the Constitution. These are the entities and processes responsible for making decisions that will lessen the burden of cancer on the people of Hawai'i.

At a more detailed level this bill creates a new appointment process outside Board of Regents policy that is inconsistent with the Board of Regents policy utilized for all other executive appointments across the UH system. It creates a new organizational construct called "administratively affiliated" that is not defined but is clearly intended to create a form of subservient relationship for the Cancer Center relative to JABSOM. And it mandates a new and ambiguous dual reporting structure to implement that subservience.

Of even more concern is new language introduced in SD1 that would create a set of new restrictions on both the UH Cancer Center and JABSOM regarding the allowable use of specific types of funds. The University of Hawai'i has worked over the past 25 years to manage itself using multiple sources of funding provided by the state as well as generated internally. Some of these are more fungible than others, but our ability to use funds relatively flexibly under HRS today has helped us cope with UH being appropriated a shrinking portion of state general funds over the last several decades. Creating major new restrictions on two significant sources of funds for two UH Mānoa campus units only will make it substantially harder to finance the vital work of these two units, which are critical to improving the health of the people of Hawai'i.

We urge that the legislature not overstep the spirit of the Constitution to legislate the internal structure and management of the university. As noted, this could have grave consequences for the continuing NCI designation of our Cancer Center. And it is unnecessary.

We strongly oppose this measure and ask that it be deferred.

ATTACHMENT

January 31, 2020

Randall F. Holcombe, MD, MBA
Director, University of Hawaii Cancer Center
701 Ilalo Street
Suite 600
Honolulu, HI 96813
rholcombe@cc.hawaii.edu



Dear Dr. Holcombe

Thank you for hosting the External Advisory Board during our recent visit to the University of Hawaii Cancer Center (UHCC). It was exciting to see the continued progress taking place at UHCC under your leadership. We will be sending you a detailed report on our recommendations concerning the various aspects of your center with a focus on performance and compliance with the NCI P30 guidelines. This letter is an executive summary that focuses on the larger issues that go beyond the details of NCI guidelines. Feel free to share this summary with others as you see fit.

First, and most importantly, we would like to comment on the remarkable progress that you, your colleagues, and University and community leaders have made over the past year. The morale and esprit de corps of UHCC members and staff are stronger than they have been for a very long time. The new faculty you have recruited to the University of Hawaii over the past two years are top tier and are already making significant contributions including obtaining funding, publishing and assuming leadership roles within the UHCC. The presentations they gave during our visit were dynamic and scientifically exciting. Bringing such quality new talent to the UHCC is key to your continued scientific success, will strengthen the base of your research programs, and will contribute economic and educational value to the University, Hawaii, and the people of Hawaii in general.

The development of an early phase clinical trial capability in Hawaii has been a topic of discussion during EAB meetings for over a decade. It is exciting to see the progress you have made over the past year including obtaining a construction grant from the NIH, securing state support, and moving forward with plans for both building the unit physically, and recruiting the talent needed to make it work. In addition, the work that you have done to secure the collaboration of your clinical partners in the Hawaii Cancer Consortium for this endeavor is exceptional. This effort should remain a top priority as it will provide the people of Hawaii with access to Phase 1 clinical trials, that is the newest cancer treatments, at a time when cancer care is advancing at a remarkable rate. It also has great potential to serve as a hub for "medical tourism" for the entire Pacific rim. Given the diversity of your patient population, we are confident big pharma and small biotech will seek out your participation in their most promising early phase trials; the resultant enhanced reputation for clinical research will benefit both the Cancer Center and all of the HCC clinical partners.

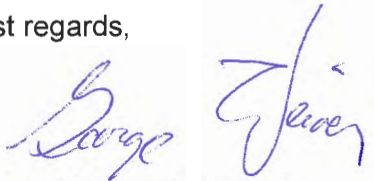
Equally impressive is the progress you and your colleagues have made in strengthening the Hawai'i Cancer Consortium. UHCC's leadership in this consortium will help the participating health systems recruit top flight oncology clinicians who see the value of clinical trials and the research that underpins them. UHCC's oversight over all oncology clinical research activity within the HCC, and the broader clinical trials network, is an outstanding example of the value-added of an NCI-designated cancer center to its home state and the benefits that can accrue to affiliated clinical partners.

UHCC is a national leader in population-based research. Particular strengths include the Multiethnic Cohort (MEC) that has led the way in helping the cancer research community explore the relationship across race and ethnicity of genetics and environment in cancer risk and the NCORP that enrolls patients from across Hawaii on NCI trials. Your basic research scientists are also making major contributions and bringing external research funding to Hawaii at a time when getting such funding at the national level is incredibly competitive.

The unique structure of UHCC, in essence a hybrid of a "matrix" center within a University and a "free-standing" center with defined authority, has been a key to the Cancer Center's success. This has enabled you as Director to expand membership in the HCC, forge new community alliances, and strategically recruit faculty researchers who support your efforts to conduct cancer research with particular relevance to your unique population. This type of authority speaks directly to NCI's expectations of a cancer center director. The structure your institution has put in place, with you reporting to the Provost and working closely with the University President, is vital for your continued success and continued NCI designation.

Once again, congratulations on your ongoing success. We look forward to seeing the future contributions being made by the UHCC to the health and welfare of the people of Hawaii.

Best regards,

A handwritten signature in blue ink that reads "George Weiner". The signature is written in a cursive, flowing style.

George Weiner, MD, Chair
Holden Comprehensive Cancer Center, University of Iowa
On behalf of the External Advisory Board Members

SB-589-SD-1

Submitted on: 2/24/2021 9:08:10 PM

Testimony for WAM on 2/26/2021 9:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Monica McLaren	Testifying for Friends of UH Cancer Center	Oppose	No

Comments:

Dear Chair Dela Cruz, Vice Chair Keith-Agaran, and Members of the Committee,

As President of the Friends of UHCC, a local community 501(c)(3) organization that has existed in some form since 1981 to support and advance cancer research in Hawai'i, our organization strongly opposes placing the UH Cancer Center into the John A. Burns School of Medicine, as bill SB589 outlines. Over the past 40 years, hundreds of Friends board members and supporters have worked tirelessly to support the work of UHCC.

Our organization's mission from the inception was to support local, innovative cancer research programs with monetary, in-kind donations, and to advance community education and advocacy. We have remained committed to this mission for four decades. Through the years we have seen UHCC successfully weather external and internal challenges, have recognized its inherent value and potential, and are so incredibly proud to see what it is presently accomplishing and its eminent position as one of only 71 NCI designated centers.

Chair Kim's report mentions the fact that other centers achieve stature without NCI designation (Washington University in Missouri and MD Anderson in Texas are mentioned as examples). While we would love to compare UHCC and JABSOM to them, to assume that UHCC would achieve the same value and consequent effect is short-sighted and shows some hubris in the assumption that UHCC can continue its impact and gains without an NCI designation.

Chair Kim's statement that the "genesis of this measure is the University's own efforts and presentations since 2014" is disingenuous, as it relies on outdated assessments and plans. At the very least and to fulfill your legislative responsibility, this committee should ask for updated reports instead of relying on the outdated information.

Despite the political morass we find ourselves in as a country, I do believe that you, our elected officials, can and should hold our community's best interests at heart, and that takes an open mind, the ability to balance the calculus of differing interests, perspectives, and money versus value.

Please do not advance SB589, and permit UHCC to continue to serve Hawaii in eradicating cancer. In its present highly effective and self-sustaining form, it has earned our (and your) confidence and support.

Sincerely,

Monica McLaren

President, Friends of UHCC

SB-589-SD-1

Submitted on: 2/24/2021 10:37:33 PM

Testimony for WAM on 2/26/2021 9:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Earl Stoner	Testifying for friends of the uh cancer center	Oppose	No

Comments:

Dear President Kouchi and members of the Senate

I am Earl Stoner, a resident of Maui and a 13 year member of the Friends of the UH Cancer Center Board and past president, now an emeritus member. I mention this history because I have been involved with the Center during a very rocky start, a difficult transition and recently, several years of success. It is very true that we had difficult years during the period covered in the report forwarded to you from Senator Kim. It is also true that Dr. Hedges did an excellent job of managing the business of the Center during the transition period after the resignation of the original director and the hiring of Dr. Holcombe. Since Dr Holcombe has been leading the Center we have seen great success, both economic and academic/research success which is the purpose many of you saw when you voted to fund the Center over a decade ago.

During this period I have seen many bills both at the House and the Senate that have tried to take funds committed by the legislature through the tobacco tax in the original approval and otherwise micro manage the the Center through manipulating how the Center and the Medical School operate. Senate Bill 589 is just another example of that. Both of these departments of the University are successful, well respected entities in their own right. They are well managed under their respective leaders and are a credit to our state. Their missions are very different, one educational and one dedicated to research. I am acquainted with both Dr Hedges and Dr. Holcombe and have great respect for both. I can assure you that Dr. Hedges doesn't want to oversee the Cancer Center and Dr. Holcombe is doing a damn good job of running it.

I defer any comment on the many problems that would occur if this ill thought out and poorly researched bill were to be enacted to the testimony of another friend, Dr. Joe Ramos. His comments provide great detail on that. My request? Simply kill SB 589. Thank you....



February 26, 2021

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SB589 SD1 Relating to the University of Hawaii – OPPOSE

Establishes the University of Hawaii cancer center (UH cancer center), an organized research unit that conducts cancer research that is administered by a director appointed by the University of Hawaii’s board of regents. Requires the UH cancer center to be affiliated with the University of Hawaii John A. Burns School of Medicine (JABSOM) with direct lines of reporting to the provost of University of Hawaii at Manoa and the dean of JABSOM. Requires funds expended from the tuition and fees special fund for JABSOM or UH cancer center to be used for educational purposes only. Requires funds expended from the research and training revolving fund for JABSOM and UH cancer center to be used for research and research-related purposes only.

Dear Chair, Vice-Chair and Members of the Committee:

The Hawaii Society of Clinical Oncology (HSCO) is a local community of oncologists, nurse practitioners, physician assistants, and other allied health professionals who provide a voice for multidisciplinary cancer care teams and the patients they serve. Founded in 1996, HSCO is the largest oncology professional organization in the state. We respectfully oppose SB 589.

The UH Cancer Center has a critical role in serving the needs of our community. The UHCC is one of only 71 National Cancer Institute (NCI) designated cancer centers in the nation. Achieving, and maintaining, NCI designation reflects all of the hard work and research excellence that is required to obtain this recognition.

While the SD1 was amended in an effort to address concerns that it would adversely affect the NCI funding and designation, the new version seems even more concerning and confusing with two reporting lines. Given this, passage of the amended measure still would threaten the P30 grant from the NCI of the National Institutes of Health (NIH). Therefore, we recommend that we don’t take that risk, especially when there seems to be little or no overall benefit.

Moreover, we are concerned that the inextricable tying together of UHCC to the John A. Burns School of Medicine for organizational and cost reduction purposes will unintentionally affect the UHCC’s ability to move agilely to address the needs of cancer patients in Hawaii. The bill as structured also would create confusion and difficulties in determining who has the authority required to allocate funding, hire faculty, and deal with space for the work. The UH Cancer Center has been working closely with Oncologists and health professionals under Dr. Holcombe and by all accounts is doing an outstanding job as currently structured. A change with no gain seems ill advised.



ASCO State/Regional
Affiliate Program

As the only NCI designated cancer center in the Pacific region, the UHCC works with partners such as the University of Guam to address cancer issues specific to the Asian and Pacific Islander populations. While cancer mortality has fallen nationally, specific populations in Hawaii continue to face a higher burden of cancer and benefit from the research conducted at the UHCC on these specific racial and ethnic groups. We oppose SB589 because we believe it will weaken UHCC's ability to continue this important work.

Thank you for your consideration of our testimony.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael", written in a cursive style.

Michael E. Carney, MD
President, *Hawaii Society of Clinical Oncology*

Group Testimony AGAINST SB 589 SD1

Submitted to the Hawai'i State Senate Committee on Ways and Means

February 26, 2020

Dear Chair Dela Cruz, Vice Chair Keith-Agaran, and Members of the WAM Committee, Senators English, Inouye, Kanuha, Kidani, Moriwaki, Shimabukuro, Taniguchi, Wakai and Fevella:

We, the faculty and staff of the UH Cancer Center, are writing this testimony to document our **strong OPPOSITION to SB 589 SD1**, which proposes to reorganize the currently freestanding Organized Research Unit of UH Manoa for cancer research (UH Cancer Center) within the UH John A Burns School of Medicine.

None of the comments made in the HRE session took into account all of the progress that the UH Cancer Center has made over the past 50 years, and especially the outstanding recovery and growth it has achieved in the past five years. The UH Cancer Center started as a research unit in 1971, and based on the research excellence and the great needs of its work for Hawaii, it was established as an independent Organized Research Unit within UH Manoa in 1981. The UH Cancer Center has retained its prestigious National Cancer Institute (NCI) designation, awarded to the top 4% of all cancer centers in the U.S., for the past 25 years. This bill intends to reverse all the accomplishments and jeopardize the NCI designation. As a NCI-designated cancer center, the UH Cancer Center can offer cancer patients in Hawaii access to experimental cancer treatments that are only available through clinical trials at NCI-designated cancer centers. NCI designation also allows the Center faculty to be eligible to compete for NCI-designation based federal research funding, which currently brings in millions of dollars annually. In addition, NCI designation signifies continuous cancer research excellence of the UH Cancer Center faculty, especially on racial/ethnic cancer disparities in our uniquely diverse populations that are not addressed by any institutions on the mainland. In particular, under Director Randall Holcombe's leadership, since 2016, the Center has been making great strides in improving grant funding and its mission to serve the people of Hawai'i to reduce the burden of cancer in the state through research, patient care, education, and community outreach.

We are deeply concerned that such reorganization will undo many of the achievements we have made in recent years. We the faculty and staff of the UH Cancer Center strongly oppose bill SB 589 for the reasons outlined below.

1. **This reorganization will jeopardize our ability to renew our NCI designation by mid-2022.** Being moved "administratively" under the Medical School means losing the director's authority on the Cancer Center's budget, faculty lines and space. It also means a decrease of UH's institutional commitment to the Center. With the amendment of a dual-reporting system, this still is the case and will translate into a worsened score for our renewal application that will be evaluated on six essential characteristics criteria, one of which is the director's independent authority. The down-grading of the Cancer Center's status reverses all of the progress that the Center has achieved over the past 5 years.
2. **UH Cancer Center is vastly different from the anecdotal examples of NCI-designated cancer centers under their medical school.** As listed in the White Paper, produced by the Cancer Center Task Force Committee in 2016, the majority of NCI-designated cancer centers are independent from their medical school/center in organization, allowing for the director's independent authority. A few centers within their medical school have a historical background of having evolved around the hospitals of their respective medical schools. JABSOM does not have a hospital. From the beginning, the UH Cancer Center has been a freestanding research institute and has flourished under this organizational structure.
3. **Last time external entities interfered with UH Cancer Center leadership, the events led to the great demise of the Center between 2008-2016.** Many legislators are well aware of the many problems at the Center in recent past, which all started in 2008 with a leadership change orchestrated by external influences and continued through the interim period of 2015-2016 when Dean Hedges of the Medical School served as Acting Director for the Center. The report referenced by HRE is a reflection of his inability to make the needed changes to improve the efficiency of the Cancer Center. We believe it would be highly problematic to return the Cancer Center to Dean Hedges' management, reversing all of the progress made by Dr. Holcombe and the current leadership over the last five years.
4. **NCI expressed concerns about the level of external interference and consequent instability at UHCC in the past.** NCI has communicated to us directly and through the External Advisory Committee that the past unusual external influences and the volatility they caused for the Center make them uncertain about their investment with the federal grant and NCI designation.
5. **The proposed reorganization will not save any costs.** The bill SB 589 does not provide any data on how the reorganization will achieve any cost savings. A number of shared functions have already been integrated since the Center's move to Kaka'ako campus in 2013. As included in President Lassner's testimony

to HRE hearing (Feb. 11), the list includes but is not limited to: joint grants, joint class teaching and mentoring, joint graduate student assistantships, joint faculty recruitments, joint genomics core, cost sharing for the vivarium, combined telecom, coordinated security and building maintenance, and coordinated parking.

6. **Putting the Cancer Center under the financially challenged Medical School will risk both units' viability.** This was broadly raised and accepted as a critical point to consider when Dean Hedges promoted reorganization of the Center under the Medical School in 2016. The financially unsustainable merger was not a good idea then and is a worse idea now.
7. **SB 589 (and SB 589 SD1) is based on an outdated external consultant review (Warbird 2016) that was commissioned by Dean Hedges, who had a clear conflict of interest.** In a clear conflict of interest, Dean Hedges promoted reorganizing the Center under the Medical School in 2016, coordinated the Warbird review, and completed the second part of the review himself. However, after considering all the internal and external reviews, the UH Administration and Board of Regents decided to retain the Cancer Center as an independent Organized Research Unit under the UH Manoa Provost's supervision and hired Dr. Holcombe.
8. **One thing SB 589 completely fails to acknowledge is the hiring of the Center's current Director, Dr. Randall Holcombe, and his outstanding accomplishments since 2016.** After considering all the internal and external reviews, including the Warbird review, UH Administration and Board of Regents decided to retain the Cancer Center as an independent Organized Research Unit under UH Manoa Provost's supervision and hired Dr. Holcombe. Dr. Holcombe and his leadership team balanced the budget, renewed NCI designation in 2018, worked closely with JABSOM to align specific shared services and research infrastructure, and steered the Center onto solid footing. Dr. Holcombe has obtained funding to begin construction of the new clinic for Phase 1 clinical trials this summer. Under Dr. Holcombe's leadership, our research, teaching and community outreach have recovered and greatly improved, according to the External Advisory Committee who annually review our performance on behalf of NCI. Our faculty and staff morale is higher than ever, and the UH Administration, the Hawaii Cancer Consortium partner hospitals, and our community advocates and collaborators all rally behind his leadership in unity to renew the NCI designation by mid-2022. The unwarranted annual attacks by the legislature on the UHCC and Dr. Holcombe's leadership are a distraction from our work and, if continued, could lead to a loss of excellent researchers.
9. **Senator Kim introduced SB 589, and the same bill last year SB 2575, based on misinformation** that the Center Director has not cooperated with the Medical

School leadership to make the Kaka'ako campus operation efficient. Senator Kim repeatedly brought up this allegation at hearings last year and this year without evidence. Not only is this allegation completely false, it is unacceptable for legislators to implement a bill based on one-sided and unsubstantiated allegations. If the allegation were true, it would have been nearly impossible to accomplish the number of operational integrations between the units in recent years.

10. **The primary missions of the two units (UHCC and JABSOM) are so different that forced merging of key operations did not work out well and led to significant financial losses in 2015-2016 under then Acting Director Hedges' management.** Between December 2014 and summer of 2016, Dr. Hedges served both as the Dean of the Medical School and the Acting Director for the Cancer Center, during which time he attempted to fold the Center's fiscal office under JABSOM operations. This caused conflicts between the fiscal office staff who were specialized in completely different and complicated operations of research vs. instructional support and led to several highly skilled staffers' departure. Furthermore, some of our faculty members were unable to get reconciliations in a timely manner on their grant accounts and, as the result, carried a substantial unobligated balance. NCI refused to award competitively scored grants to UHCC totaling >\$2 million that year because of the fiscal dysfunction.
11. **UH must have autonomy** from external influences in its internal structure and personnel management, as required by the WASC (Western Association of Schools and Colleges) accreditation standards, even when the institution is supported by the government.
12. **Not having NCI designation as a Cancer Center will exclude the UH Cancer Center from renewing its U54-PIPCHE grant.** This partnership grant between the UH Cancer Center and the University of Guam has been successfully renewed uninterrupted since 2008 and is a hallmark of the Center's accomplishments in reducing cancer health disparities in the Pacific, a key component of the mission of the UH Cancer Center that sets it apart from all other NCI designated cancer centers.
13. **Not having an NCI designation will exclude the Center faculty from applying for many grants.**
14. **A task force charged by the then Interim Chancellor Robert Bley-Vroman in October 2016 to review the reorganization of the Cancer Center with JABSOM (see the White Paper attached), proposed by Dean Hedges, came to the conclusion** that a merger:
 - a. would not lead to cost savings and if there would be any they could be accomplished without merging

- b. would weaken the UHCC to fulfill its mission of conducting cancer research
- c. would hinder UHCC's management to operate and function timely and efficiently
- d. would conflict with some requirements imposed by NCI to retain NCI designation as Cancer Center.

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UNIVERSITY OF HAWAII

CANCER CENTER

**University of Hawaii Cancer Center
Administrative Organization
Kakaako Campus**

**UHCC Task Force Report
October 2016**



UNIVERSITY OF HAWAI'I

CANCER CENTER

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Task Force Report on the University of Hawaii Cancer Center Administrative Organization within the Kakaako Campus

Summary and Conclusions

In mid-June 2016, the University of Hawaii Cancer Center (UHCC) faculty was charged by the Interim Chancellor and the Vice-Chancellor for Research with reviewing the proposed re-organization of the Cancer Center with the John A. Burns School of Medicine (JABSOM) and making recommendations about organizational changes that would increase administrative and reporting efficiency. A task force was assembled consisting of various leaders of Cancer Center Programs and diverse Center activities and services. The task force met multiple times during the summer, sought input from UHCC faculty and staff and provided this report to the incoming UHCC director, Dr. Randall Holcombe, on October 17, 2016.

The Task Force concluded that there are a number of activities on the Kakaako campus that can be shared between the Cancer Center and JABSOM, potentially resulting in cost savings. However, the merging of these activities can be accomplished without a full-fledge reorganization. The Task Force also found that there is a preponderance of Cancer Center activities that are mission-critical or mission-specific that cannot be shared with JABSOM. Integrating these activities in a full-scale re-organization, including a change in the UHCC director's reporting line, as proposed by the Dean of the Medical School, would weaken the ability of the Center to conduct its cancer research efforts, hinder the management of its operations and budget in a timely and efficient manner, and directly conflict with some requirements imposed by NCI on NCI-designated cancer centers. In addition, any reorganization at this juncture would be extremely untimely, as it would distract from the highly demanding task of renewing the Cancer Center's NCI core grant in the Fall of 2017. The activities that can potentially be shared and those that cannot are summarized below.

Activities Deemed Sharable

The Task Force identified a number of activities on the Kakaako campus that could be integrated or combined in a cooperative manner and possibly result in cost-savings. Indeed several of these activities currently share duties (e.g.-mailroom, vivarium, and communications) or are undergoing active efforts to merge their services (e.g., Genomics Shared Resource, Microscopy and Imaging Shared Resource, phone system, and data security). Grounds keeping, security, parking, compliance, and management of grant and fiscal records are additional activities that could be examined in the near future to determine if integration between UHCC and JABSOM could result in cost-savings and higher efficiency. Sharing these activities and services on the Kakaako campus can potentially conserve resources and improve efficiencies. This can be accomplished without the need for a major re-organization effort.

UHCC-Specific Activities That Could Not Be Shared

The Task Force identified multiple essential Cancer Center activities that cannot be integrated with JABSOM. The most important of these activities relates to the authority of the Cancer Center Director who must control and approve the Center budget, all revenues, and bond management. The Director must also control all permanent and temporary faculty lines, Cancer Center laboratory and office space, and shared (core) resources, and provide the primary leadership of the Cancer Center matrix partners and its activities. The Clinical Trial Office is

organized to support clinical oncology research and, thus, must remain within the purview of the Center Director. The Center Director must also be able to evaluate all grant proposals initiated by Center faculty to determine if they meet the mission of the Center and goals of the P30, and provide support to these applications. The Center Director is also the Principal Investigator of the NCI Cancer Center Support Grant (CCSG), which supports the senior management and core activities of the Center. The Center Director is the only scientist administrator holding decision-making authority over all aspects of the CCSG and supporting activities. The preservation of the director's authority is critical to the Center's ability to remain a NCI-designated cancer center and, more generally, to be successful in conducting cutting-edge innovative cancer research aimed at decreasing the cancer burden in our community.

The Cancer Center Shared Resources (currently: Analytical Biochemistry, Biostatistics/Bioinformatics, Metabolomics, Genomics, Microscopy Nutrition and Pathology), provide essential support of the faculty's diverse areas of cancer research. Because these Resources are unique to the Center with no similar counterparts in JABSOM (except Genomics and Microscopy, see above) they cannot be shared.

Similarly, the Operations and Fiscal Services, Human Resources, and Facilities Management of the Center cannot be shared with JABSOM because they provide essential supportive services that are critical to the Center's mission. Other units/Centers at UH Manoa that are part of a larger School/College typically maintain independent operations, fiscal, HR, facilities management activities. Operations Services provides direct support to the Director, Associate Directors, and Center administrative departments in fiscal and procurement matters related to Center operations and administration. The Fiscal office services unique accounts at the Center, such as the CCSG, Center Special Fund, and philanthropic revenues and supports Center faculty activities related to the preparation of grant budgets, monitoring expenditures and reporting. Human Resources supports the Center Director and Associate Directors in all matters related to Center faculty and staff, including hiring, tenure and promotion, and confidential disciplinary actions and grievances. Facilities Management maintains an advanced physical plant that is 6 years newer than JABSOM's with unique systems in HVAC, security, and automation. The Center also houses a high capacity liquid nitrogen storage system with an associated liquid nitrogen supply system. It also maintains an on-site 24/7 wireless freezer monitoring system. These systems are not replicated in JABSOM.

Several additional services were also identified as unlikely to be sharable with JABSOM. These include: Information Technology, Human Subjects Research Compliance, Research Education and Training, Community Partnership, and Events/Information/Communications coordination. These activities were either too specific to cancer research or UHCC's stakeholders, or present technical incompatibilities which would prevent close integration with JABSOM.

Given that the majority of the essential activities of the Cancer Center must remain within the exclusive control of the Center and its Director, there is insufficient rationale for a major re-organization that would place the Center under the administrative oversight of the JABSOM Dean. The inability to demonstrate clear benefits with minimal impairment to both units makes approval of the re-organization currently proposed by Dr. Hedges by the relevant reviewing groups (UH Manoa administration, UH Manoa Faculty Senate, UHPA, and HGEA) highly

unlikely. Unencumbered by the substantial task of preparing a complex re-organization proposal, the Director, faculty and staff of the Center would be able to focus their full attention on the upcoming major effort aimed at renewing its CCSG.

The Task Force does recognize the value of longer-term efforts aimed at a major re-organization of the activities on the Kakaako campus which would place the Cancer Center and JABSOM, and possibly other health-related schools, on equal footing, with the respective Director and Dean(s) reporting to a new, higher level administrator in the context of a new Health Sciences campus.

Background

Creation and Charge of the Task Force

Following a meeting of the Cancer Center Faculty Senate and the meeting between the Center faculty and staff and the Interim Chancellor and Vice-Chancellor for Research on June 1, the Task Force was assembled consisting of various leaders of Cancer Center Programs and diverse Center activities and services. At its first meeting, on June 15, 2016, the Task Force was charged with the task of providing faculty and staff input on the potential reorganization of the Cancer Center

Composition

Erin Bantum, Namrata Gurung, Michelle Kau, Alan Lau (co-Chair), Loic Le Marchand (co-Chair), Annette Lum, Joe Ramos, Ioannis Stasinopoulos, James Turkson, and Lynne Wilkens

Process

The Task Force met as often as possible during the summer of 2016 to discuss the issues of the re-organization and to prepare this document. Since the meeting with the Chancellor and Vice-Chancellor for Research on June 1, the Task Force has met seven times. On Friday August 12, it met with the incoming Center Director, Dr. Randall Holcombe, to inform him of the Task Force's charge, process and preliminary findings. The Task Force also met separately with the Center faculty and staff, on September 14 and 23, respectively, when a near complete draft of the report was available. The Task Force co-Chairs will meet with Dr. Holcombe on October 17 to present its findings in the final report.

Deliverable and Organization of the Report

Based upon input from the Cancer Center leadership, faculty and staff, the Task Force decided at its first meeting to prepare a report for Dr. Holcombe that would detail the activities and services that may potentially be shared between the Cancer Center and JABSOM and may result in cost-savings. Most importantly, the document would also describe various aspects that are specific to the Center and should remain separate from JABSOM. The activities that can potentially be shared and those that cannot are described in the following Sections I and II, respectively, with additional supporting information provided in the Appendix.

I. Potentially Shared UHCC Activities that May Create Cost-Savings

The task-force identified some areas of activity/responsibility which could be shared at the level of the Kakaako campus. Some have recently been integrated between UHCC and JABSOM (e.g., Vivarium, Microscopy and Imaging), some have started to be the topic of discussion between the two entities (i.e., phone system and Genomics Shared Resource), and others have not yet been considered for increased integration, as discussed below.

A. Activities Deemed Sharable

Grounds Keeping

The Kakaako campus includes 9.9 acres where the UHCC is responsible for 27% of the total area. The UHCC currently has 2 FTE employees (1 dedicated, plus 1 back up) to maintain 2.6 acres of ground covering and landscaping. The water sprinkler systems between JABSOM and the UHCC are independent, but share one main water source line. Currently, each unit is responsible for its garden lawn equipment and the grounds keeping responsibilities are split 73% JABSOM and 23% UHCC.

Security

Both JABSOM and UHCC share security personnel assigned from the UH Manoa (UHM) Department of Public Safety (DPS). All security operations are carried out and overseen by the DPS Administration. Further integration would require the upgrade of the JABSOM system to make it compatible with the more modern UHCC security system.

Parking

Parking is managed by JABSOM and UHCC separately because the parking allotment distribution (parking stalls assigned to each unit) are paid upfront and reimbursed to the respective employees who buy parking on a quarterly basis. However, UHCC employee parking payments are coordinated with JABSOM, so one combined check is provided to the parking vendor for Lot C employee parking. All Lot B parking is coordinated independently by each unit through UHM Commuter Services and paid through employee payroll deduction. Lot A parking needs to be controlled by UHCC to support its study participants and visiting guests.

Mailroom

Currently both JABSOM and the UHCC operate their mail room distribution independently within their own buildings. The sharing of mail services between JABSOM and the UHCC currently applies to mail pick up runs to UHM campus or whenever either unit is short-staffed and/or crossover support is deemed necessary. The UHCC designated courier provides limited mail runs based on three hours a day, Monday through Friday from 8:30-11:30 am. The mail runs involve travel between the Kakaako campus, UHM, and Queens Medical Center campus. Given the limited amount of resources (mail courier FTE's) that both the UHCC and JABSOM have at the present time, both units appear to be providing essential integrated mail operations support for the entire Kakaako campus efficiently.

Vivarium

Vivarium operations are solely managed by the UH Animal Veterinary Services (AVS), and not by the UHCC or JABSOM. The AVS charges investigators animal per-diem fees to maintain animal welfare (food, water, bedding changes). Moreover, JABSOM annually charges the UHCC (\$300,000) to lease 1/3 of the space in the Vivarium Suite 1. The UHCC has also invested in the Vivarium by providing over \$1 million for individual ventilated cages, changing stations, and water bottles to support dedicated infrastructure for its own animal research. These cages are shared with JABSOM and managed by AVS. The UHCC also pays a proportionate share for the disposal and hauling of animal

waste bedding which has a cost distribution of 1/3 UHCC and 2/3 JABSOM. It does not appear that the Vivarium could be further integrated.

Communications

JABSOM is in the process of hiring a Media Design and Production (MDP) FTE employee to join its communications team. One of the main functions of this employee will be to film various events using a broadcast-style digital camera, audio equipment and lights; to edit and upload digital images and footage. The Center's communications team has used the services of JABSOM's casual hire. The employee's duties included filming and he has filmed various Center interviews and events. The MDP full time employee position services could be shared between JABSOM and the Center. Filming does not require extensive knowledge of JABSOM or Center missions. It could save the Center a future FTE position.

Genomics Shared Resource

At the moment there are up to four entities providing or planning to provide Genomic analysis services (sequencing related) at the Kakaako campus:

- 1) UHCC GSR (Directed by Maarit Tiirikainen) provides a broad range of genomic analysis services, from nucleic acid extractions to genomic data analysis (using commercial software). Specialized targeted sequencing services offered on the PyroMark pyrosequencer.
- 2) JABSOM Genomics Core (Directed by Ralph Shohet). Upon losing the manager a few years ago, the only service left is Sanger Sequencing on an AB capillary sequencer. All other equipment is either not in use or is already or soon to be obsolete. The use of the high-throughput Sanger sequencer is heavily subsidized by the COBRE grant that supports the core (but is ending soon). GSR is already providing services to the JABSOM users, except for Sanger sequencing. Dr. Shohet has been willing to merge his core with GSR for some time now and has written a shared real-time PCR instrument into a COBRE supplement application.
- 3) JABSOM Epigenomics Core (Directed by Alikea Maunakea). The core has a benchtop NGS sequencer (IonTorrent PGM), but it has not been widely used, mostly due to the lack of manpower needed for offering actual campus-wide core service. This core is not being considered for any joint efforts at the moment.
- 4) Next Generation Sequencing (NGS) core/service is being planned and will be connected to JABSOM's recent hire of a Bioinformatician, Yuoping Deng (starting date September 5th). Dr. Deng has requested an Illumina NGS system as part of his start-up package. He will be hired into the Department of Tropical Medicine, under John Chen (JABSOM Biostatistics Director) and Vivek Nerurkar (Department Chair). UHCC representatives plan to meet with Dr. Deng soon after he has arrived.

Negotiations are on-going on the following issues:

- Which NGS system should be purchased, Illumina or some other?

- Where to locate the system (JABSOM or UHCC GSR)?
- Will a new Kakaako core be established providing NGS and related services, or will there be a campus-wide joint genomics core for all services?
- If the NGS services will be provided by a joint core, will there be one director (from which unit?) or co-directors (one from each unit)?

There are several pros and cons to consider as a final decision on establishing a joint Genomics Core (including the NGS services) is being contemplated:

Pros

- Would remove any overlap in equipment and services (consolidate for efficiency and remove competition).
- Possibility of shared financial support for the personnel and maintenance contracts.
- Would provide high-quality discounted genomic services for the whole campus with experienced personnel from the GSR (and from a person Dr. Deng might hire).
- Would introduce full-service NGS starting from biological sample extraction to expert data analysis (by Dr. Deng).

Cons

- Separate book-keeping and/or accounts would possibly be needed for JABSOM vs UHCC customers; or P-30 members vs non-members; or NGS vs other services.
- Separate rate schedules would possibly apply to UHCC (members, non-members) and JABSOM? The extent of discounted rates would depend on the extent of support provided to the core by the two entities.
- Oversight would be provided by both institutions, one concentrating on cancer research, the other with various specialties and interests. Will the needs be similar?
- Expectation of priority access to services by one of the entities could be an issue (e.g. priority to NGS for JABSOM, all/other services for P-30 members?).

Microscopy and Imaging Shared Resource

The Microscopy and Imaging Shared Resource of the UHCC and the Microscopy Core of the JABSOM have been in the process of merging since August of 2015. The merger of the two cores was to take place in three phases, as follows:

- 1) Merge on the Kakaako Campus
 - a. Create common user agreement form
 - b. Create common reservation system
 - c. Create common fee schedule
 - d. Share personnel
- 2) Merge publically
 - a. Create a merged core website
 - b. Become a resource to access to other instrumentation in Manoa
 - c. Create workshops/seminars to offer at Kakaako and Manoa
- 3) Merge fiscally
 - a. Share budget & expenses
 - b. Share billing account
 - c. Create & share funding mechanisms

So far, Phases 1 and 2 are nearly complete. Phase 3 is on hold until the RCMI grant funding for the JABSOM core has completed its cycle. The merged core leadership intends to apply for an S10 grant in 2017.

In the case of a joint Microscopy and Imaging Core, the potential pros and cons are as follows:

Pros

A recent NIH study (*Chang, et al., J Biomol Tech. 2015 Apr; 26(1): 1-3*) has shown core consolidation improves:

- 1) capability to purchase more advanced instrumentation
- 2) access to career instrumentation expertise
- 3) access to management expertise
- 4) integration of information management
- 5) cost recovery to support core operations
- 6) efficiency in billing, purchasing, scheduling, and tracking

Cons

- 1) complications in terms of how usage of the core will be reported for CCSG grant requirements
- 2) complications in terms of how much financial support and FTE will be provided by each institute
- 3) complications in terms of flow cytometry services also offered through the MISR
- 4) complications in terms of access to the buildings and the lack of an "building access protocol" at UHCC

Summary: The main benefit for combining cores is to improve the capacity to purchase more advanced instrumentation. Having access to a greater number of PI's and their projects increases the chances of obtaining funding for new instrumentation (such as through the S10 grant mechanism). This benefit would outweigh any of the potential complications.

Phone System

Currently, the UHCC and JABSOM have separate VoIP phone systems. Both sites use the Cisco Unified Call Manager (CUCM) and use the same type of hardware, software and licensing. Merging the two IP phone systems is expected to be logical and cost effective for both the UHCC and JABSOM. Once merged, the CUCM will reside in one location reducing the hardware and software costs. Licensing costs may be reduced somewhat, but is expected to remain similar since the total number of users will not change. Collaboration and work efficiency between the UHCC and JABSOM will improve once the IP phone system is merged as a combined phone directory, which will display phone numbers for all UHCC and JABSOM listings.

IT Data Security and AV Services

Currently, the UHCC and JABSOM IT teams work together to ensure that their respective network meets data security benchmarks. Both units recognize the need for data security but neither unit has a full-time technician dedicated to data/network security. However, the sharing of such a position has been discussed. This capability is

becoming increasingly important with the rise in researchers using sensitive data and increased collaboration in the Consortium.

JABSOM has a dedicated AV technician who has been willing to help at the UHCC. While the IT staff at the UHCC is fully trained on its AV system, it is helpful to have a person with the knowledge that can provide back-up assistance when necessary. Both units have similar equipment running on the same basic core software (Crestron and BSS).

Regulatory, Financial and Administrative Compliance

There are specific Federal, State and private funding regulations, sponsor and donor financial and administrative policies, and UH/RCUH/UHF fiscal administrative policies and procedures that are consistent among all University departments, programs and units. Thus, it makes sense that compliance activities in these areas could be provided as shared services. Compliance activities may include developing adequate tracking mechanisms to ensure timely processing of documents, verifying and processing effort certifications to comply with annual and grant reporting, responding to internal audit issues, generating and processing payroll and general expense adjustments to comply with funding authorizations, and managing and ensuring purchasing mechanisms utilized comply with procurement requirements, fund appropriateness, allowability, reasonableness, and availability. Integrating these activities could be explored.

Management of Grant/Fiscal Records per State and Federal Regulations

The UHM and the RCUH view the fiscal office as the gate keeper of all "official/original" financial records that support all funding sources for record-keeping and audit purposes. Thus, activities including, managing files through tracking systems, archiving and destroying files in accordance with Federal, State, and sponsor-driven fiscal retention schedules and the maintenance of a record of physical inventory are universal services which could be shared between the UHCC and JABSOM.

B Potential Savings and efficiency gain

The Task Force's charge did not include detailed cost analysis of any savings that could be achieved by the combining of services between UHCC and JABSOM. This will require a much more in-depth analysis and access to cost information that was not available to the Task Force. However, a cursory examination of the activities listed above suggests, as it has already been stated by the leaders at both institutions, that any savings resulting from combining some or all of these services would be minimal. Of note, is that the merging of some of these activities (e.g., GSR, IT security) would require some immediate investment to meet the needs of both institutions. Another important observation from the list of sharable activities above is that none of these potential changes would require a major administrative re-organization to be implemented. Indeed, as stated above, some of these changes have already been implemented (e.g., Vivarium) or are being negotiated (e.g., phone system, GSR, Microscopy and Imaging).

II. UHCC-Specific Activities That Could Not Be Shared

A. Director's Authority

Fiscal Controls:

Revenues (cigarette tax, G funds, tuitions, RTRF, philanthropy (UHF, Friends) clinical revenue, institutional grants, Hawaii Cancer Consortium)

Budget

Bond management

Revenue streams (cigarette tax, G funds, tuitions, RTRF, philanthropy, any clinical revenue, grants, Hawaii Cancer Consortium), budget design and implementation, and bond management should be controlled by the UHCC Director to ensure that the intent on the use of funds is fulfilled and is purposely being utilized to support Cancer-relevant activities, as well as to support the sustainability of the Center as a successful NCI-designated Cancer Center. The Director has a background in cancer research and, therefore, is best placed to make these determinations. The Cancer Center receives unique revenue streams, such as the legislatively appropriated Hawaii Cancer Research Special Fund (304A-2168, HRS), nonprofit support from the Friends of the UH Cancer Center, and private funding from the Hawaii Cancer Consortium, which all have specific use requirements that support cancer research, clinical trials, and Cancer Center operations so independent budget controls are imperative. In addition, the Cancer Center receives bonds for the purpose of financing or refinancing the costs of the construction and maintenance of the Center specifically. The UHCC bond series are uniquely secured by the Hawaii Cancer Research Special Fund established pursuant to 304A-2168, HRS, to pay for debt service and the current and capital expenditures of the UHCC.

Permanent and Temporary Faculty Lines

(Faculty Recruitment/Retention, Tenure/Promotion Decisions)

Cancer Center Laboratory/Office/Common Space, Laboratory equipment

Oversight of Shared Resources

Leadership/Coordination of Cancer Center Matrix Partners and Activities

Philanthropic activities

The Director must control all Cancer Center permanent and temporary faculty lines; laboratory, office, and common space; and shared resources (Analytical Biochemistry, Biostatistics/Bioinformatics, Metabolomics, Nutrition, and Pathology). The Director must also provide the primary leadership of the Cancer Center matrix partners and its activities, which are focused primarily on cancer-related issues. Preservation of the Director's authority is an essential requirement of NCI-designated cancer centers as stipulated by the NCI. The inability to demonstrate this essential characteristic would seriously jeopardize the successful renewal of the CCSG.

B. *Clinical Trials Office*

Currently, the CTO purely supports oncology research as defined by its mission within the UHCC. As JABSOM is part of the Hawaii Cancer Consortium, the CTO already functions as a resource for them in regards to oncology clinical trials. The feasibility of expanding CTOs clinical research scope beyond this could be examined but CTO would then need considerable support as they are currently understaffed.

Two CTO resources that could be discussed for merging with JABSOM are Regulatory and OnCore. The CTO's regulatory department is in the process of expanding to support protocols throughout the UHCC and currently provides support to cancer protocols within the consortium. While the Western IRB costs associated with this are covered and agreed upon by the consortium, we would need to consider how protocols that are not part of the consortium/UHCC mission would be covered (in other words, any non-cancer related protocols). Any expansion of the regulatory department to include other types of trials would require significant additional manpower.

Some institutions (UAB and Stanford, for example) have expanded the use of their informatic clinical research management system (OnCore) beyond their oncology research programs. This enterprise-wide implementation could be considered as part of a re-organization but would incur significant costs not currently covered by the consortium agreement for oncology clinical trial use. However, these programs also have robust OnCore departments managing education, data integrity, IT/coding specialists, security, etc. while the CTO currently has 1.0 FTE serving the UHCC and HCC.

Because merging the regulatory and Oncore activities would require considerable additional financial resources, they are currently not under discussion and have a low priority.

B. Grant Applications and Pre- and Post-Award CCSG Activities

Institutional Approval of Grant applications

As a Level 5 unit within the UHM, the UHCC Director maintains Center-level approval authority for all extramural funding applications. The Director evaluates whether a grant application would benefit the Center and support its mission. The Center Director, in consultation with the Faculty, delineates the research priorities of the Center and encourages the development of specific research areas. He also commits resources (space, administrative support, etc.) under his control in support of the submitted grant application when funded. He approves such applications or recommends modifications. Approval of all extramural proposals must reflect UHCC research priorities and can only be made by the UHCC Director and his designees.

Pre and Post Award CCSG-related Activities

The National Cancer Institute Cancer Center Support Grant (CCSG) supports the administrative leadership, shared resources, the clinical trials office, and developmental research activities of the UHCC. The UHCC Director is the Principal Investigator (PI) of the CCSG. The CCSG coordinates and supports all cancer-related research activities at the University. The Director/CCSG PI holds the ultimate decision-making authority over all aspects of the CCSG and delegates organizational and oversight responsibility concerning the execution of the CCSG's Specific Aims to Center researchers and administrators. At each of the 69 NCI-designated Cancer Centers, the Center Director PI maintains ultimate authority over pre- and post-award CCSG activities. Sharing final decision-making and the control and execution of these activities with another UH entity would dilute the Center's competitiveness in the eyes of the NCI both in terms of the Director's authority and the implementation and execution of cancer-focused administrative activities. The Director's decision-making authority and the Center's cancer focus are two "*essential characteristics*" that are independent merit descriptors as detailed in the CCSG Guidelines.

C. Shared Resources (Analytical Biochemistry, Biostatistics/Bioinformatics, Metabolomics, Nutrition, Pathology)

For most Shared Resources, no equivalent entities exist at JABSOM that could be the basis for a merger with these UHCC shared resources. JABSOM investigators can access the services provided by the UHCC shared resources, through non-member rates. The Biostatistics and Informatics Shared Resource (BISR) is an exception in that a biostatistics function exists at JABSOM (Office of Biostatistics and Quantitative Health Sciences). UHCC has some bioinformatics functionality and JABSOM has recruited a bioinformatician. The need for bioinformatics is growing in both units, so it may be useful to explore collaboration on this aspect in the future. There is a possibility for the Biostatistics units to cover for each other and collaborate more; however, the structures, priorities, and funding mechanisms for the two cores are very different (CCSG for UHCC with subsidized rates for members and RMATRIX and COBRE for JABSOM), so combining these groups would be difficult, and is not a present priority.

D. Administrative/Operations Services

The Operations team supports the Center Administration departments with fiscal related transactions, managing the Sullivan Conference Center account, and provides procurement support. This team will continue to function at the highest efficiency under the direction of the UHCC Operations Coordinator in the Director's Office.

E. Fiscal Services

The Cancer Center's Central Fiscal Services include (details in Appendix): budget development and management; financial reporting; contract and grant financial administration, procurement; accounts payable and receivable processing; shared resources fiscal support services (including rate development and chargeback services); philanthropic account coordination and management support service; bond fund management support service; Hawaii Cancer Consortium account management services; and administrative support services (including interpretation, advice, and training to Administration and Program Support Staff on fiscal-related regulations, policies and procedures for the Cancer Center and assists with the Cancer Center's planning process).

These services must be maintained under the UHCC as the sole authority in order to ensure that fiscal services support cancer-relevant activities to benefit the UHCC's mission and the CCSG. In addition, dedicated fiscal services ensure that funds are utilized in accordance with funding authorizations (e.g. 304A-2168, HRS for the Hawaii Cancer Research Center Special Fund) to support cancer research and operations. The Cancer Center has specific priorities under the leadership of the UHCC Director. The UHCC fiscal support services support these priorities, which includes the management of financial details that are essential to the determination of the proper usage of funds.

F. Human Resources

Overseeing the faculty and staff recruitment, faculty tenure and promotion, disciplinary issues and grievances, maintaining personal records of approximately 350 employees are some of the main elements of the UHCC Human Resources Office. The UHCC HR office is in charge of drafting contract language for each employee hired at the UHCC. These functions are the exclusive privilege of the Director in conjunction with various offices at UHM. All issues discussed with the UHCC Director and Associate Directors are confidential. These elements are mission critical and must remain exclusively under the authority of the UHCC Director. Blurring reporting lines with another administrative entity would compromise the UHCC personnel-related functions at this critical juncture for the successful renewal of the CCSG.

G. Research Education and Training

Currently, this program is organized and coordinated by a single full-time employee who is dedicated to the UHCC sponsored scientific conferences, seminars, and symposia. These activities include, among others, making travel arrangements, communicating directly with speakers and guests, and reproducing educational materials for distribution. These many tasks are efficiently and effectively fulfilled by enlisting the cooperation of over 10 staff members from the Epidemiology, Cancer Biology/Natural Products, and Prevention and Control Programs, and the UHCC administration and Clinical Trials Office. This activity also oversees the UHCC CME program and coordinates faculty and the Hawaii

Consortium for Continuing Medical Education (HCCME) for the planning and execution of the CME activities at the UHCC. These activities could potentially be shared with the Medical School, and especially for the CME program, which has already been working with the Medical School.

For the renewal of the CCSG, this program is also responsible for scheduling and coordinating the External Scientific Advisory Committee site visits and the NCI site reviews. In addition, this program oversees and supervises the CURE Internship Program, fulfills reporting requirements for the P30 CURE supplement, coordination of other research education and training events, and appearances by candidates for faculty recruitment. These activities are strictly cancer-research related and regulated by CCSG guidelines and must remain within the UHCC.

H. Information Technology

The UHCC network provides the Center faculty and staff with a secure network environment for internet access, data storage, file sharing, email and IP phone system. Secure, local access to shared files is imperative to the daily work of the faculty and staff. The UHCC network infrastructure and organization is very different from JABSOM and it would require a large investment to merge the two into a true single network infrastructure. Given the need for local servers at both CC and JABSOM and the different levels of support provided at each site, a true single network infrastructure would not provide a return on the investment.

However, there could be an underlying shared network infrastructure that would allow for some shared services, but not within a shared IT department. Creating one campus network infrastructure with one IT department that would manage a single network is doable, but it is not currently under discussion because it will take a large investment and many labor hours to accomplish. Moreover, as the UHCC and JABSOM have separate missions, there is a vital need for two IT departments which provide separate service.

I. Human Subjects Research Compliance

The laws and regulations related to human subject protections, grant and trial accounting, effort reporting, scientific misconduct, privacy and security and clinical trial billing are highly complex and always evolving. Clinical research compliance has rightfully become a major focus area of the Hawaii Cancer Consortium partners, External Advisory Board, other regulatory bodies, funding agencies and research participants in recent years. The risks are both human and financial and the trend is expected to continue to grow. Clinical research is highly regulated, and as such, the role of compliance is vital to ensuring continuation of clinical research at the UHCC. Of note, in the clinical community, compliance functions between research and other departments is not shared due to the specific mission of the compliance function. Research compliance focuses heavily on

audits, monitoring, safety and reporting. Human subjects research compliance activities at the UHCC are specific to oncology drug clinical trials and related research (e.g., intervention studies). The separate missions and visions of the UHCC and JABSOM do not enable or support compliance as a shared resource.

Furthermore, compliance often deals with highly confidential information about research subjects, financials, individual actions/behaviors and proprietary information. This information is very much programmatically and individually held in confidence and is rarely openly shared. Internal operations at the UHCC have recently faced stability difficulties in managing and performing operations, activities, growth and compliance. These challenges will continue for the foreseeable future. A cross-functional unit may inadvertently lead to human subjects research compliance being compromised or perceived as an afterthought, a way to conserve resources, or a way to diminish the needs and complexities and uniqueness of each organization, and not a core value of either entity.

J. Community Partnership Coordination

This activity aims to engage community partners and collaborate with community organizations to initiate and coordinate external partnership programs and educational activities to address the mission of the UHCC. Projects include: 1) Hawai'i Comprehensive Cancer Coalition to plan, implement, and evaluate the Hawai'i Cancer Plan; 2) No Ke Ola Pono o Nā Kāne, the Kāne Initiative, a statewide project to improve the health and well-being of Native Hawaiian men; 3) Clinical Trials Shadowing Program introduces JABSOM first-year students to clinical trials research by working with oncologists; and, 4) Outreach at Hawai'i Seniors' Fair and other educational events. These duties require specific knowledge of the UHCC and its mission.

K. Events/Information/Communications Coordination

The Center's events, information, and communications coordination is a part of the Center's Communications department's duties. Communications develops news articles, publications, press releases, correspondences and other forms of social media to share with external and internal audiences. Creating these documents requires full knowledge of the Center's mission, research scope, and details of the Center's departments. Additionally, the department creates and implements comprehensive communication plans for both internal and external audiences, which includes highlighting the scientific achievements of the researchers. Communications also provides leadership to Center's senior level administrators and managers in managing crisis communication, along with plans of how to manage external affairs, which includes communication, community relations, government relations, development support, and education and partnerships. Communication employees can only provide this leadership with knowledge of the Center's history and goals based on its mission. The Center's

website content that is handled by communications also needs to follow guidelines that follow the mission of the Center.

Communications also coordinates bookings and events held in the Sullivan Conference Center as well as non-faculty/administration-driven events. Duties from bookings, producing quarterly newsletters sponsored by the Friends of the UH Cancer Center, creating and updating faculty profiles, coordinating educational and informational events for the public and summer interns requires knowledge of the Center's mission in order to remain on course with the overall vision and mission of the Center. Communications also acts as the liaison between the Center and the Friends of the Center, the nonprofit organization whose mission is to support and promote the Center. A Center specific employee needs to coordinate with the Friends since their mission is to support the Center specifically. Other duties that require extensive knowledge of the Center's mission and history includes providing tours for intermediate through college level students, prospective and current donors, faculty recruits, and visitors. Cancer specific knowledge is required to fulfill other duties such as developing outreach education opportunities for rural Oahu and neighbor island communities. Field telephone and email inquiries of general and specific natures regarding cancer also needs cancer specific knowledge.

L. Facilities Management and Planning (details in Appendix)

Built in 2012, the UHCC is an advanced building that incorporates energy efficient features such as variable frequency drives and unique building infrastructure platforms in HVAC, security, and building automated systems that require specialized training in order to provide uninterrupted service for the specific research needs of its researchers. The UHCC facilities personnel have obtained the necessary training to operate and maintain its HVAC system, building management system (with current software upgrades), security surveillance systems and equipment which are specific to the UHCC facility. The UHCC has very specific research needs that are required to meet the mission of the Center. The UHCC freezer monitoring system was recently upgraded, which required the training of UHCC facilities and lab personnel. This unique system offers wireless monitoring and remote web-browsing to all end users on a 24 hours, 7 days a week schedule. The UHCC also provides liquid nitrogen to its investigators. The UHCC facilities personnel also monitors, services, and maintains its own building chiller plant.

The JABSOM's facility was built in 2006 with a building automated software (BAS) system that is several versions behind the current UHCC's version. JABSOM does not maintain a freezer monitoring system similar to UHCC but utilizes security personnel performing a daily physical walk-thru monitoring of its freezers every 4 hours 24/7. JABSOM also does not provide liquid nitrogen to their researchers. Its chiller plant operations are exclusively maintained and serviced by the Board of Water Supply, which aims to save financial resources

but means that there is no one to support potential shared service activities with the UHCC. Moreover, the JABSOM security system would require significant fiscal resources to upgrade to the operating platform currently being used by UHCC. Such an upgrade at JABSOM would be required to create a shared resource activity in all aspects covering HVAC, security, freezer monitoring, and 24/7 BAS monitoring.

III. Relationship with Instructional Departments at UH Manoa

The UH Cancer Center was created over 35 years ago to bring together researchers from various disciplines to conduct research on a public health issue of great importance to the state. The Center has greatly benefited from the UHM Organized Research Unit model as it allowed for a horizontal organizational structure which facilitates integration among research groups (versus a silo model with departments). It also provided clear authority to the Director on budget, faculty lines, administrative support staff and space. These two attributes, interactions across research programs and Director's authority, match very tightly the requirements for NCI- designated cancer centers.

Because UHCC is a multidisciplinary research center, its faculty members are affiliated with a variety of instructional departments on the Manoa campus. Teaching by UHCC faculty, either as classroom teaching or student supervision, takes place in multiple departments, schools and colleges at UHM, such as Public Health (School for Social Work), Human Nutrition (CTHAR), Cell and Molecular Biology (JABSOM), Chemistry (College of Natural Sciences), Psychology (College of Social Sciences), and Medicine (JABSOM). Thus, there is not a single natural affiliation with a particular school that could be proposed for the whole Cancer Center.

IV. Organizational Models of NCI Designated Cancer Centers

There are currently 69 NCI-designated cancer centers in the U.S. (<http://www.cancer.gov/research/nci-role/cancer-centers>). There are 3 categories of designation: basic science cancer centers (N=7), clinical cancer centers (N=17), and comprehensive cancer centers (N=45). The organizational models of the designated cancer centers were analyzed by viewing their websites. A summary is given in the Appendix. There are 44 clinical or comprehensive cancer centers within universities, of which 40 operate as a medical center or are part of a health care system. There are 4 common organizational models for the 44 with a clinical program: 45.4% operate within health science campuses headed by a VP or CEO for health, 27.3% operate as independent organizations, 15.9% operate within university hospitals, and 11.4% operate under medical schools. The UHCC is a clinical cancer center that has operated since its inception in 1977 as an independent organization (Organized Research Unit) within the University. UHCC cannot adopt an organization model that is followed by most of the NCI-designated cancer centers since UH does not operate its own hospital or as part of

a health care system. Although there is not one accepted organizational model for NCI-designated cancer centers that ensures success, the NCI requirements related to the director's authority are more straightforwardly met in an independent center. UHCC is also unique in that its research is largely based on population sciences, with >60% of funding from this research area, rather than basic or clinical science. UHCC was described by the former director of the NCI Cancer Centers program (www.....) as "*a population science research center*", even though this is not an official category. Population sciences researchers generally are aligned with Schools of Public Health rather than Schools of Medicine. UHCC has been able to succeed by creating an original path and organizational model that capitalizes on the unique resources that Hawaii offers, namely its multiethnic population and natural environment. Any reorganization of UHCC that does not recognize this history will likely lead to failure to retain the NCI designation.

More generally, research centers without clinical revenues or large endowments such as UHCC depend almost completely on federal grants for their success. Grants have become much more competitive and less funding is available for investigator-initiated research which now competes directly with large government initiatives. To be able to seize funding opportunities and change priorities quickly, it is essential that administrative structure and reporting lines be kept simple and direct to maximize efficiency.

APPENDIX

Organizational Models of NCI-Designated Cancer Centers

Number	Cancer center environment	Name	Type of Center*	Matrix Center?	Does U have School of Public Health?	Does U have Medical School (MED)?	Does U have Health Sciences** (HS) Campus?	Does U have Health Care System / Hospital (HP)?	Within MED, HS, HP?
1	Centers within Hospitals, Not attached to Universities	City of Hope Cancer Center	P						
2		Dana-Farber Cancer Center	P						
3		Fox Chase Cancer Center	P						
4		Mayo Clinic Cancer Center	P						
5		Memorial Sloan Kettering Cancer Center	P						
6		Roswell Park Cancer Center	P						
7		St. Jude Children's Research Hospital	P						
8		The Tisch Cancer Institute at Mount Sinai	C						
9	Standalone Research Centers	Cold Spring Harbor	B						
10		Jackson Laboratory	B						
11		Salk Institute	B						
12		Sanford Burnham Medical Discovery Institute	B						
13		The Wistar Institute Cancer Center	B						
14	Standalone Medical Universities (Not academic campuses)	Dan L. Duncan Cancer Center, Baylor College of Medicine	P						
15		Cancer Therapy & Research Center, University of Texas Health Science Center	C						
16		Harold C. Simmons Cancer Center, University of Texas Southwestern Medical Center	P						
17		Hollings Cancer Center, Medical University of South Carolina	C						
18		Knight Cancer Center, Oregon Health and Sciences University	C						
19		Sidney Kimmel Cancer Center at Thomas Jefferson University	C						
20		University of Texas MD Anderson Cancer Center	P						
21		UCSF Helen Diller Cancer Center	C						
22	Independent Cancer Centers affiliated to universities	Fred Hutchison Cancer Center (affiliated with University of Washington)	P						
23		Moffitt Cancer Center (affiliated with USF and FSU)	P						
24	Cancer Centers within Universities	Abramson Cancer Center, University of Pennsylvania	P	X		X		X	MED
25		Siteman Cancer Center, Washington University	P	X	X (PHI)	X		X	
26		Einstein Cancer Center, Yeshiva University	C	X		X		X	MED
27		Arizona Cancer Center, University of Arizona	P	X	X	X	X	X	HS
28		Karmanos Cancer Center, Wayne State University	P			X			
29		Cancer Institute of New Jersey, Rutgers University	P	X	X	X	X		
30		Chao Cancer Center, UC-Irvine	P	X		X	X	X	HP

31	Case Cancer Center, Case Western University	P	X		X		X	
32	Koch Institute for Integrative Cancer Research, MIT	B						
33	Duke Cancer Institute, Duke University	P			X	X	X	HS
34	Buffett Cancer Center, University of Nebraska	C	X	X	X	X	X	HS
35	Lombardi Cancer Center, Georgetown University	P			X	X	X	
36	Irving Cancer Center, Columbia University	P	X	X	X	X	X	HS
37	Huntsman Cancer Institute, University of Utah	P			X		X	
38	Holden Cancer Center, University of Iowa	P	X	X	X	X	X	HS/MED***
39	Indiana University Simon Cancer Center	C	X	X	X	X	X	
40	Jonsson Cancer Center, UCLA	P	X	X	X	X	X	
41	Perlmutter Cancer Center, NYU	C			X	X	X	HS/MED
42	Markey Cancer Center, University of Kentucky	C	X	X	X	X	X	HS
43	Masonic Cancer Center, University of Minnesota	P	X	X	X		X	
44	Massey Cancer Center, Virginia Commonwealth University	C			X	X	X	HS
45	Norris Cotton Cancer Center at Dartmouth	P			X	X	X	HS
46	The Ohio State University Cancer Center	P	X	X	X	X	X	HS
47	Purdue University Center for Cancer Research	B						
48	Lurie Cancer Center, Northwestern University	P			X		X	
49	Kimmel Cancer Center, Johns Hopkins University	P	X	X	X	X	X	HS
50	Stanford Cancer Institute, Stanford University	C			X		X	MED
51	The University of Kansas Cancer Center	C			X		X	HP
52	UAB Cancer Center, University of Alabama – Birmingham	P	X	X	X		X	
53	University of Maryland Greenebaum Cancer Center	P	X	X	X		X	HP
54	UC Davis Cancer Center	P			X	X	X	HS
55	University of Michigan Cancer Center	P	X	X	X	X		HS/MED
56	UC San Diego Moores Cancer Center	P	X		X	X	X	HS
57	University of New Mexico Cancer Center	P			X	X	X	HS/MED
58	University of Pittsburgh Cancer Institute	P	X	X	X	X	X	HS+HP
59	Lineberger Cancer Center, University of North Carolina	P	X	X	X		X	MED
60	University of Virginia Cancer Center	C			X	X	X	HS
61	University of Chicago Cancer Center	P	X	X	X		X	HP
62	University of Wisconsin Carbone Cancer Center	P			X	X	X	HS
63	University of Colorado Cancer Center	P	X	X	X	X	X	HS
64	USC Norris Cancer Center	P			X	X	X	HS
65	University of Hawaii Cancer Center	C			X			
66	Vanderbilt-Ingram Cancer Center	P			X	X	X	HS
67	Wake Forest Cancer Center	P			X		X	HP
68	Winship Cancer Institute, Emory University	C	X	X	X		X	HP
69	Yale Cancer Center	P	X	X	X		X	MED

* C = Cancer Center, P = Comprehensive Cancer Center, Basic Laboratory

**** Health Sciences campuses include several schools and institutions, such as medicine, nursing, pharmacy, and public health, and have an overall administrative structure, generally governed by a VP for Health Sciences or CEO for Health. Universities with VP for Health Sciences that included only one school/institution, they are not included as Health Sciences campuses (e.g., University of Minnesota).**

***** H/M indicates that the Cancer Center is under the Health Sciences campus where the VP is also the Medical School Dean.**

CC Type	Institutional academic official of highest rank		Total
	# reporting to Dean, Medical School	# reporting to academic official above Dean*	
NCI designated Comprehensive Cancer Center	8	12	20
NCI designated Cancer Center	4	10	14
Totals NCI only	12	22	34
	35.3%	64.7%	
Non-NCI designated Cancer Center	4	8	12
Totals all Cancer Centers	16	30	46
	34.8%	65.2%	

* examples include VC for research, VC Health Affairs, President, Chancellor, CEO, Board of Trustees
 * hospital presidents, medical center CEO not included

Source: 2013 AACI Cancer Centers survey

APPENDIX I

Clinical Trials Office

APPENDIX I

UHCC Clinical Trials Office

I. Major Functions of CTO Staff

- a. Provide infrastructure and operational support for cancer clinical trials at UHCC
- b. Operationalizing approximately 150 clinical trials at any given time
- c. Assist investigators and sponsors throughout the entire lifecycle of a protocol from inception to study closure
- d. Central point of contact for investigational pharmacy, laboratory (specimen processing, storage, and shipping/receiving), nursing, NCI, investigational sites and other collaborating academic institutions.
- e. Study Coordination
 - i. Regulatory services
 - ii. IRB submissions, continuing reviews, amendments
 - iii. Processing of Safety Reports
 - iv. ClinicalTrials.gov reporting
 - v. Enrolling, registering, and following clinical trial patients per protocol
 - vi. Central Drug storage
 - vii. Specimen processing/shipping
- f. Fiscal Services
 - i. Developing and negotiating budgets and amendments for trials with cooperative group and industry sponsorship
 - ii. Post award support to research staff
- g. Education and Training of Clinical Trial Staff
 - i. Regular educational meetings for research staff in oncology and research management
 - ii. Orientation for new hires
 - iii. Clinical research newsletter and email communications
- h. Clinical Research Group Support
 - i. Oversee clinical research group flowcharts and webpages
 - ii. Post trial listing to UHCC website, clinicaltrial.gov and NCT CTRP reporting
- i. OnCore Clinical Trial Management System (CTMS)
 - i. Set up user-specific OnCore access and training
 - ii. Develop study-specific calendars
 - iii. Facilitate data collection and reporting of clinical cancer research per NCI requirements
- j. Investigator Initiated Trial Pipeline
 - i. Coordinate protocol writing, IND submissions, and NCT reporting
 - ii. Feasibility and Scientific reviews and approvals
 - iii. Ongoing study management throughout life of protocol

Potential for Shared Resources with SoM

Currently, the CTO purely supports oncology research as defined by its mission within the UHCC. As JABSOM is part of the Hawaii Cancer Consortium, we already function as a

APPENDIX I

resource for them in regards to oncology clinical trials. We could examine the feasibility of expanding our clinical research scope beyond this but would need considerable support as we are currently understaffed.

Two resources that could be discussed within the CTO are Regulatory and OnCore. Our regulatory department is in the process of expanding to support protocols throughout the UHCC and currently provides support to cancer protocols within the consortium. While the WIRB costs associated with this are covered and agreed upon by the consortium, we would need to consider how protocols that are not part of the consortium/UHCC mission would be covered (in other words, any non-cancer related protocols). If the reorg would want to expand the regulatory department to include other types of trials, we would have significant manpower hurdles to jump.

For OnCore, some institutions (UAB and Stanford, for example) have expanded OnCore use beyond their oncology research programs. This enterprise-wide implementation could be considered for the reorganization but would incur significant costs not currently covered by the consortium agreement for oncology clinical trial use. However, these programs also have robust OnCore departments managing education, data integrity, IT/coding specialists, security, etc. The CTO currently has 1.0 FTE serving the UHCC and HCC.

APPENDIX II

Communications

APPENDIX II

Communications
October, 2016

COMMUNICATIONS

Total FTE: 3.0

Community Partnership Coordinator
Events and Information Coordinator
Communications and External Affairs Director

COST SAVINGS

In September 2015, Communications lost its Communications Director. For about a year the Public Information Officer was fulfilling both duties. Since then, the new Communications Director fulfills both duties. To cut costs, it was decided not to replace the Public Information Officer position.

Major Functions:

1. Center Communications

Information about the Center

Create the Center's news articles/publications, press releases, correspondences and social media. Communications also includes oversight of Center's website content. As well as being a media relations coach to administrators and faculty, and provide Cancer Center specific talking points. The department works with the media to communicate research, news and events to the public.

Manage external affairs

This includes communication, community relations, government relations, development support, education and partnerships. This also includes responding to public inquiries: address call/walk-ins requesting cancer information, and providing tours of the UH Cancer Center.

Events

Work collaboratively with the UHCC Research, Education, and Training Program Director to orchestrate various major UHCC events that includes, the Melanoma Symposium, Global Liver Cancer Conference, EAC visits. The department organizes and executes events that focus on increasing public awareness, education or fundraising on the Center's behalf. We also coordinate Sullivan Conference Center Events.

2. Community Partnership: Identify and collaborate with community organizations to address the mission of the University of Hawai'i Cancer Center.

Hawai'i Comprehensive Cancer Control Coalition (HCCCC): Statewide Coalition of approximately 80 cancer control stakeholders addressing the objectives identified in the Hawai'i Cancer Plan which are based on the data in the Hawai'i Cancer Facts and Figures.

- a. Plan, implement, and evaluate the Hawaii Cancer Plan.
- b. Address specific areas of the Cancer Plan.

APPENDIX II

No Ke Ola Pono o Nā Kāne: (for the good health of Hawaiian men), **Kāne Initiative:** since 2002, this statewide project seeks to improve the health and well-being of Native Hawaiian men by conducting community discussion groups. Partners include Ke Ola Mamo (Oahu Native Hawaiian Health Care System), American Cancer Society, Queen Lili`uokalani Children's Center, Aha Hui o na Kauka (Association of Native Hawaiian Physicians), Native Hawaiian Civic Clubs, and neighbor island Native Hawaiian Health Care Systems.

Clinical Trials: Support a research project, in collaboration with JABSOM, to introduce clinical trials to first year medical students. This includes problem-based scenarios, training, NCI materials, and community clinical mentoring program.

3. Community Outreach

Educational sessions

- a. **New Frontiers:** outreach event on outer islands (Maui and Kauai) to reach medically underserved area (MUA/MUP)
- b. **Melanoma and Weinman Symposium**
- c. **Global Liver Cancer Conference**
- d. **HERO honoring clinical trials**
- e. **Run for Hope on the Big Island**
- f. **Quest for a Cure**
- g. **Cancer Moonshot Summit**

Hawai'i Senior's Fair: annual 3-day event in September at NBC Exhibition Hall, reaches over 20,000 people. Booth sponsored by Star Advertiser (member of the Friends).

Provide Cancer Center Information Material: Community Health Fairs (i.e., Bank of Hawai'i, HMSA): provide NCI and other health education materials

- a. **The Melanoma Symposium, Global Liver Cancer Conference, P30 visit, Weinman Symposium, HERO event, Run for Hope on the Big Island, Quest for a Cure.**

APPENDIX III

Research, Education & Training

APPENDIX III

Research, Education, and Training Program

Major Functions

1. Organize center-sponsored national and international scientific symposium, seminars, and conferences. Responsible for travel and local arrangements for visitors. Identifies and produces materials for researchers attending symposium.

This activity could be very time demanding and labor intensive, and at times we could need help from the Medical School, since we are short-staffed here at the center for big center-wide conferences and events.

2. Coordinate review visits by UH Cancer Center External Advisory Committee and other National Cancer Institute site visits under the supervision of the Associate Director of Administration.

This activity should stay within the center faculty and staff to avoid communication disruptions, and to ensure successful EAC and NCI site visits, as the center faculty and staff are more experienced with EAC reviewers and P30 guidelines and requirements.

3. Oversees the center CME program and coordinates with faculty and the HCCME for planning, executions, and CME accreditation of events at the center.

We are already working with SoM HCCME board for the planning and implementation of CME activities at the center.

4. Coordinates internal training program for faculty, staff, and students, such as CURE summer and year-round internship program, and NCI research training. Be responsible for intern student hire, weekly journal club training, management, and final presentation.

We tried to work with SoM native Hawaiian education summer program and combine their summer program with CURE intern program. However, CURE program is regulated by P30, and the two programs have different goals and systems, funding sources, and target students, so it is hard to merge.

5. Assists in the development of the center by organizing the logistics of recruitment of new research faculty and specialists, arranging interviews with search committee chairs, Consortium members, scheduling and managing interview visits.

APPENDIX III

Research, Education, and Training Program

We have a clearer sense of the UHCC programs, faculty, and staff members at the center.

Currently, even though this is a one-person program, I have spent a better part of my role to leverage resources, maximize and prioritize my own focus so that every major function was fulfilled successfully without being labeled as a one-person show. I would say I can count on a team of over 10 staff members supporting my efforts in the center, and I tapped resources from each program, having supports from administration supports of each program, and the center administration. There are 3 or 4 staff members at SoM doing for the Medical School what I do for the Cancer Center. I think it is much more efficient and cost effective to have me assigned 100% at UHCC where depending on needs, I can count on a well-established network of supporting staff that is familiar with UHCC and thus could get things done more efficiently.

APPENDIX IV

Fiscal Office

APPENDIX IV

UH Cancer Center Fiscal Office

MAJOR FUNCTIONS--

1) Budgets:

- a. Develop and control institutional (General, Tuition, Special-Cig Tax, and Revolving-RTRF) budget for submittal to the Manoa Budget Office (MBO).
- b. Review and approve budgets for myGrant proposals.
- c. Assist with budget development to support the Shared Resources annual service order renewal through RCUH.

2) Financial Reporting:

- a. Reconcile all institutional and extramural (Approx.: Revolving-13, State/Institutional-76, Federal- 65, Private-111, UHF-94) accounts monthly and record all in transit and projected expenditures as provided by program personnel.
- b. Assist with the preparation of sponsor-related financial reports for all sources of funds.
- c. Assist with the preparation of financial data in response to UH, UHF, RCUH and Cancer Center program requested reports.
- d. Fiscal Director provides quarterly financial reports to the MBO on all General, Tuition, RTRF, and Cigarette Tax expenditures and provides semi-annual financial reports on the Cigarette Tax Fund to the State Legislature.

3) Procurement, Accounts Payable (A/P), and Accounts Receivable (A/R)

Processing:

- a. Resolve account and transactional issues that arise daily from vendors, sponsors, program, and other UH, RCUH, and UHF offices. (e.g., outstanding payment issues, grant compliance matters, etc.)
- b. Review and approve all procurement documents (e.g., sole source verification, price cost reasonableness, competitive bids, terms and conditions compliance, etc.), including ensuring fund availability and assigning proper object codes.
- c. Review and process all UH, RCUH, and UHF purchasing, reimbursement, and payment documents, as it relates to the delivery of goods and

services. (e.g., mileage reimbursements, domestic and foreign travel documents, interdepartmental orders (IDO), purchase orders (PO), deposit of wire transfers, parking collections, and payments for project billables, etc.)

- d. Coordinate, maintain, and manage the Cancer Center's petty cash accounts.
- e. Complete annual financial closing activities, including but not limited to, A/P and A/R recording, reclassing expenses from RCUH to UH systems, cash transfers, institutional account service order extensions, etc.)

4) Shared Resources Revolving Account Fiscal Support Services:

- a. Assist with rate development through the provision of actual historical cost data.
- b. Assist with shared resources usage data compilation to support viability of shared resource.
- c. Coordinate with the Vice Chancellor of Research's Office and RCUH on all revolving accounts service ordered to the RCUH for management.
- d. Maintain and process invoicing/billing of all shared resources services.
- e. Monitor income and expenses for shared resources revolving accounts.
- f. Fiscal Director assists the P.I.s in locating, testing, purchasing and implementing a Shared Resource Management Software

5) University of Hawaii Foundation (UHF) Fiscal Coordination and Management:

- a. Manage, maintain, and process all UHF accounts and documents by reviewing account balances and transactions for compliance, allowability and funds availability.
- b. Coordinate with the UHF Development and Fiscal personnel to ensure appropriateness of fund usage.

6) Bond Management:

- a. Process monthly payments for the Cancer Center building improvements, which requires close coordination with the UH System Bond Office, Office of the Vice President of Administration, UH Manoa Facilities Management Office (Design Branch), OPRPM, and Disbursing.
- b. Fiscal Director manages the Cancer Center's bond use through processing transfers (e.g., debt service payments, bond administration and management fees, depreciation reserve compliance, etc.) and ensures

compliance with bond requirements by working with the UH System Bond Office (e.g., Cancer Center Sullivan Center use).

7) Hawaii Cancer Consortium Support Services:

- a. Manage and maintain Hawaii Cancer Consortium funded accounts through coordination with ORS and UH System Offices, includes personnel and operating expense management.

8) Administrative Support Services:

- a. Review and approve UH and RCUH human resource actions for allow ability and funding availability (includes hiring, terminations, employee changes, current or retroactive account distribution changes, and vacation payout verification and transfers).
- b. Maintain UH, RCUH, and UHF financial system access records for Cancer Center personnel. Manages access for administrative personnel.
- c. Attend trainings and regular meetings to keep a breast of the latest research administration and fiscal developments at the UH to provide administration and support staff assistance as needed.
- d. Fiscal Director coordinates relocation reimbursements with the Cancer Center's executive and HR personnel to ensure that all new employees are properly informed of reimbursement requirements and to facilitate a smooth transition for the selected candidate.
- e. Fiscal Director provides interpretation, advice, and training to Administration and Program Support staff to ensure compliance with the UH Administrative Procedure Manual and RCUH Regulations. In addition, the Fiscal Director develops fiscal-related policies and procedures for the Cancer Center.
- f. Fiscal Director assists with the Cancer Center's planning process.

Current FTE--

Currently, the fiscal office has the following personnel-

-APT A's – 6 total

2 for Center (Admin, Communications, Facilities, HR & IT), UHF, and P30

2 for EPI, SEER, P&C, U54, and Shared Resources

2 for Cancer Biology, Thoracic Oncology, NPET, and CTO (includes consortium support)

-APT B's – 4 total

Currently, there aren't enough APT Bs, so overlap of program coverage is required to

meet program support needs. Therefore:

3 overlap coverage for Center, UHF, P30, EPI, SEER, P&C, U54

1 for NPET and CTO (includes consortium support)

Note: 1 (APT A in Interim TA position for APT B so doing dual coverage) for Cancer
Biology and Thoracic Oncology

Shared resources fiscal responsibilities are currently being covered by 3 JABSOM
personnel (Coco Seymour, Cheryl Yasunaga, and Keenan Lee)

APPENDIX V

Grants Office

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UHCC Grants Office (2.0 RCUH FTE)

1. CCSG (NCI designation grant) Functions To:

A.1. CCSG NCI and EAC Annual Progress Reports.

- Manage the submission of written reports from ~15 individuals associated with NCI and EAC progress reports
 - Program Leaders (3)
 - SR Leaders (7)
 - Admin – Dev Funds – Senior Leadership – Planning & Evaluation (Fiscal x2, AD, Dir)
 - AD for Clinical (1)
 - EAC site visit organizations (1)
- Communicate timetables, ensure timely submission, devise templates, ensure uniformity of all components and contents, update participants of changes in rules, proofread, and compile submission (~400 pages for the NCI and ~200 pages for the EAC).
- Assemble DT 1-2 (Membership, Leadership & Grants)
- Ensure DTs 3-4 (Accruals) are correctly assembled
- Compare DTs with prior submissions and tracks research program performance
- Communicate with Program and SR Leaders for Cancer Relevance of ~120 publications
- Ensure compliance of publications with federal open access laws
- Verify SR operating budgets and usage
- Orchestrate Annual Budget Request with the CCSG PI and ADRI

A.2. CCSG EAC annual site visit.

- Manage the submission of presentations to the EAC (~135 slides) prior to site visit
- Prepare test runs for all speakers
- Ensure that EAC site visit paper submission match presentations

B. Manages CCSG Budget.

- Ensure compliance of 20-component CCSG budget with all special NCI guidelines.
- Monitor expenditure projections
- Ensure expenditure report for parent and supplement grants

C. Supplements.

- Distribute CCSG supplement opportunities, devises nomination process for funding announcement, and distributes to eligible cancer center members
- Monitors expenditures and collects interim and annual progress reports

D. Meetings.

Attend national meetings relevant to the CCSG grant and updates the parties regarding the upcoming changes in the CCSG submission

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- E. Assist Director /AD on CCSG communications with UH, BOR, community stakeholders & the NCI.
- F. Discuss CCSG with new faculty recruits & interact with administrators on all related matters.

2. Non-CCSG Functions To:

- A. Final Review of all CC Grant Proposals to Sponsors.
 - Oversee all CC Faculty proposals annually submit ~130 proposals requesting \$120 M mostly from NIH
 - Review SF424/PHS398/ASSIST documents prior to submission ensuring application compliance with University and sponsor requirements
 - Work with program staff and fiscal to fix proposal budgets
 - Coordinate the timely processing of every proposal through the University record system (myGRANT) with all parties and the University AOR (ORS)
 - Maintain director-level signature for all proposals and recommends Director's approval or requests changes from the PI
- B. *Offer coordination of grant preparation when requested.*
- C. *Grant writing and editing of scientific components.*
- D. *Assist PIs on drafting letters of support from the Director.*
- E. *Communicate cost-sharing and other commitments to the executives.*
- F. *Track proposal submission metrics.*
- G. *Assist PIs with RPPRs and Just-in-Time as needed.*
- H. *Communicate funding announcements weekly, while highlighting most relevant announcements to faculty members.*
- I. *Prepare Comprehensive Facility Resource Documents.*
- J. *Communicate award and proposal details to other UH departments as requested.*
- K. *Update UHCC Faculty for changes in grant requirements from the federal government.*

3. Model for Re-org with JABSOM

- A. CCSG Functions

The CCSG is the grant award provides the UH Cancer Center its NCI-designation since 1996. The grant of the PI is the Cancer Center Director. All CCSG reporting and execution should by definition stay under the control of the UHCC Director as it has been for the last 20 years. This direct reporting line ensures immediate access and accountability for the performance of the grant for which the Director, Cancer Center Faculty and administration are responsible. No examples exist in which designated Cancer Centers share the CCSG administration with Medical schools or other units. Merging these functions with another administrative units would result in

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co-governance of the grant and would dilute the authority of the director to the staff executing the grant terms and conditions. Blurring the CCSG administration reporting lines will introduce an unnecessary and unprecedented challenge to the upcoming CCSG application. One FTE is responsible for all aforementioned CCSG functions.

B. Non-CCSG functions.

The major source of income of the UH Cancer Center are funds that are federally funded peer-reviewed applications. The major non-CCSG function of the UH Cancer Center Grants office is the approval of all proposals by the UHCC Director is a require University procedure. Following the Director's policies regarding the interest of the cancer center the grants office signs for all Cancer Center proposals. While similar policies exist at the School of Medicine significant differences remain reflecting policies and philosophies that can be changed, though at this stage we do not see how this will improve the submission of JABSOM or Cancer Center proposals.

Personnel: One FTE is charged with the approval of all Cancer Center proposals, while the second FTE complements this proposal. In the three years of the tenure in the Grants office the Cancer Center has never had a proposal administratively rejected by any sponsor. We do not see how this can become more efficient.

Objective: The Director's approval in the University electronic route log represents the director's signature for every proposal. As such the approving delegate needs to represent the exclusive interests of the Director and as such report directly to Cancer Center executives.

Policies that ensure minimum authority for a level-5 UH unit

Cancer Center Proposal Policies after re-org with JABSOM

Stated policies cover UH Manoa unit-level proposal development procedure changes in the proposed re-org with JABSOM. They do not propose or reflect any changes in the way the Cancer Center interacts with the fiscally responsible institution (University of Hawaii), its Office of Research Services, or sponsor agencies.

Policies below are intended to cover proposals submitted to units MA1423, MA1424, MA1425, MA1426, and MA1427 and Cancer Center units that may result from the re-organization under consideration:

Cancer Center Proposal approval tree remains the exclusive privilege of the Cancer Center Director, or his/her designated delegate. The proposal approval tree for JABSOM units and Cancer Center units remains separate, while proposal approvals are delegated to a dedicate Cancer Center Only staff member whose approval represents the Center's interests as viewed by Director.

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The merged grant proposal development (pre-award) office approves or requests changes to proposals solely in response to the recommendation of the Cancer Center Director, or his/her designated delegate.

The merged grant proposal development (pre-award) office enforces cost-sharing (and other monetary commitments) at the proposal level and NIH grant policies solely in response to the recommendation and policies of the Cancer Center Director, or his/her designated delegate.

The merged grant proposal development (pre-award) office follows the approvals of the Center Director as shown in all COI declarations of all Cancer Center faculty by virtue of his/her responsibility as the supervising signatory. The Director's signature in annual COI forms cannot be delegated.

The merged grant proposal development (pre-award) office follows the direction of the Center Director, or his/her designated delegate, regarding the allocation of Cancer Center RTRF during proposal development.

Hiring of staff for the merged proposal development (pre-award) office involves an equal number of interviewers from the Cancer Center and JABSOM. Applicant information is co-reviewed by the Center Director, or his/her designated delegate. All new staffing and offers of employment for the ASK proposal development (pre-award) office must be approved by the Cancer Center Director, or his/her designated delegate.

The JABSOM executive leaders exclude themselves from approvals recommended by the Director, or his/her designated delegate(s). The Kakaako executive team maintains no authority over the recommendations of the Cancer Center Director for Cancer Center proposals.

Materiality: Given that i) no cancer center proposal has ever been administratively rejected from a sponsor since the current UH Cancer Center Grants Office personnel have been in charge, ii) all level 5 unit directors' authorities need to be maintained as described above, and iii) all non-CCSG functions are overseen by a single staff member, these proposed changes appear burdensome and without any material benefit to the Cancer Center or JABSOM.

APPENDIX VI

Operations and Human Resources

APPENDIX VI

OPERATIONS

Summary:

The Cancer Center Operations team is a part of the Cancer Center Directors' office and the primary duties are to support the Admin Departments (IT, Facilities, Events/Outreach, Media, etc.) and the Center Administration with preparing fiscal related documents such as requests for purchase orders and payments on facility utility bills, invoices, etc. The team also provides such services as working with the parking vendor, coordinating distribution of parking passes and maintaining internal records of vehicles for Center faculty/staff, procuring office supplies, and managing the Sullivan Conference center account. During long term absences of program staff, this team provides back-up assistance with fiscal matters and coordinates coverage with other program support staff.

It is in the best interest of the Center Director to keep the Operations team within his office and to maintain the current reporting structure. The major services provided by this team directly serve the Center faculty and staff. Sharing these services with JABSOM will not result in cost savings because the workload will not change. The volume of tasks involved in supporting the various departments under center-wide administration will still require a minimum of two people. Cost savings have already been realized in the reduction of one staff, from three 1.0 FTEs to two 1.0 FTEs. (One position was not filled in December 2014 to cut costs.) The workload of the third person was distributed between the two remaining Operations staff members.

Justification:

The major functions listed below detail the work done by the Operations team and highlights the importance of keeping those services separate and solely with the Center.

1. Provide admin support to all Center Admin Departments:

Individual admin departments such as IT, Facilities, Communications, Grants, Fiscal, HR do not have dedicated admin support and these departments depend on the Operations team to take care of the procurement duties for them.

The Operations team also provide assistance to the Center programs when needed. For example, Shared Resources (SR) did not have their admin/fiscal support staff for almost a year. One FTE was temporarily assigned to assist the SR faculty/staff in processing various administrative, fiscal, and personnel related documents. Similarly, another FTE was temporarily assigned to assist the P&C department last year. This temporary assignment is in addition to their regular duties. The intent of this service is to minimize disruptions in processing admin/fiscal documents at the program level if their support staff is on an extended leave or if the position is vacant.

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2. Parking

- a. LOT C: Since JABSOM parking coordinator is the primary contact for Kakaako, Operations already works very closely with JABSOM to coordinate parking with HCDA (State of Hawaii Hawaii Community Development Authority) LOT C contractor for the Center faculty/staff.
- b. UH Manoa Parking placards should be handled in house since these are passes ordered based on needs of the Center.

3. Sullivan Conference Center (SCC)

SCC is very unique to the Center. In June 24, 2011, Mrs. Joanna Sullivan signed a pledge agreement for \$3 million to UH Foundation to: a) designate and recognize the new conference center at the Center; and b) to primarily support the maintenance and furnishing of the SCC, and secondarily for equipping and furnishing other components of the Center facility.

According to the current SCC guidelines, SCC can be booked or rented by programs/external organizations related to cancer education and research benefitting the Center faculty, staff, and other researchers or the community, or other support functions relating to the Center or JABSOM operations. Therefore, special events at the SCC should be managed by the Center. Also, billing the users should be managed by the center. The money raised by renting the SCC, which is minimal, should go towards paying the IT/Custodial staff who provides assistance. Sharon Shigemasa, SCC Coordinator, works with the Operations team to bill SCC users.

4. Center bill payment and creating requisitions could be shared with JABSOM.

HUMAN RESOURCES

There are about 350 faculty and staff at the Center supported by two 1.0 FTEs. The HR office is responsible for advising and providing guidance to faculty and staff on various HR matters including recruitment, selection, staff development, compensations, benefits, and retention. A few of the major functions of the HR Office are:

1. Responsibility for Faculty and Staff Recruitment (UH and RCUH)
 - a. Developing position descriptions;
 - b. Posting positions and tracking applications;
 - c. Drafting offer letters in consultation with the Director/ADA;
 - d. Preparing and reviewing new hire documents ensuring completion of required forms and compliance with laws, policies, and procedures;
 - e. Assembling and processing onboarding documents.
2. Maintenance of various HR databases and PeopleSoft records containing personal information of employees, position control and leave documentation.

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- a. Ensuring accuracy and appropriateness of appointments (i.e. salary, title, tenure);
 - b. Monitoring contract renewal and non-renewals;
 - c. Processing termination of employment;
 - d. Maintaining confidentiality agreements and ensuring Conflict of Interest declarations are current.
3. Serving as the official custodian of the UH personal records for all UH employees; serv as the Center Departmental Personal Officer for Employee Health Trust Fund and Employers Retirement Fund; and also serves as the Center Equal Employment Opportunity personnel.
 4. Handling disciplinary issues and grievances by observing the steps on progressive discipline, assisting in fact-finding procedures and investigations, and drafting responses. HR is responsible for communicating with Manoa and Systems HR, the various unions, Academic Affairs, and the Office of the Title IX, if needed.
 5. Coordination the tenure and promotion process, providing administrative and professional support to the DPC in charge of reviewing faculty actions related to promotion, tenure, & evaluation.
 6. Preparing technical reports and responses to inquiries from various offices such as the Board of Regents, Office of the President, Office of the Chancellor, Vice Chancellor's Offices and EEO Office. Preparing HR and admin related action memos for approval from the VCR, Chancellor, and the President.
 7. Assisting the ADA in drafting MOUs with the Hawaii Cancer Consortium and UH Foundation in regards to funding and coordination with ORS, and RCUH (if needed) to execute the MOUs.

APPENDIX VII

Human Subjects Research Compliance

APPENDIX VII

UH Cancer Center Human Subjects Research Compliance Director

Summary

Human subjects research compliance at the UH Cancer Center is currently staffed by a single individual and is responsible for assuring compliance with all human subjects related federal and local regulations and grant/contract obligations including reporting requirements pertaining to the conduct of human subjects' research. Reports to the Director of the UH Cancer Center. The goals of the program are to ensure human subject safety in the research process, fulfill contractual obligations, promote adherence and compliance with local and federal regulatory requirements, and quality data reporting. Primary focus of the program has been on oncology clinical trial operations. Major functions include:

- Monitors, educates and ensures compliance with legal and local requirements for human subjects including HIPAA, Privacy and Security/Common Rule, Stark, CCSG, etc.
- Serve as knowledge expert collaborator on cross departmental issues – tumor registry/bio specimen banking, security, privacy, FDA, ICH Good Clinical Practice, information technology, safety, risk assessment, subject medical care, institutional process etc.
- Identifies potential areas of compliance vulnerability and risks, and reporting issues, developing and implementing corrective action plans for resolution of problematic issues, and providing general guidance on how to avoid or deal with similar situations in the future.
 - Conducts audits and reviews and reports findings through data collection and analysis – requires medical, research, regulatory and contractual knowledge set
 - Collaborates on development/review/implement/oversight of standard operating procedures
 - Develops and conducts training and education
- Develop and manage Quality Assurance Program – includes internal and external auditing and performance improvement and metrics
- Administrator for Data Safety Monitoring Committee
- Administrator for UH Cancer Center Privacy Board
- Administrator Research Resonance Benchmarking
- WIRB Administrative Approval Official
- Conflict of Interest Committee
- Required Regulatory Reporting
- Registered Nurse Member Protocol Review and Monitoring Committee
- Registered Nurse Member Community Research Advocacy Board
- Completes/Compiles required reporting including:
 - Data Tables 3 and 4 (CCSG)
 - Community Trials Reporting Program (NCI Required CTRP)
 - Ceded research reporting to UH IRB
 - Institutional Metrics for benchmarks and resource reporting
- Conducts random internal audits on institutionally generated trials that are monitored by DSMC – 10% of institutionally generated and 5 % of the Cooperative group trials reviewed by PRMC. Audits at the Cancer Center and at Consortium sites as available/required:
 - Includes subject medical records
 - Case Report Forms

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- Adverse Events
- IRB Documentation (regulatory compliance)
- Informed Consent
- Drug Accountability
- Liaison for external regulatory and review boards (UH, IRBs, OHRP, OIG, etc.) to address issues
- Acquires information on all external audits performed by NCI sponsored cooperative research bases and other research sponsors and consults on corrective action plans as needed (translates new information)
- Maintains a Master File of all contracts executed for research supported by CTO and monitors compliance with deliverables
- Consortium Support (From MOA)
 - Tracks Cancer Trials, ensures review by PRMS, coordinates DSMC, NCI CTRP Reporting for trials, audits for quality/compliance, develop/maintains SOPs, WIRB Account Manager

In order to complete tasks, compliance must collaborate with all areas of the UH Cancer Center, University of Hawaii and Consortium members and affiliates. Examples of activities include: working with IT to provide secure computer files/data storage; training across departments to improve reporting of research/trials in support of P30 requirements and maximum use of available resources, compliance education in support of human subject research protections, support for HSRP accreditation for UH IRB, cross training such as eProtocol system, etc.

Review of proposed Cancer Center Organization and Description

In order to achieve financial and operational stability a new proposal to share functions when feasible and complimentary to achieve administrative efficiencies and promote collaborative work that serves the community of Hawai'i between the UH Cancer Center and JABSOM is in development.

The UH Cancer Center offers a compliance function as previously described. JABSOM currently provides an office of one in The Office of Risk and Clinical Affairs (ORCA) that is responsible for developing, managing, and monitoring contracts and relationships with The John A. Burns School of Medicine's affiliated community hospitals, affiliated non-profit organizations, State agencies and business partners. As described by the current ORCA Director, the office does not engage in an audit function, but does conduct cross collaborative efforts (HIPAA training, regulatory awareness education, annual compliance week) within various areas of the medical school, serves as a knowledge expert for the Dean and manages special projects. This is not a comprehensive summary of the office and is produced solely on recall of meetings and discussions with the current Director.

Other areas in JABSOM also support compliance functions such as HIPAA training, IT security, regulatory education etc. specific to the needs of the school of medicine.

UH Cancer Center Compliance and JABSOM Risk and Clinical affairs have worked collaboratively in the past and regularly consult one another on topics of mutual interest or engagement. This is key – specific knowledge of research methods and procedures, program needs and areas of focus, systems used and

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regulatory/legal requirements require unique knowledge sets and collaboration with individual experts. Joint engagement supports service to dual, complimentary missions.

Clinical research compliance has become a major focus area of compliance professionals, regulatory bodies and research participants in recent years. The risks are both human and financial. The trend is expected to continue to grow and evolve. Clinical research is highly regulated and as such, the role of a compliance professional is vital to maintaining compliance with NIH, FDA, ORI and OMB requirements. The laws and regulations related to human subject protections, grant and trial accounting, effort reporting, scientific misconduct, privacy and security and clinical trial billing are highly complex and always evolving. Multiple cross functional roles are needed and require continued development to support quality, maximize efficiencies and use of resources, and require a very specific skill set.

Recommendations

The current materials (July 2015 organizational chart and supporting descriptive document) do not directly or specifically indicate a compliance function. Compliance as an administrative function is not clearly defined or focused at UH Cancer Center or JABSOM. The hallmark of compliance reporting is an independent, direct reporting function to ultimate decision makers. The reason for this is to preserve the integrity of the review while providing confidential, fair, accurate and reliable information with recommendations that are not influenced or biased by a competing value or need. Compliance is not a decision making authority body, compliance is reviewing or consulting on specific needs and providing recommendations and guidance as a function for decision making. The UH Cancer Center Director is responsible for 'program review and evaluation'. Compliance is a part of the internal evaluation and growth process as it brings education and awareness to areas that could remain dark or at risk; but the compliance function also provides untapped opportunities for quality and excellence promotion.

Noted previously, Clinical Research Compliance has become a major focus of regulatory bodies. Because of the size and scope of the funding received both at the cancer center and the school of medicine, compliance, risk management and quality are areas of high visibility with an increasing focus externally (ongoing local focus) and thus must be developed internally in anticipation of ongoing review (UH/ORS/CCSG/EAC/NIH/Accrediting bodies/FDA/OHRP etc.) and potential new reviews and audits. The potential benefits of achieving, promoting and continually demonstrating compliance are currently an untapped resource in showcasing the achievements of both organizations.

The scope and oversight of the compliance role is highly defined and controlled by senior leaderships' assessment of need and the risks and benefits to defined mission and vision. Compliance often deals with highly confidential information about research subjects, financials, individual actions/behaviors and proprietary information. This information is very much programmatically and individually held in confidence and is rarely openly shared. Compliance is data and fact driven, but also requires independence, strong relationships, and networks to promote fulfillment of obligations, collaboration, accountability and information sharing. Compliance is also frequently seen as punitive and controlling if not championed as a quality function or maybe seen as non-essential if not utilized by senior leaders.

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Internal operations at the UH Cancer Center have faced stability difficulties in managing and performing operations, activities, growth and compliance. These challenges will continue for the foreseeable future across the center.

A strong, potentially cross functional administrative compliance unit in partnership with JABSOM may support the potential attraction of additional stakeholders, demonstrate a commitment to quality in a joint mission to serve the community, promote collaboration across functional areas or may offer efficiencies in hard resources; but will be almost impossible to support with soft resources, appropriate skill sets and limited funding. Current functions could be more effective and productive in producing quality deliverables internally and externally for both organizations if appropriate support and buy in is established. Alternatively, a hastily instituted cross functional unit may be perceived as an afterthought, a way to conserve resources, a way to diminish the needs and complexities and uniqueness of each organization and not a core value of either entity.

A shared, cross functional Compliance Program with specific definitions, mission and vision development, risk assessment, confidentiality of mission and operations and resource allocation must be carefully considered before instituting major changes in administrative functions between the UH Cancer Center and JABSOM in our current environment. Collaboration is currently ongoing. Sharing, growth and change in function will require strong process development, comprehensive education and awareness, time to implement, intra-department growth and most importantly buy in from a large number of individuals with complete collaboration between the senior leaders of both organizations.

APPENDIX VIII

Information Technology

APPENDIX VIII

UH Cancer Center Information Technology (Center IT)

Summary

While serving as the Interim Director of OIT at JABSOM, I was able to see how the Center IT office and the JABSOM OIT were similar, different and which services could possibly be merged for efficiency. It is my opinion that the merge is not necessary and the two IT offices should remain as two separate offices - each serving their respective organization, as merging the two offices would not yield significant cost savings for the Cancer Center or add efficiency.

From a financial and user support viewpoint, the two IT offices support their users very differently in that, unlike JABSOM, Center IT offers services at the Unit and the Department level. While there could be potential savings for the Center by changing the way services are provided at the Unit and Department level, we can accomplish this without merging the two IT offices. The change could occur internally within the Center but would directly impact Center faculty by way of their budgets.

The only reasonable merge that would provide an eventual true cost savings would be to merge the two phone systems. Also, continued collaboration between the two IT offices for data security and audio visual would be beneficial to the campus as a whole.

Justification

While it seems logical that the two IT offices could be merged and share services across the campus, the reality is that it wouldn't be any more efficient or cost-saving. Some shared services could produce a small cost saving but merging the staff would not.. The IT staff have specific roles to support the Centers' technology needs – we have no real overlap other than to cover for each other in absence.

The Center network is managed differently than the JABSOM network. There would be a significant investment of time and money to redesign the overall network. It would not be favorable to force one network to change to the others' design. This would also have an impact on users in both organizations. There would also be no reduction in the network equipment that would support the two organizations. While the idea of sharing resources is logical, the physical separation of the two buildings would require us to keep the servers holding the shared drives local to each building for performance reasons. The Center personnel managing this equipment would remain.

If the helpdesk staff were merged, the actual work load would increase for the two sides due to the wider scope of coverage and the perception of a larger IT office for both sides would cause unrealistic expectations of increased support.

The similarities for the two IT offices are that the two generally provide the same basic services: a secure, local network, shared drives, phone system, AV and user support. However, the two IT offices support their respective users so differently that merging the two IT offices would either decrease customer service for the Cancer Center users or increase the cost of support for the SoM administration.

A major difference between the two is how software and services are provided to their users. Center IT provides basic and specialized software that is needed for everyday tasks performed by Cancer Center faculty and staff. Video and web-conferencing are made available as needed for all Center faculty and staff.

Other services such as poster printing and specific AV needs are also made available at no cost.

At the SoM, software/software licenses, video and web-conferencing, poster printing are not provided as a basic service to all users/departments. I am not certain, but I believe these services are charged directly to the departments and ultimately the faculty and staff.

Due to the size of the SoM and the large number of on-campus and off-campus departments that are supported by OIT, it is understandable that they cannot provide the same type of support that is provided to the Cancer Center faculty and staff. It also would not be reasonable to change how they provide such services. Likewise, reducing the services to Center faculty and staff and increasing their program expenses would not be viewed as favorable by the Center faculty and staff.

The one service that could be shared would be to continue with the plan of merging the two phone systems. From a campus standpoint, it would be both feasible and cost-efficient if the Cancer Center and SoM were on the same phone system. Collaboration would be much easier if the two organizations were seen as one unit when trying to make a phone call. This is possible if we merge the phone system. Cost savings would be seen through the years as hardware and license fees can be merged and cost shared.

Although the phone system itself could be merged, the management and administration of the respective phones would be kept separate. It would not be feasible or desirable to change the phone numbers for Cancer Center faculty and staff. There are many studies and programs that have established phone numbers.

The Center IT staff currently consists of 6 positions, 5 filled and 1 vacant. Below is a listing of each position (by working title), staff name, type of position and a brief description of that position.

1. Director of Information Technology, Wendy Richards (APT)
The Director of Information Technology directs, oversees and maintains all the administration and operation of the Center IT office. The primary responsibility is to ensure the continuous delivery of IT services for the Center which includes the local network and data infrastructure, VoIP phone system and voicemail, external and internal website programming and management, audio visual systems and video conferencing systems. Ensures network and data security. Also provides vision and strategic planning to offer technology solutions to improve services. Manages and directs major projects and upgrades relating to areas of oversight. Each Center IT staff member manages a different IT service with overlap each other to provide coverage and support. The Director provides guidance and support to the IT staff.
2. HelpDesk Coordinator, Hazel Rems (APT)
The HelpDesk Coordinator manages the Center helpdesk ticket system which provides users the ability to submit trouble tickets to the Center IT staff. The HelpDesk Coordinator receives all incoming requests and assigns the request to the IT staff member who can best resolve the issue. The HelpDesk Coordinator is also responsible for managing and maintaining the server and software for the HelpDesk system ensuring that the software is up-to-date and functioning correctly. The HelpDesk Coordinator is a layer 2 respondent to issues. This position handles the more complex issues and consults with the IT Director when necessary. This position also manages the equipment inventory for the Center via an internal inventory system. This includes coordinating eWaste events for the Center. The HelpDesk Coordinator serves as the interim IT Director when the IT Director is not available.
3. Infrastructure/Server Management, G. Grant Gathagan (RCUH)
This position currently manages both the network infrastructure and data management for the Center. The Server Management position is currently vacant. The primary responsibility is to ensure that the internal Center network, which consists of servers, switches, routers, wireless access points and all other networking equipment are fully functional and connectivity is maintained. Equally important is the

responsibility to keep all software applications such as Center email, VoIP phone system and data infrastructure fully functional and connectivity is maintained. Manages network security by monitoring activity and performing hardware and software patches.

4. IT Specialist, Phillip Lau (APT)

The IT Specialist is the first level responder to the helpdesk requests received from Center users. This position responds to both simple and complex issues and escalates the request as necessary to the HelpDesk Coordinator. This position is supervised by the HelpDesk Coordinator (Hazel Rems).

5. Web Developer, Harry Sonson (APT)

The primary responsibility of the Web Developer is to manage and maintain the Centers' external and internal websites. The Web Developer works closely with the Communications team to post content on the external website in a timely manner. This position also works closely with various groups in the Center to develop, manage and improve study web pages.

APPENDIX IX

UHCC Facilities Management & Planning

APPENDIX IX

UH Cancer Center Specific Services/Activities – *Administrative Operational Services* Director's Authority and Control to Support Research Mission Activities

UHCC Facilities Management and Planning (i.e., Physical Plant Management, Custodial and Grounds, Mail Operations, Environmental Health and Safety, Lab Refrigeration Support and Remote Monitoring – 15 FTE's)

- Custodial and Grounds-keeping specifically within UHCC Facilities
- Contract Administration for Security Equipment Preventative
- Internal mail room operations and UHM scheduled pick ups
- Maintenance Contracts (servers, cctv's, access readers, access card programming, software updates, parking gates, door hardware interfacing)
- Contract administration for all autoclaves and cold room services
- Contract administration for lab coat services
- ASSA key duplicates for all access doors
- 24/7 Emergency on call with HECO and first responders
- 24/7 Daily monitoring of lab freezers, refrigerators and cold rooms
- 24/7 monitoring support for UHCC Freezer Farm Facility at UH Mānoa Campus and stand-by emergency power for HVAC System
- Stand-by emergency generator annual servicing and testing
- Annual contract administration for automatic transfer switches for stand-by emergency power mode
- Internal lab freezers/lab equipment repair support
- Office furniture reconfigurations with outside contractors
- LN2 (Liquid Nitrogen) annual renewal services for lab research
- Daily oversight of Building Management System (support A/C controls, lighting, oversight and monitoring of daily alarms, chillers, pumps, cooling towers, variable frequency drives, motors, etc.)
- Daily oversight of building maintenance (HVAC System, chillers electrical, mechanical plumbing, filters, belts, UV lighting)
- Space allocation, infrastructure support to PI's and their Research Mission Activities
- Oversight of Elevator program maintenance with manufacturer
- Building Maintenance Support Staff – Additional FTE required to hire state classified positions to minimize solicitation of outside contractors per UH (System) HR mandates.
- Project Management Oversight for all UHCC Capital Improvements Projects and Bond Fund Management of Series 2010 A-1 and Series 2010 A-2 Expenditures
- Interface with UH Mānoa Facilities Management Office – Design Section for all Architectural/Engineering, Project Management/Construction Management Services Contracts and Coordination of Award of Contracts

with UH System Office of Procurement and Real Property Management
APM Policies and Procedures

- UH Cancer Center Laboratory Infrastructure Operations
- Cancer Center Offices/Common Areas, Laboratory Equipment Support
- UHCC Nutritional Kitchen Support (i.e. walk-in freezer, refrigerator, coolers, gas stoves) and State of Hawai'i Department of Health Permits
- UH Cancer Center Sullivan Center Infrastructure Support
- UH Cancer Center Fiscal interface to process requisitions, purchase orders, sole source, cost price reasonableness unique to UH Cancer Center operations



The Committee on Ways and Means
February 26, 2021
9:30 AM, Videoconference

RE: **SB 589, SD1 Relating to the University of Hawaii**

Attention: Chair Donovan Dela Cruz, Vice Chair Gilbert Keith-Agaran and Members of the Committee

The University of Hawaii Professional Assembly (UHPA) **strongly opposes the passage of SB 589, SD1.**

SB 589, SD1 is an intrusion into the authority of the UH regents and faculty. It would statutorily mandate a reorganization of UH-Mānoa's lines of reporting and supervision of the UH Cancer Center. This would subject the University's internal structure and management -- properly a purely academic matter -- to statutory law.

Successful universities operate under a principle of shared governance, pursuant to which professionals in the affected field have significant input into matters that may be regarded as managerial. This bill not only tramples on the regents' managerial prerogatives, but those of the faculty, who, pursuant to tradition, constitution, statute, and contract, have a role in defining such items as academic organization.

To make matters worse, the unintended consequence of such a bill, should it be enacted, would threaten the federal funding that supports the UH Cancer Center. The NCI-designation (P30 grant) that has been strengthened under the current director, Dr. Randy Holcombe.

UHPA **strongly opposes** the passage of SB 589, SD1.

Respectfully submitted,

Christian L. Fern
Executive Director
University of Hawaii Professional Assembly



American Cancer Society
Cancer Action Network
2370 Nu'uau Avenue
Honolulu, Hi 96817
808.432.9139
www.fightcancer.org

Committee on Ways and Means
Senator Donavon M. Dela Cruz, Chair
Senator Gilbert S.C. Keith-Agaran, Vice Chair

SB 589 SD1 – RELATING TO THE UNIVERSITY OF HAWAII

Cynthia Au, Interim Government Relations Director – Hawaii Pacific
American Cancer Society Cancer Action Network

Thank you for the opportunity to provide comment on SB 589 SD1: RELATING TO THE UNIVERSITY OF HAWAII which would require the UH Cancer Center be affiliated with the University of Hawaii John A. Burns School of Medicine and funds for educational purposes only.

The American Cancer Society Cancer Action Network (ACS CAN) is the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society. We support evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem.

The University of Hawaii (UH) Cancer Center is one of 71 research organizations in the U.S. designated by the National Cancer Institute (NCI) and the only one in the Hawaii Pacific region.¹ The creation of the cancer research unit for cancer research at the University of Hawaii John A. Burns School of Medicine (JABSOM) would result with UH Cancer Center's inability to meet the guidelines of the Cancer Center Support Grant funding announcement from the National Cancer Institute (NCI). NCI Cancer Centers Program was created as part of the National Cancer Act of 1971 and is one of the anchors of the nation's cancer research effort. Through this program, NCI recognizes centers around the country that meet rigorous standards for transdisciplinary, state-of-the-art research focused on developing new and better approaches to preventing, diagnosing, and treating cancer.²

Maintaining the requirements set by NCI is important for UH Cancer Center to keep its designation to continue to receive \$15 to \$20 million in extramural funding of the P30 Cancer Center Support Grant. This outside funding supports research for more treatments and improve cancer patients' quality of life.

Thank you for the opportunity to comment on this matter.

¹ University of Hawaii Cancer Center <https://www.uhcancercenter.org/50years>

² NCI <https://www.cancer.gov/research/infrastructure/cancer-centers>



Alana Dung Research Foundation

February 25, 2021

LATE

Ways and Means Committee Members

As a supporter of the UH Cancer Center, we strongly oppose SB 589.

Last year we provided the Center with a Grant to support its Early Phase Clinical Trials Research Center. Under the exceptional leadership of Dr Randall Holcombe a 6.5 million federal grant from the National Institute of Health was secured for this project which has the potential to save lives and test innovative therapies.

The UH Cancer Center is in an elite class. There are approximately 1,600 Cancer Centers in the US; only 71 of them have the National Cancer Institute recognition.

SB 589 would jeopardize our NCI designation.

This would result in the loss of millions of dollars in federal grants.

The UH Cancer Center is a success story. Since Dr Holcombe's arrival the operational budget is balanced. Roughly 30% of tenure-track faculty bring in approximately 30% of their salary. The Center focuses on cancers distinctive to Hawaii's population.

The UH Cancer Center has a number of world-renowned scientists on its staff. In this post COVID-19 era we ought to be supporting and encouraging the work they do. SB 589 is short sighted, not thought out.

Donna Kim and her committee references the Center's situation during 2014-2016. So much has changed since then.

It is our hope that you take the time to visit and learn about the Center which is about our vision for our future.

Sincerely,

Adelia C. Dung
President

Address: 3468 Waiālae Avenue # 222 Honolulu HI 96816

SB-589-SD-1

Submitted on: 2/26/2021 8:01:41 AM

Testimony for WAM on 2/26/2021 9:30:00 AM

LATE

Submitted By	Organization	Testifier Position	Present at Hearing
Laurie Chun	Testifying for Friends of the UH Cancer Center	Oppose	No

Comments:

I am **opposed to SB5859** . The bill is trying to solve a problem that does not exist. In the last 5 years, Dr. Holcombe has balanced the budget, renewed the NCI designation and worked closely with JABSOM to align shared services and research infrastructure. The bill creates financial problems instead of solving them.

Moving the UH Cancer Center into the John A. Burns School of Medicine will irretrievably damage it and undermine its mission to serve Hawaii for the following reasons:

1. The proposed changes will jeopardize the UH Cancer Center's NCI designation.
2. There will be no financial savings from changing the organizational structure
3. There will be major financial losses from reorganizing the UH Cancer Center
4. Dr Holcombe, who has an MBA as well as an MD, has with the current organization the freedom to rebudget as needed to reduce costs and ensure a structure that is financially sustainable.
5. There is no advantage for faculty, staff or students.
6. The mission of the UH Cancer Center is different than JABSOM.
7. Dr. Holcombe, MD, MBA is an OUTSTANDING Director!

For these reasons, I am **opposed to SB589**.

Dear Chair Dela Cruz, Vice Chair Keith-Agaran, and Members of the Committee:

I am writing personal testimony as a Professor in the UH Cancer Center to voice my strong **OPPOSITION to SB589** which would place the UH Cancer Center into the John A. Burns School of Medicine.

I do not understand why this bill exists.

During the hearing in HRE, a business plan by Dean Hedges of JABSOM and a report from Warbird from **five years ago** were cited. At that time under the Dean of the medical school the Cancer Center was facing challenging times. We no longer are. Indeed we are making great strides improving grant funding and our service to the people of Hawai'i to reduce the burden of cancer in the state through research, patient care, education, and community outreach.

In the **five years since that report** the Cancer Center hired a new Director (Dr. Holcombe, who has an MBA in addition to his MD) and under his leadership we have balanced the budget, renewed our NCI Designation, worked closely with JABSOM to align specific shared services and research infrastructure, and are now on solid footing. There is no problem to solve and indeed putting us back under the Dean who was responsible for the very report being cited seems incredibly shortsighted and wasteful. This Bill creates financial problems, it doesn't solve them.

I do not understand why our legislature is using reports that are completely outdated (5 years old) to create bills. Even in conveying the SB589 to you, HRE cites only things that happened in 2014, 2015, and 2016. That is deeply concerning.

As a Cancer Center Professor in senior leadership in 2015, I was aware that Dean Hedges sought help (using UH Foundation funds NOT tax dollars) from the Warbird Corporation (they advise mostly Hospitals and Enterprise networks – NOT Academic Cancer Centers). The Dean did not elect to get the second phase of their plan. He noted several flaws in their analysis himself. Instead, he developed his own business plan incorporating some of the ideas from Warbird (the one referenced in the HRE hearing) that included 10 specific strategies to improve efficiencies. Many of those were sound and almost all have been accomplished in the last five years with no reorganization of the Cancer Center into JABSOM:

- Our operational budget is balanced (and we re-budgeted this year for loss of the Governor's funds)
- We refinanced the revenue bonds last October at an overall savings of \$19M (about \$1M per year)
- We renewed NCI designation in 2018 (with an "EXCELLENT" rating)
- All our new faculty are extramurally funded, and all letters of hire include an expectation that new faculty will cover at least 25% of their salary from extramural sources. (Our tenure-track faculty overall currently bring in roughly 30% of their salary from extramural funds)
- We regularly review internal departments and faculty and have released unproductive faculty and reduced administrative and staff positions over the last 4 years.

- There are also many, many new synergies between JABSOM and UH Cancer Center like combined telecom, joint grants, joint teaching, coordinated parking, joint genomics core, etc. Many of these were listed in President Lassner's testimony to HRE.

I have been at the UH Cancer Center for over 16 years and came here from another National Cancer Institute (NCI) Designated Cancer Center. My comments derive from my experience serving the UH Cancer Center first as Leader of the Cancer Biology Program, then as interim Associate Director for 2 years (first with Interim Director Dean Jerris Hedges then with current Director Dr. Randall Holcombe) and currently as Chief Scientific Officer and Deputy Director. I also have a secondary appointment in JABSOM and teach in the Cell and Molecular Biology program there in addition to my undergraduate teaching through several UH Cancer Center training programs. I know the finances and faculty of the UH Cancer Center in great detail.

I have written large sections of our last two UH Cancer Center NCI Designation renewals, attend the annual National Cancer Center Meetings, sit on site visit teams to review other Cancer Centers for the NCI Designation, and review biomedical research and training grants at every level for the National Institutes of Health (NIH). I therefore know the requirements of the NCI Designation thoroughly. The following bullet points explain why moving the Cancer Center ORU into the John A. Burns School of Medicine (JABSOM) will irretrievably damage it and undermine its mission to serve Hawaii:

- 1) **The proposed changes will jeopardize our NCI Designation.** The current organization with our Director reporting solely to the Provost and having flexibility to control space, faculty hires, and budget is essential to preserve our National Cancer Center Designation. A central criterion by which we are evaluated every five years to renew our designation and the associated funding is the "Authority of the Director". We have received top scores on this measure in each of our renewals. The demotion of our Director to reporting to the Dean rather than the Provost will be viewed as weakening the Cancer Center by our external reviewers and will take away one of our great differentiators. Even with the HRE change to have the Director reporting to both the Dean and the Provost (which is odd and problematic to implement), the loss of control of budget, hiring, and space will be viewed just as negatively and as a demotion. Recovering the NCI designation once lost would be tremendously challenging and expensive.
- 2) **There will be no financial savings** from changing the organizational structure. We have previously investigated in great detail whether moving the Cancer Center into JABSOM would provide any financial benefit. No significant savings was identified that could not be gained more easily and affordably through collaboration and coordination of activities. This is recorded in a Whitepaper produced by faculty and staff at that time. Where we saw benefit, we have already enacted agreements with the medical school. We share a phone system, vivarium, and maintain joint research cores (Genetics and Bioinformatics) and instrumentation. UH provides the campus with a single security team. Finally, we coordinate parking, groundskeeping, and other overlapping Kaka'ako campus activities. There is no savings gained from merging fiscal or grants management because the amount of work requires a specific number of personnel and is not reduced by combining. Having our own personnel on site and trained in the areas we require

expedites management and quality of these activities and keeps costs in check. To be sure we do not miss opportunities at finding savings, our Associate Director of Administration (Cliff Martin, who is himself an MBA and expert in NCI Designation requirements) meets regularly to coordinate where possible with the Executive Director for Administration at JABSOM.

- 3) **There will be major financial losses from reorganizing the Cancer Center.** This will come as we lose our NCI Designation and the grant funding and high caliber faculty that come with that. It will come as we waste time and effort on organizational restructuring and training instead of getting grants and doing research, education and outreach. We will lose all the financial investment the state, university, hospitals, and faculty have put into getting and maintaining the NCI Designation and all the significant benefits it brings to cancer care in the islands over the last 25 years.
- 4) The current organization has allowed **Dr. Holcombe, who is an MBA as well as an MD**, to have the freedom to carefully and thoughtfully re-budget to reduce costs and set in place a structure going forward that is financially sustainable. He worked closely with our Associate Director of Administration Cliff Martin, MBA, and the Cancer Center Senior Leadership. Because of their knowledge and expertise in NCI Designated Cancer Centers, we have been able to do this without weakening the core strengths of the Cancer Center. Indeed, by balancing the budget the last three years we have improved our competitiveness and renewed our NCI designation.
- 5) **There is no advantage for faculty, staff, or students.** Faculty already move freely between the two organizations. We have faculty that teach in JABSOM and serve on many JABSOM committees already. Indeed, we provide funding for first year Graduate Students in the Cell and Molecular Biology Program in JABSOM – more than JABSOM itself provides. I teach in three courses there, have a secondary appointment and professorship, and serve on the curriculum committee. Importantly faculty of the Cancer Center teach in programs on the main campus as well. Our undergraduate and graduate students come from throughout related programs across UH. I also have the pleasure of working jointly with many great JABSOM faculty on grants and have federal grants with some of them. The Cancer Center is by its very nature a UH-wide and Statewide Center - it thrives on knocking down silos and has the greatest flexibility to do this as an independent ORU in the current organizational structure.
- 6) **The mission of the Cancer Center is different than that of the Medical School.** The Medical School's primary mission is to educate medical students. Our Central mission is cancer research that will directly benefit the people of Hawaii. We need to keep our focus on this and build on our recent accomplishments without getting subsumed into a new organization with different goals and a different culture.
- 7) **Dr. Randall Holcombe MD, MBA is an OUTSTANDING Director** and is recognized for his expertise across all the 71 NCI Cancer Centers. Please see our recent external advisory report that was shared with you for a sample. Since his arrival the Center has renewed its designation (in just ONE year after his arrival!), stabilized its finances,

started increasing by leaps and bounds its donor support, and initiated several new programs aimed at helping the people of Hawaii. Putting the Cancer Center into JABSOM is a demotion for him and will wipe out these hard-won gains in a single move. It will destroy the fantastic positive and collegial culture we currently enjoy that has enabled wonderful new research, millions in new grants, and new Hawai'i and Pacific focused initiatives for the health of the people of Hawai'i.

For the reasons above I am strongly **OPPOSED SB589**. It is an attempt to solve a problem that no longer exists and will instead cause many negative unintended consequences that will lead to greater financial burden as grants are lost and other costs of reorganization accrue. It will decimate the ability of the Cancer Center to continue to do the good work it does for cancer patients and the people of Hawai'i.

Thank you for this opportunity to share this information.

Joe W. Ramos, PhD
Professor and Deputy Director
UH Cancer Center
&
B.H. and Alice C. Beams Endowed Professor in Cancer Research
John A. Burns School of Medicine

Dear Chair Dela Cruz, Vice Chair Keith-Agaran, and Members of the Committee:

I am writing as a Professor in the UH Cancer Center to voice my strong **OPPOSITION to SB589 SD1** which would place the UH Cancer Center into the John A. Burns School of Medicine.

My name is Loic Le Marchand. I have been a faculty member at UHCC since 1987. I currently am a Professor (Researcher) and serve as the Center's Associate Director for Ethnic Diversity Research. I have been the Principal Investigator of multiple large grants, including the Multiethnic Cohort Cohort that has been following 215,000 Hawaii and California residents for cancer since 1993. This unique scientific resource, shared with many UH researchers and students, including at JABSOM, has brought over \$150M to the University in federal grants. I have served on multiple expert panels for the National Cancer Institute and have reviewed programs at mainland cancer centers. I believe I am well familiar with the requirements for maintaining a NCI-designated cancer center in Hawaii and what it brings in terms of health and economic benefits to our community.

I am testifying **AGAINST** Bill SB589 as I strongly believe it would be disastrous for the Center and our progress in reducing the burden of cancer and other chronic diseases (e.g., diabetes, heart disease, etc.) in our community. Moreover, it would not achieve any savings in state funds.

This bill constitutes an existential threat to the Cancer Center.

1. Being moved "administratively" under the Medical School means that the Center would lose authority on budget, faculty hires and space. It also means a lowering of UH's institutional commitment. This will translate into a worsened score on the "Six Essential Characteristics" of cancer centers (see: <https://www.advarra.com/blog/six-characteristics-nci-designated-cancer-center/>) for our upcoming renewal. It will be seen as a demotion of the Director and will make a negative impression on reviewers and NCI. Cancer centers that are under a medical school envy our current "free-standing" administrative status. The consequences are likely to be the loss of the NCI-designation for our Center. This will result in a tens of \$M loss in grants and the departure of the most productive faculty. So, this bill not only will not achieve any substantial saving but will cause very substantial losses.
2. The revised bill with dual reporting to JABSOM's dean and the provost does not mitigate any of these concerns.
3. The Center is doing very well administratively and scientifically under Dr. Holcombe's directorship. There is no budget deficit; our grant awards are up; our translational work is bringing increasing benefits to our community, we are developing new initiatives that will significantly improve cancer care and cancer prevention in Hawaii. We are on track to renew our NCI-designation as a Cancer Center in a year and a half.
4. Our current director has publically stated that he will leave if the Center is placed under the Medical School.

5. Why placed a well-functioning unit under one that has financial difficulties and has a different mission (teaching vs. research). This does not make administrative sense. Such an internal reorganization should be under the purview of the University, not that of the Legislature. President Lassner and Chancellor Bruno have not been supportive of such a change.

There is no valid justification for such an action, and certainly not the one given in the bill.

1. As justification, the bill only mentions, without being at all specific, the conclusions of a report of 5 years ago when Dean Hedges was acting Director of the UHCC. This report was completed by consultants who were not in the academic field and the conclusions were controversial, even to Dean Hedges, who only released part of it.
2. The Legislature must use current information to draft new bills. This information can be obtained from the UH and UHCC leaderships if not provided already. Please come down to the Center. We would be delighted to show you what we do, how we do it and what kind of impact we have in improving our progress, and answer all of your questions.
3. We have been able to overcome past challenges under the current UHCC leadership and we would very much appreciate being given a chance to build on our progress without interference. All the troubled times the Center went through several years ago and spilled into the public eyes resulted from actions imposed on us from outside the University. We do not want to re-live these very difficult times which almost brought the Center to its demise. We were told by NCI when we last renewed our NCI designation renewal that they funded us for 3 years instead of the usual 5 years because of “our past leadership issues” and “a past director that had no cancer research experience”. Because of our progress under Dr. Holcombe, NCI has now extended our designation for the full 5 year period.
4. In the past four years, we have substantially increased synergies between JABSOM and UH Cancer Center, where this was possible, such as combined telecom, joint grant applications, joint teaching, joint mentoring, parking coordination, joint research cores, etc. We continue to look for ways to improve efficiencies and coordination on the Kakaako campus.
5. If ORUs were to be consolidated under schools, JABSOM is not necessarily the one that would make the most sense. UHCC faculty also teach in Public Health, Nutrition, Psychology, Life Sciences, etc.
- 6.

The requirement that the tuition and fees fund not be used for supporting research is misplaced and seems to result from several misunderstandings:

- 1) Research should not be viewed as separate from teaching. Researchers teach and educators do research. Importantly, both types of faculty are evaluated based on their accomplishments in three areas: teaching, research and service.
- 2) The Researcher faculty line that UH has is quite unique and is not typically found in other universities. The great majority of UH researchers would hold the title of Professors in other universities. The title of Research Professor or Research Scientist found elsewhere do not correspond to our title of Researcher. Those are usually positions that are not tenurable and are typically given to support faculty.
- 3) As President Lassner explained to HRE members, for historical reasons, the two funds are not used for specific types of expenses and are interchangeably used at UH.

For the reasons above I am strongly **OPPOSED SB589**. It is an attempt to solve a problem that doesn't exist for reasons that are not explicitly given. It will instead cause many negative unintended consequences that will lead to greater financial burden as grants are lost and costs of reorganization accrue. It will lead to the dissolution of the Cancer Center and the good work it does to reduce the burden of cancer in Hawai'i.

Thank you

Loic Le Marchand, MD, PhD
Professor (Researcher), Epidemiology
UH Cancer Center

SB-589-SD-1

Submitted on: 2/24/2021 11:11:34 PM

Testimony for WAM on 2/26/2021 9:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Lynn Murakami-Akatsuka	Individual	Oppose	No

Comments:

I am writing as a member of the Hawaii Skin Cancer Coalition to voice my **Strong Opposition** to SB 589, SD 1.

I do not understand why this bill wants to make organizational changes that requires the UH Cancer Center (UHCC) to be affiliated with the University of Hawaii John A. Burns School of Medicine (JABSOM) with direct lines of reporting to the provost of University of Hawaii at Manoa and the Dean of JABSOM. **The collaboration between UHCC and JABSOM already exists** through their combined telecom, joint grants, joint teaching, coordinated parking, joint genomics core, etc.

What is the purpose of having UHCC reporting to the Dean of JABSOM where the line of reporting is already established with the UH Provost and working closely with the UH President? Is there a rationale reason behind this? Has the UH Board of Regents been consulted or involved in this change of lines of authority? Isn't the Legislature overstepping its authority?

The turnaround of UHCC from 2016 is a reflection of UHCC Director Dr. Randall Holcombe's leadership, business acumen, and collaborative relationships with his faculty, staff, community partners, and colleagues from various Schools within the University system. Even with the community groups such as our Coalition and others involved with UHCC; he has made time to get to know our group, and to learn about our participation in the UHCC's community outreach education component.

Action speaks louder than words. Dr. Holcombe has credentials of an MBA as well as an MD and brought his experience in re-budgeting the costs and past declining tobacco tax revenue to a current organization that is financially sustainable. He has made a great impact since he took over as the UHCC Director in 2016 to present.

Your Committee report states that the genesis of this measure is a business plan by JABSOM Dean Hedges and a report from Warbird from five years ago. In the five years since that report, Director Dr. Holcombe has balanced the UHCC budget, renewed their National Cancer Institute (NCI) Designation, brought in new grant funds and excellent researchers with it, and worked closely with JABSOM to align specific shared services

and research infrastructure. **Again, there is no problem to be solved that SB 589, SD 1 appears to create.**

"The current lines of reporting that our UHCC Director has with the UH Provost and working closely with the University President" was noted by the External Advisory Committee (EAC) as vital for the UHCC's continued success and continued NCI Designation. This is a significant evaluation from EAC and this bill will create unnecessary and negative unintended consequences if passed.

Therefore, I **Strongly Oppose** SB 589, SD 1 for the reasons I stated above and urge that it be deferred.

Dear Chair Dela Cruz, Vice Chair Keith-Agaran, and Members of the Ways and Means Committee:

I am writing as a private individual, a resident of the state of Hawai'i, to voice my **STRONG OPPOSITION to S.B. No. 589 S.D. 1**, which would reclassify the University of Hawai'i Cancer Center as an organized research unit within the John A. Burns School of Medicine.

This testimony and the views herein are my own. I have written this on my own time, independent of my job. That said, I am a long-time member of the research staff at the UH Cancer Center, where, among other duties, I manage the day-to-day operations of multiple federally funded research studies.

I am asking you to put this talk of reorganization/reclassification to rest once and for all. In her report from the Committee on Higher Education, Chair Donna Mercado-Kim cites various actions and reports dating back *only as far as February of 2016*, as justification for this proposed reorganization. However, much has changed in the past 5 years, including the following:

1. Robert Bley-Vroman, whose work is cited several times in this measure, served as *interim* Chancellor for the Manoa campus (under which the Cancer Center and JABSOM serve as independent units), and he *opted not to seek an extension* as Chancellor as his contract drew to an end; thus, his term came to an end in August 2016. In the time since – in fact, as recently as this month – the President and Provost of the University have testified that they oppose the implementation of any such restructuring.
2. In October 2016, the Cancer Center officially welcomed Dr. Randall Holcombe as Director. As others have noted, Dr. Holcombe's arrival completely changed the atmosphere at the Cancer Center. One might liken it to a change in presidential administrations.
3. In 2018, the National Cancer Institute renewed the Cancer Center's designation, with a rating of "EXCELLENT" and effusive praise for the progress made in a short amount of time, under Dr. Holcombe's leadership.
4. External Advisory Committee reports in subsequent years, including an oral report to Center faculty and staff as recently as last month, have continued to praise the "remarkable progress" that Cancer Center leadership has made from year to year since Dr. Holcombe's arrival, including the recruitment of "top tier" faculty, as well as establishing a plan and funding for the Early Phase Clinical Research Center, for which construction will begin this year.

Even in the process of drafting S.D. 1, HRE on one hand had to acknowledge that having the Dean of JABSOM present Cancer Center Director candidates to the Board of Regents for approval, rather than having the Provost do so, would conflict with the NCI's expectations for the Cancer Center in terms of its designated status. But then on the other hand, S.D. 1 demands that the Cancer Center Director report directly to the Dean of JABSOM *in addition* to reporting to the Provost. It makes no sense to make one concession but insist on the other. **The only concept that comes through loud and clear is a vote of no confidence in Cancer Center leadership, which NCI will recognize and weigh accordingly in their consideration of the Cancer Center's upcoming designation renewal.** We cannot afford for this to happen.

As I stated earlier, I submit this testimony as a private citizen. However, I have been working at the Cancer Center for 21 years, under the leadership of four different directors, through all the public relations nightmares as well as the recent triumphs. Prior to Dr. Holcombe's arrival, many of us who worked at the Cancer Center were demoralized by the constant negative press and by warnings of impending doom from within the University. It's a different world now: We can do our work without having to worry that someone with signing authority is going to say no to, or, perhaps worse yet, ignore our requests because they just don't "get" how things relate to cancer. Dr. Holcombe gets it, and the NCI sees that as much as any of us do. Please don't take this away by changing the proverbial pecking order.

Thank you for considering my testimony **in strong opposition to S.B. No. 589**. I humbly ask that you stop this measure from moving forward.

Crissy Terawaki Kawamoto

Dear Chair Dela Cruz, Vice Chair Keith-Agaran, and Members of the Committee:

I am writing to express my **STRONG OPPOSITION to SB589** for the following reasons:

- (1) Despite what the Bill states, there is no financial advantage in combining the Cancer Center with the School of Medicine. Procedures to cut financial burden, such as the use of joint research cores or combined maintenance operations, are already in place and do not require the merger of Cancer Center into the School of Medicine.
- (2) The current organizational structure, with the Cancer Center Director reporting directly to the Provost, ensures the necessary degree of flexibility and autonomy in managing the Cancer Center, which is essential for maintaining the NCI designation for the Cancer Center. The proposed reorganization will jeopardize the NCI designation, which would severely reduce federal funding for the Cancer Center and thus be very harmful to its mission.
- (3) The current Cancer Center leadership, in particular the Cancer Center Director Dr. Holcombe, have made a remarkable turnaround of the previously struggling Cancer Center in recent years. These days, the Cancer Center is a thriving research unit on a solid financial footing, a fact that has been recognized and praised by the Center's External Advisory Committee. Limiting or undermining the authority of the Cancer Center Director would do a great disservice to the Cancer Center, its mission, and to research in Hawaii in general.
- (4) The stated rationale for this bill is based on outdated information from the year 2016 and is therefore misleading. The Cancer Center is currently on solid financial footing, and making it part of the financially troubled JABSOM will not help either unit. The proposed bill would necessitate wasting a lot of people's time and precious resources to do an unnecessary and unjustified reorganization, instead of focusing on productive work.
- (5) The questions of the organizational structure of research and academic units rest with the University; any attempt by the Legislature to intervene in these questions would violate the University's internal autonomy. Such external interference is strongly discouraged by the federal funding agencies and will jeopardize the Cancer Center's prospects for extramural funding.

For the reasons above, I **STRONGLY OPPOSE SB589**.

Thank you,

Yurii B. Shvetsov, PhD
Assistant Professor
University of Hawaii Cancer Center

LATE

February 25, 2021

Ways and Means Committee Members

My name is Stephen Dung.

I am a concerned citizen who strongly opposes SB 589.

The UH Cancer Center is in an elite class. There are approximately 1,600 Cancer Centers in the US; only 71 of them have the National Cancer Institute recognition.

SB 589 would jeopardize our NCI designation.

This would result in the loss of millions of dollars in federal grants.

The UH Cancer Center creates jobs, save lives and is focused on improving the quality of life. It is thriving, growing and has exciting projects on the horizon.

SB 589 does nothing to enhance the work being done.

I strongly oppose SB 589.


Stephen Dung

SB-589-SD-1

Submitted on: 2/25/2021 4:29:18 PM

Testimony for WAM on 2/26/2021 9:30:00 AM



Submitted By	Organization	Testifier Position	Present at Hearing
sheri higa	Testifying for Friends of UH Cancer Center	Oppose	No

Comments:

I am in strong opposition of this bill.

Passing this bill will take away much needed funding the for UH Cancer Center and it's valuable NCI designation. We should be applauding Dr. Holcombe and his staff for their dedication and hard work. People often speak of the need to diversify Hawaii's economy and the UHCC does just that. Research will generate income and bring in and retain the brightest physicians and scientists.

We need to take a hard look at where our money should be spent to have a sustainable Hawaii.

SB-589-SD-1

Submitted on: 2/26/2021 8:22:11 AM

Testimony for WAM on 2/26/2021 9:30:00 AM

LATE

Submitted By	Organization	Testifier Position	Present at Hearing
Carl Chun	Individual	Oppose	No

Comments:

As a private citizen, I would like to state my **opposition to SB589**. The UH Cancer Center provides a much needed resource to the people of Hawaii. We are so lucky to have an NCI designated facility in Hawaii.

I am impressed by their research that impacts the varied ethnicities in Hawaii, the patients they help in their clinical trials and by their Director, Dr. Holcombe. The UH Cancer Center under his leadership is thriving and financially stable. Please do not pass a bill that will change or impede the progress that Dr. Holcombe and the Center has made.