



UNIVERSITY OF HAWAII SYSTEM

Legislative Testimony

Testimony Presented Before the
House Committee on Lower and Higher Education
and
House Committee on Health
February 7, 2020 at 2:00 p.m.
by
David Lassner
President
University of Hawai'i System

HB 2564 – RELATING TO THE UNIVERSITY OF HAWAII

Chairs Woodson and Mizuno, Vice Chairs Hashem, Quinlan, and Kobayashi, and members of the Committees:

Thank you for this opportunity to provide testimony in strong opposition to HB 2564, which proposes to legislate the internal structure and management of the University of Hawai'i (UH) by moving the UH Cancer Center under 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 suggested by the Legislature without regard for the potentially devastating impacts of such a change.

We oppose this bill for three reasons:

First, passage of this measure would gravely threaten the P30 grant from the National Cancer Institute (NCI) of the National Institutes of Health, which carries our formal designation as one of only 71 NCI-designated cancer centers in the nation. This is a critical designation for which we have worked diligently and in which the university and State have invested significant resources.

Second, a legislative mandate regarding internal restructuring is not 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 this specific matter of internal structure and management for the reasoned views of the UH, which is responsible to maximize the ability of the Cancer Center to reduce the burden of cancer on the people of Hawai'i.

Threat to NCI designation

Earlier this year the University of Hawai'i Cancer Center was 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 about 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 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.

During our outbrief with the EAC, we discussed some recent changes in the NCI P30 guidelines for cancer center designation. They noted in particular the importance of our current structure to the success and continuing designation of the Center. I have excerpted the most relevant paragraph below (with emphasis added):

*The unique structure of the 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 [Hawaii Cancer Consortium], 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.***

I also reached out directly to the Chair of the EAC, Dr. George Weiner, regarding the changes in the NCI guidelines and he provided additional rationale for the language above:

Most institutions are interpreting this language as meaning the cancer center director should have the authority equivalent to that of a dean. This is particularly important for your center for a number of reasons. The UHCC is one of the smallest centers in the NCI cancer center program and has faced challenges at various times over the past decade that resulted in modification of the usual 5 year funding period from the NCI. For these reasons, the

institutional support and authority of the UHCC director will receive extra scrutiny from the NCI. While some NCI designated cancer centers are embedded within Health Systems, these centers are making changes to comply with the new guidelines. In addition, such cancer centers are located within universities that have major clinical operations. This assures synergy between the cancer center and the broader clinical mission of the institution. Cancer centers in Universities that do not have such clinical operations organizationally report to the University as a whole or are free-standing. The structure your institution has put in place with your reporting to the Provost and working closely with the University President is vital for your continued success including continued NCI designation.

It is clear that implementing this legislation would create significant risk for the NCI designation of the UH Cancer Center with grave consequence to our ability to reduce the burden of cancer on the people of Hawai'i.

Achieving Synergies

It is important also to note that modern cancer research reaches across the entire University, including but not limited to the our medical school. We do recognize that there are opportunities for synergies at our Kaka'ako campus, and want to note that major synergies and efficiencies have been achieved through collaboration not only with JABSOM in Kaka'ako but also with many other parts of UH. Faculty are the heart of our Cancer Center, and 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 19 collaborating members.

Some additional specific examples of synergies and efficiencies include:

- Joint faculty appointment with Nursing (July 1, 2018)
- Support for 25% of a nuclear magnetic resonance (NMR) specialist with Chemistry (recruitment ongoing)
- Participation in the Colleges of Health Sciences which includes not only JABSOM but Nursing & Dental Hygiene, Social Work & Public Health, and Pharmacy (UH Hilo)
- Support for two out of three of the 1st year graduate students in JABSOM's Cell and Molecular Biology (CMB) program
- Cancer Biology faculty providing course direction and teaching in the JABSOM CMB department
- T32 grant led by the Cancer Center involving JABSOM (CMB, Tropical Medicine, Developmental and Reproductive Biology), CTAHR (Molecular Biosciences and Bioengineering), and the College of Natural Sciences (Chemistry)

- Support of 2 graduate students per year in Public Health (School of Social Work) or Nutrition (CTAHR)
- 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 a College of Natural Sciences (Chemistry) faculty member
- UH Cancer Center NMR facility is housed in JABSOM
- Cancer Center endowed chair awarded to a Chemistry faculty member
- JABSOM faculty member (Palafox) heads the Cancer Center effort on a research partnership with Guam
- Cancer Center faculty participation in innumerable graduate committees for programs in other units, particularly Cell and Molecular Biology (JABSOM), Molecular Biosciences & Biotechnology (CTAHR), and Public Health (Social Work)
- UH Cancer Center faculty participate as members of JABSOM recruitment committee for Cell and Molecular Biology, and the Curriculum Committee for Cell and Molecular Biology
- Multiple UH Cancer Center clinically oriented faculty with joint appointments in JABSOM (Medicine, OBGYN, Pediatrics, Pathology)
- Merged phone systems with JABSOM to improve efficiencies
- Split common area maintenance charges with JABSOM
- Coordinate with JABSOM on achieving parking solutions for Kaka'ako campus
- Dean of JABSOM participates as a member of the Hawaii Cancer Consortium
- Cancer Center Director serving as chair of the IFA Director search committee
- Standing meetings between Cancer Center and JABSOM administrative directors
- Significant amount of Cancer Center pilot research funds has been awarded to JABSOM faculty (>\$150,000 over the last 3 years)
- Nomination of JABSOM faculty researchers for grant mechanisms restricted to Cancer Centers

Our work is not done. But it is clear that a continuing effort to identify further opportunities for synergies and efficiencies 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

We urge that the legislature not 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. As you know, 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, with disregard for the university's consultative shared governance processes, would overrule the judgments of those who are responsible for the internal structure and management of the university under the Constitution and who are directly responsible for making decisions that will lessen the burden of cancer on the people of Hawai'i.

We strongly oppose this measure and urge 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.

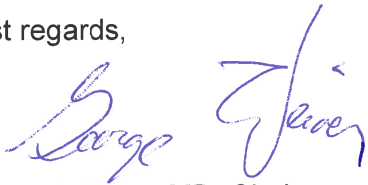
Equally impressive is the progress you and your colleagues have made in strengthening the Hawai'i Cancer Consortium. UHCC's leadership in this consortium will help the participating health systems recruit top flight oncology clinicians who see the value of clinical trials and the research that underpins 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,



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

HB-2564

Submitted on: 2/6/2020 12:38:06 PM

Testimony for LHE on 2/7/2020 2:00:00 PM

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

Comments:

Dear Chairs Woodson and Mizuno, Vice Chairs Hashem, Quinlan, and Kobayashi, and Members of the Committees:

I am writing as the President of the Friends of the UH Cancer Center to express our strong **OPPOSITION to HB2564** which would place the UH Cancer Center into the John A. Burns School of Medicine.

The Friends of the University of Hawaii Cancer Center is a nonprofit organization whose purpose is to support and promote the efforts of the University of Hawaii Cancer Center. It has been in existence for decades. Our goal is to generate community support for the Cancer Center in its efforts to find cures for cancer, to educate the people of Hawaii on cancer prevention and to improve the quality of life of those diagnosed with cancer. To fulfill our mission and goal, the Friends is actively involved in advocacy by bringing awareness to our community of the excellent and unique research taking place at the Center.

The Friends raises funds to support various initiatives and programs for UHCC and underwrites the bi-yearly publication and mailing of a Center and Friends' newsletter. From honoring Center staff, to providing funds for neighbor island clinical patients to travel to the Center for treatments, to providing stipends for high school and college summer interns, the Friends have a substantial investment in time and effort to support the Center and the remarkable work it does. Through thick and thin, the Friends have stood with and by the Center to ensure this incredible resource continues to serve the people of Hawaii and beyond.

We believe that this bill significantly threatens that resource. UHCC was recently awarded a renewal of its NCI designation, and with that came substantial new grants and funds, as well as great new faculty who are excited to work at this world-class center. This change would jeopardize that NCI designation. Losing that designation would be catastrophic to the work and funding of the Center in terms of reputation and access to funding and world-class researchers. It would change what is currently an asset to a liability, and in doing so, NOT serve the people of Hawaii and beyond well with cutting edge research and trials.

Please consider this bill and its ramifications carefully and vote against HB2564.

Sincerely,

Monica McLaren

President

Friends of UHCC Board



The House Committee on Lower and Higher Education
and
Committee on Health
February 7, 2020
2:00 pm, Conference Room 309

RE: **HB 2564 Relating to the University of Hawai'i**

Attention: Chairs Justin Woodson and John Mizuno, Vice Chairs Mark Hashem,
Sean Quinlan and Bertrand Kobayashi and members of the Committees

The University of Hawaii Professional Assembly (UHPA) **opposes the passage of HB 2564.**

HB 2564 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, were it enacted, is to 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 opposes the passage of HB 2564.

Respectfully submitted,

Christian L. Fern
Executive Director
University of Hawaii Professional Assembly

University of Hawaii
Professional Assembly

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The House Committee on Lower and Higher Education & Committee on Health

February 7, 2020 (2pm)

Individual Testimony AGAINST HB 2564
Re-organization of the University of Hawaii Cancer Center
within the UH John A Burns School of Medicine

Dear Chairs Woodson and Mizuno, Vice Chairs Hashem, Quinlan, and Kobayashi, and Members of the Committees:

I herein submit my individual testimony AGAINST the bill HB 2564 (and SB 2575) to reorganize the UH Cancer Center within the UH JABSOM Medical School.

This bill does not provide any specific, let alone convincing, rationale for the re-organization. It seems to be based on an unsubstantiated assumption that the State can save costs significantly and maintain the mission of two organizations that are important for the people of Hawaii by simply merging them. I testify against this bill because we have concrete and objective evidence that such re-organization will critically jeopardize the National Cancer Institute designation and possibly the very existence of the UH Cancer Center.

If a thoughtless merger is the goal, *why not re-organize the JABSOM Medical School within the UH Cancer Center?* Putting both units under Dr. Holcombe's capable leadership will not jeopardize either unit's survival and will most likely lead to better management of finances and also educational and research missions. Over the past 3 years, Dr. Holcombe has demonstrated outstanding leadership abilities and achievements, through a creative and collaborative working style, for all of which we have undisputable evidence and a large number of witnesses from the Consortium and community.

This bill does not acknowledge that re-organization of any UH units will have to take due processes within the University that has internal autonomy. This bill was brought forward by Lawmakers who do not seem to have any regards for rules and regulations if not to their liking, which seems to be the practice every year. Legislators wrote this bill without *any* engagement of the UH Cancer Center leadership or UH Administration for that matter. Worse, some Legislators seem to have had one-sided communication with JABSOM members according to the December hearing by the Senate Committee on Higher Education. *I believe that is abuse of power and exercise of undue and biased interference by the Legislators*, which will harm the relationship of both units and their affiliated communities for years to come.

I suggest that the Legislators put aside their personal biases, communicate their concerns fairly with both unit's leadership and the UH Administration, and make evidence-based recommendations to increase efficiency, now that we have an outstanding leader at the UH Cancer Center, and the faculty, staff, students and community are thriving to catch up with years of mismanagement that was thrown upon us. I respectfully ask you to vote against the bills HB 2564 and SB 2575.

Unhee Lim, Associate Professor, UH Cancer Center

The House Committee on Lower and Higher Education & Committee on Health

February 7, 2020 (2pm)

Individual Testimony AGAINST HB 2564

Re-organization of the University of Hawaii Cancer Center within the UH John A Burns School of Medicine

Dear Chairs Woodson and Mizuno, Vice Chairs Hashem, Quinlan, and Kobayashi, and Members of the Committees:

I herein submit my individual testimony AGAINST the bill HB 2564 (and SB 2575) to reorganize the UH Cancer Center within the UH JABSOM Medical School.

My name is Loïc Le Marchand. I have been a Faculty member at UHCC since 1987. I currently am a Professor and serve as the Associate Director for Ethnic Diversity. I am the Principal Investigator (PI) of several large grants, including the Multiethnic Cohort Study, a prospective study that has been following 215,000 Hawaii and California residents for cancer since 1993-1996. This scientific resource, shared with many researchers and students at UH, including at JABSOM, has brought in over \$150M to the University. 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 having a successful NCI-designated cancer center in Hawaii and what it can bring in terms of benefits to our community.

I am testifying against Bill HB 2564 as I strongly believe it would be disastrous for our efforts to decrease the cancer burden of our community for the following reasons:

- The UHCC director would lose most of his authority on budget, space and positions. This would make the renewal of our NCI-designation (P30 grant) pretty much impossible since the authority of the Director is one very important "essential characteristics" on which NCI-designated cancer centers are evaluated. NCI has already indicated that the reason they originally renewed our new P30 grant for 3 years instead of 5 was the multiple changes in the grant's PIship, including a previous leader with no cancer research experience. Because of the very significant progress we have made, NCI awarded us a fourth year on our P30 and will be considering giving us a fifth year this year, if this progress is sustained. This extension, and the subsequent renewal, will not happen if the Center is moved under the medical school dean as this substantially weakens the authority of the Director.
- We have made great progress under our current director in strengthening our research programs through recruitment. Losing our P30 will make recruitment of top-notch researchers much more difficult and would make current cancer center members much less competitive for getting NIH grants and conducting their research.
- The justification for the change seems to be to save money. We already considered this issue in 2016 when Dean Hedges proposed to move the Center under JABSOM when he was acting UHCC director. We (the UHCC Faculty and staff) completed a comprehensive survey of the functions of each office and program at the Center, and demonstrated in a white-paper (available upon request) that only a few of them could be merged with JABSOM. Since that time, we have assiduously worked to integrate what could be integrated between the two units. We continue to assess opportunities for integration and improved efficiency on the Kaka'ako campus.
- The mission of the two units are so different that it does not make programmatic sense to merge them. One (JABSOM) is almost exclusively organized and oriented toward the critical mission of teaching and training medical students for our state. UHCC is primarily organized to facilitate research and obtain NIH funding in order to conduct the research that will solve the cancer issues specific to our state population. This is the reason why we have been so successful. We have set up a system to manage and support research that is the envy of every researcher at UH and we do research that uniquely serves our state needs, in addition to contributing to the national cancer agenda. Under JABSOM, we would

lose this organizational edge which is in great part why we are able to compete nationally for grants. I have had a first-hand devastating experience from an attempt to fold the Center's fiscal office under JABSOM operations when Dean Hedges was UHCC Director, this instead of replacing UHCC fiscal officers who had left. Because we were unable to get timely reconciliations on our grant accounts and carried a substantial unobligated balance, NCI refused to award me several large grant supplements I had successfully applied for. I was able to get ~\$400K in grant supplements in the last two years while our fiscal office was well run under the current administrative management.

- Randy Holcombe, our current director, would most certainly leave if that happens. Since his arrival three years ago, he has turned around the Center, solved its operational deficit, and has been remarkably successful in renewing our P30 grant and launching new large initiatives that will very significantly benefit Hawaii, including extending the Hawaii Cancer Consortium and obtaining \$14M dollars (half state/half federal funds) to build an early phase clinical trials unit at the Center. Working more closely with the hospitals and making available the newest cancer treatments to Hawaii patients will completely transform cancer care in Hawaii. In my opinion, and based on my many years at UHCC, Dr. Holcombe has proven to be an outstanding director and the ideal person to, finally, build clinical research in Hawaii with the results it will have in improving patient care in our community.

In my 33 years at the Center, it is the first time I see it poised to fully realize its potential for the people of Hawaii. Please do not change the administrative reporting of the Center. You would jeopardize the great progress that we have made in the past 3 years. Thank you.

Loïc Le Marchand, MD, PhD

Professor of Epidemiology, Population Sciences in the Pacific Program

Associate Director for Ethnic Diversity

University of Hawaii Cancer Center

HB-2564

Submitted on: 2/5/2020 10:00:07 PM

Testimony for LHE on 2/7/2020 2:00:00 PM

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

Comments:

As a 25 year UH Cancer Center community partner, I **strongly oppose HB 2564 (and SB 2575)** to reorganize the UH Cancer Center within the UH JABSOM Medical School. The bill does not provide any rationale for the proposed re-organization and will critically jeopardize the University of Hawaii Cancer Center's National Cancer Institute (NCI) designation. The loss of this NCI designation will limit the ability of UH Cancer Center's (CC) investigators to continue to bring in more than \$50 million dollars of research funding and provide needed clinical trial funding for our residents to access services here in our state each year. Over the past 3 years, under the UH Cancer Center's Director Dr. Randall Holcombe's capable leadership, he has: 1) reduced budget deficits inherited from the past Center administration, 2) increased NCI funding, 3) recruited and hired excellent research investigators to bring their cancer specialties's expertise and research projects funding, 4) added new partners to the clinical trials/research consortium, 5) developed a business plan to utilize the remaining CC space for supporting biotech lab opportunities, and 6) promoted and encouraged a creative and collaborative working environment for the staff, the Consortium, and the community partners after years of mismanagement. The UH Cancer Center is already a viable and sustainable research unit under his leadership. It would be a grave mistake to reorganize the CC within the UH JABSOM Medical School. **Therefore I strongly oppose HB 2564 and its companion SB 2575.** Thank you for the opportunity to testify.

Lynn Murakami-Akatsuka, MPH, CHES

**HOUSE OF REPRESENTATIVES
THE THIRTIETH LEGISLATURE
REGULAR SESSION OF 2020
February 7, 2020
2:00 PM
Conference room 309
HB 2564**

TESTIMONY Against Establishing an Organized Research Unit for Cancer Research within the University of Hawaii John A. Burns School of Medicine

Chair and Members of the Committee:

My name is Dr. Michelle L. Matter, and I am an Associate Professor at the University of Hawaii Cancer Center. In my work, I have identified a new gene called PTRH2 that is important in human development and in cancer. It is especially important in the children's cancer neuroblastoma where high expression of this protein provides a survival signal in these cancer cells. This is an important advantage that these cancer cells use as they metastasize to new sites. My group is working to understand how this survival advantage occurs and if PTRH2 it is a therapeutic target for treating neuroblastoma and other cancers.

I am writing to express my concern and disapproval for the bill establishing an organized research unit for cancer research within the University of Hawaii John A. Burns School of Medicine. At this time the UH Cancer Center is at an exciting pivotal point where we are in the position to make new discoveries and move treatments forward for the people of Hawaii. Dr. Holcombe as Director has been a tremendous asset for the UH Cancer Center. During his short tenure at the UH Cancer Center he has been able to dramatically increase faculty morale. Through his leadership the faculty has become a cohesive collaborative group that works together in research and in preparing for the UH Cancer Center NCI designation renewal. Importantly, the UH Cancer Center External Advisors Committee spent several days here in 2020 and reported to our entire UH Cancer Center faculty that they saw a huge improvement in collaborations, research and faculty morale. This committee was extremely positive and stressed that we were in great shape to obtain our next NCI designation renewal. It was the most positive meeting with our external advisors since I joined the UH Cancer Center in 2012.

Moving the UH Cancer Center into JABSOM will negatively impact faculty morale and will bring into question whether the NCI designation can be renewed when such drastic changes are being implemented. This will have negative impact on faculty recruitment and potentially faculty retainment. As Vice-Chair of the UH Cancer Center Faculty Senate I am concerned that the faculty has not had any internal discussions or the ability to defend the UH Cancer Center against such a move into JABSOM.

The UH Cancer Center is one of only 71 institutions in the United States that hold the prestigious National Cancer Institute (NCI) designation and is the only NCI-designated center in the Pacific. The NCI designation provides cancer researchers in Hawai'i with greater access to federal funding and research opportunities. More importantly, it gives the people of Hawai'i and the Pacific region access to many innovative and potentially life-saving clinical trials without the necessity of traveling to the mainland.

I respectfully urge this Committee to block this bill and **NOT** establish an organized research unit for cancer research within the University of Hawaii John A. Burns School of Medicine.

Aloha mai kakou,

I am a Research Corporation of the University of Hawaii (RCUH) employee with over 25 years of experience at the University of Hawaii Cancer Center (UHCC). I have worked under 3 directors and 1 interim director, and without a doubt, I am **opposed to the SB2575 (HB2564)**. Our current director, Dr. Randal Holcombe, has brought our center out of severe low morale amongst the employees to a center where everyone has a common goal for the future of Cancer Research. With the renewal of the most competitive national honor as National Cancer Institute (NCI) designated cancer center, we are in a great position to move forward with our shared vision of a new clinic for Phase 1 Clinical Trials. Not an easy goal set by our director, but one that we see for our future. This could not happen without his independent authority over all decisions for his vision as the premiere Cancer Research Center in the Pacific which includes monies, space, and all faculty recruitments that make sense for his vision. In addition to making our vision a reality, Dr. Holcombe needs a direct line of communication with UH administration to work on support from the community that can only happen with access to system's resources. This bill introduces unfounded allegations that we are running inefficiently and that there is a need to "integrate our resources to avoid unnecessary duplication of administrative expenses or conflicting priorities". There is an assumption that the administration that works for a medical school could also function to support an NCI designated Cancer Center that have completely different criteria to be successful. Until there are fiscal numbers that support this statement that we would 'save' on resources, this bill has no grounds to stand on to place the UHCC as an ORU in the School of Medicine.

PLEASE RECONSIDER WHAT YOU ARE ASKING IN THIS BILL. Dr. Randal Holcombe has blessed us with a fresh take on what our Center could be, and with his forward vision, this bill would stop us short of what we could be for the people of Hawaii.

Thank you for your consideration,

Annette Jones, BA. (University of Hawaii-Manoa)
Research Lab Analyst, Genomics and Bioinformatics Shared Resource (GBSR)
University of Hawaii Cancer Center

HB-2564

Submitted on: 2/6/2020 11:43:09 AM

Testimony for LHE on 2/7/2020 2:00:00 PM

Submitted By	Organization	Testifier Position	Present at Hearing
thomas wills	Individual	Oppose	No

Comments:

I oppose this bill. Although the intent may have been to be supportive, the outcome would not be a good one. The consequences will be harmful for cancer etiology and prevention research in Hawaii.

Dear Chairs Woodson and Mizuno, Vice Chairs Hashem, Quinlan, and Kobayashi, and Members of the Committees:

I am writing as a Professor in the UH Cancer Center to voice my adamant **OPPOSITION to HB2564** which would place the UH Cancer Center into the John A. Burns School of Medicine.

I want to personally thank you for the work you do on behalf of the citizens of Hawaii. Like you, we, the faculty of the UH Cancer Center, are working tirelessly to help the people of Hawaii. Our goals are to reduce the burden of cancer on the people in the state by improving cancer prevention, diagnosis, treatment, and education. While I am sure the motivation behind this bill was to help the UH Cancer Center it will rather have the opposite effect and will devastate the Cancer Center and irretrievably weaken it.

I have been at the Cancer Center for over 15 years and came here from another NCI Designated Cancer Center. My comments derive from serving the Cancer Center as interim Associate Director for 2 years (first with Interim Director Dean Jerris Hedges then with new Director Dr. Randall Holcombe) and currently as Chief Scientific Officer and Deputy Director on our Cancer Center Support Grant. I also have a secondary appointment in JABSOM and teach in a graduate program there. I know the finances and faculty in great detail. I have written large sections of our last two UH Cancer Center NCI Designation renewals, attend the annual Cancer Center Meetings, sit on Cancer Center review site visits, and review biomedical research grants at every level. I therefore know the requirements of the NCI Designation thoroughly. The following bullet points explain why moving the Cancer Center ORU into the medical school will clip its wings and undermine its mission to serve Hawaii:

- 1) **The proposed change will jeopardize our NCI Designation.** The current organization with our Director reporting 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 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 (and previously Vice Chancellor for Research) will be viewed as weakening the Cancer Center by our external reviewers and will take away one of our great differentiators.
- 2) 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. Because of his knowledge and expertise in NCI Designated Cancer Centers he has been able to do this without weakening the core strengths of the Cancer Center. Indeed, by balancing the budget the last two years he has improved our competitiveness for the next renewal.
- 3) 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 and graduate students. Research is secondary. Our Central mission is cancer research that will impact 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 a different goal and different culture.
- 4) **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 and is attached as addendum. 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 of these activities and keeps costs in check. To be sure we do not miss opportunities at finding savings, our Associate Director of Administration (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.

- 5) **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.
- 6) 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. I teach in two courses there, have a secondary appointment and professorship, and serve on the curriculum committee. Importantly other faculty of the Cancer Center teach in programs on the main campus. Our undergraduate and graduate students come from JABSOM and throughout related programs across UH. Indeed, we provide funding for first year Graduate Students in the Cell and Molecular Biology Program in JABSOM – more than JABSOM itself provides.
- 7) **Dr. Randall Holcombe MD, MBA is an OUTSTANDING Director** and is recognized for his expertise across all the NCI Cancer Centers. Please see our recent external advisory report that was shared with you for a sample (I also attach here for convenience). 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. This change 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 and initiatives for the health of the people of Hawai'i.

For the reasons above I am strongly **AGAINST HB2564**. It is an attempt to solve a problem that doesn't exist and will instead cause many negative unintended consequences and increased costs.

Thank you,

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

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.

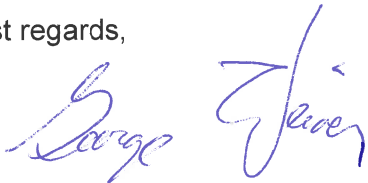
Equally impressive is the progress you and your colleagues have made in strengthening the Hawai'i Cancer Consortium. UHCC's leadership in this consortium will help the participating health systems recruit top flight oncology clinicians who see the value of clinical trials and the research that underpins 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,



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



UNIVERSITY OF HAWAI'I

CANCER CENTER

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

**UHCC Task Force Report
October 2016**



UNIVERSITY OF HAWAI'I

CANCER CENTER

Cancer Center Task Force Committee

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

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 Alike 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

APPENDIX V

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

HB-2564

Submitted on: 2/6/2020 12:27:32 PM

Testimony for LHE on 2/7/2020 2:00:00 PM

Submitted By	Organization	Testifier Position	Present at Hearing
Yurii Shvetsov	Individual	Oppose	No

Comments:

Dear Chairs Woodson and Mizuno, Vice Chairs Hashem, Quinlan, and Kobayashi, and Members of the Committees:

I am writing to express my **STRONG OPPOSITION to HB2564** 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 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.

It is for these and other reasons that when a similar reorganization was considered recently, it was ultimately decided not to proceed with it. All relevant factors were considered in making that decision, and I urge the Legislators not to bring up again a question that has already been settled. Besides, 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.

For the reasons above, I **STRONGLY OPPOSE HB2564**.

Thank you,

Yurii B. Shvetsov, PhD

Assistant Professor

University of Hawaii Cancer Center

Dear Chairs Woodson and Mizuno, Vice Chairs Hashem, Quinlan, and Kobayashi, and Members of the Committees:

I am an Associate Professor at the UH Cancer Center. I'm writing to express my strong **opposition to HB2564**; a proposal which would place the UH Cancer Center with the structure of the John A. Burns School of Medicine.

Although the bill is well-intentioned, I believe it would have a detrimental effect on the UH Cancer Center, and would hamper our efforts to reduce the burden of cancer on the people in the state by improving cancer prevention, diagnosis, treatment, and education. Further, I believe the bill (if passed) could actually increase costs, and decrease our ability to acquire large research grants from the National Cancer Institute (NCI).

The UH Cancer Center has made great strides in recent years under the outstanding leadership of our new Director Dr. Randall Holcombe. Moving the UH Cancer Center into the School of Medicine would create the appearance that Dr. Holcombe is being demoted. This could seriously undermine UH's standing with the National Cancer Institute (NCI), and could jeopardize our status as a designated NCI Cancer Center. This, in turn, would reduce our eligibility to obtain various large research grants.

For these reasons and others, I **oppose HB2564**.

Thank you for your consideration,

Thaddeus Herzog, PhD
Associate Professor
UH Cancer Center

The House Committee on Lower and Higher Education & Committee on Health
February 7, 2020 (2pm)
Individual Testimony AGAINST HB 2564

**Re-organization of the University of Hawaii Cancer Center within the UH John A Burns
School of Medicine**

Dear Chairs Woodson and Mizuno, Vice Chairs Hashem, Quinlan, and Kobayashi, and
Members of the Committees:

I Kevin Cassel, am writing as an Assistant Professor at the UH Cancer Center to voice my adamant **OPPOSITION to HB2564** which would place the UH Cancer Center into the John A. Burns School of Medicine. I am testifying against Bill HB 2564 as I strongly believe it would be disastrous for our efforts to decrease the cancer burden of our community for the following reasons:

- 1) The current organization with our Director reporting 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 is the “Authority of the Director”. We have scored top scores on this measure in each of our renewals. The demotion of our Director to reporting to the Dean rather than the Provost (and previously Vice Chancellor for Research) will be viewed as weakening the Cancer Center by our external reviewers and will take away one of our great differentiators.
- 2) 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. Because of his knowledge and expertise in NCI Designated Cancer Centers he has been able to do this without weakening the core strengths of the Cancer Center. Indeed, by balancing the budget the last two years he has improved our competitiveness for the next renewal.
- 3) 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 and graduate students. Research is secondary. Our Central mission is cancer research that will impact 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 a different goal and different culture.
- 4) 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.
- 5) There will be significant 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.
- 6) 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. I teach a course there. Other faculty of the Cancer Center teach in programs on the main campus. Our undergraduate and graduate students come from JABSOM and throughout related programs across UH. Indeed, we provide funding for first year Graduate Students in the Cell and Molecular Biology Program in JABSOM – more than JABSOM itself provides.

- 7) Dr. Randall Holcombe MD, MBA is an OUTSTANDING Director and is recognized for his expertise across all the NCI Cancer Centers across the US. Please see our recent external advisory report that was shared with you for a sample. Since his arrival the Center has renewed its designation (a short 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. This change is a demotion for him and will wipe out these hard-won gains in a single move.

Finally, the current administration of the UH Cancer Center recently received the Governor's Team Award for "Exemplary and Outstanding Performance in Serving the Citizen's of Hawaii. The recognition from the Governor for the UH Cancer Center's administration was given as follows:

"Your team, comprised of various administrative offices, invested valuable time and your combined talents to improve the efficiency and operational productivity of your individual units. This resulted in employee work satisfaction, cost savings, and achievement of key mission-based objectives. Your team helped revitalize the Cancer Center with robust community outreach to educate the public about cancer prevention, renewed an active collaboration with community organizations, and reinforced the need for cancer research. In addition, by employing a rigorous budget review process, your team reduced annual expenditures by over \$2 million. A critical and defining moment occurred when the National Cancer Institute (NCI) recognized the unique contributions of the UH Cancer Center and rewarded your efforts by continuing the NCI designation. For Hawaii, this means that family and friends will have access to cutting-edge cancer treatments and the highest quality of cancer care. Due to your extraordinary teamwork and tireless dedication, the UH Cancer Center has flourished as an academic unit and service organization."

For the reasons above I am strongly **AGAINST HB2564**. It is an attempt to solve a problem that doesn't exist and will instead cause many unintended costs and consequences.

Thank you,

Kevin Cassel
Assistant Professor
UH Cancer Center

HB-2564

Submitted on: 2/6/2020 1:54:27 PM

Testimony for LHE on 2/7/2020 2:00:00 PM

Submitted By	Organization	Testifier Position	Present at Hearing
Namrata Gurung	Individual	Oppose	No

Comments:

I am testifying to appose this Bill.

I have been a HR personnel for the last 13 years at the University of Hawaii Cancer Center. In these 13 years, I have seen many ups and downs within the UH Cancer Center administration. But the last 3 plus years (after Dr. Randall Holcombe was hired as the Director) has been the most important years for the UH Cancer Center. I have never seen any Director working so well with the entire Faculty, staff, UH administrators (includes UH Dean/Directors), and community partners. As HR personnel, I have to work with the employees very closely and I have personally seen the change in these 3 and half years - the change in their willingness to learn, to participate, to collaborate, and work together to achieve the one goal of the UH Cancer Center of finding cure for Cancer. With this testimony I am apposing the introduced bill.

The House Committee on Lower and Higher Education

and

Committee on Health

February 7, 2020

2:00 pm, Conference Room 309

RE: HB 2564 Relating to the University of Hawai'i

Attention: Chairs Justin Woodson and John Mizuno, Vice Chairs Mark Hashem, Sean Quinlan and Bertrand Kobayashi and members of the Committees

I write to express my opposition to HB 2564, defining the University of Hawai'i (UH) Cancer Center as an Organized Research Unit (ORU) within the administrative and management purview of John A. Burns School of Medicine (JABSOM).

I joined the UH Cancer Center as Associate Director for Administration in July, 2017, after having worked in cancer center administration for the previous 20 years, at the NCI-designated University of Virginia Cancer Center and more recently at the West Virginia University Cancer Institute, a center which is often referred to as an "emerging" cancer center with aspirations of becoming NCI-designated. Though I am acutely aware of the past history during some trying and tumultuous years for UH Cancer Center, I feel as though my perspective on the issue of reorganization, as proposed in this proposed bill, may be valuable to you as legislators.

Working together with JABSOM: First, the introduction of this bill seems to be in response to issues long since put to rest regarding the UH Cancer Center and JABSOM working together toward a common goal of research (encompassing basic sciences, population sciences and clinical research), education, community outreach. From an administrator's point of view, the school and the center have a good working relationship, employing synergistic oversight of many of the functions necessary for the day-to-day operations of the Kaka'ako campus. Examples include combined strategies on parking, cooperating on campus security, sharing major purchase (e.g., land lease, utilities, telephone infrastructure, etc.), practice plan operations (through UHP), high level human resources collaboration, etc. The JABSOM CFO (Ms. Foster) and I have an excellent working relationship and meet regularly to maintain administrative cooperation and tackle common topics among our units.

Reorganization effect on NCI-designation: As mentioned in many forums, NCI-designation is coveted honor conferred upon the university and the state. There are currently a total of 71 NCI-designated cancer centers, one of which is the UH Cancer Center. There are fourteen states in which there is no NCI-designated cancer center, yet each of those states have universities with cancer centers aspiring to become NCI-designated. It is a testament to UH and the state for supporting NCI-designation of cancer center for the past 25 years as a resource for discovery and dissemination, given the ethnic diversity of Hawai'i's population, found at no other cancer center in the US. Loss of this designation would be a setback to the progress made in cancer research that applies directly to the people of Hawai'i.

Among the guidelines utilized in determining the eligibility for NCI-designation are what is termed “The Six Essential Characteristics of an NCI-designated Cancer Center.” These include: Physical Space, Organizational Capabilities, Transdisciplinary Collaboration and Coordination, Cancer Focus, Institutional Commitment, and Center Director. A reorganization of the cancer center would create particular concerns regarding several of these Essential Characteristics.

Physical Space: The cancer center building is an excellent resource for the transdisciplinary research which occurs within the building and provides a launching point for the many collaborations that exist among cancer center members whose homes are with many schools and departments within the UH system, including JABSOM. A reorganization will be seen as dilution of the focus for cancer research within the physical space.

Organizational Capabilities: From the review of the competitive renewal of NCI designation in 2017: “Dr. Holcombe as Center director, occupies leadership positions within the University of Hawaii equivalent to a dean thus enhancing integration of the Center, and facilitating a stronger impact of the Center priorities on university initiatives.” A reorganization would demote the Director to a level similar to that of a department chair, which would be seen as a loss in this Essential Element.

Cancer Focus: A reorganization would dilute the effect of the current focus on cancer related topics among the cancer center members. While there are many cancer center members within JABSOM, many JABSOM faculty do not perform cancer related research. As a matrix center the current organization allows for cancer focus to be achieved through collaborations with individuals in many schools and departments. This collaboration may be in jeopardy if a reorganization restricts collaboration through a silo-type organizational structure under a single school.

Institutional Commitment: This element will likely be one of the most affected of the Six Essential Elements, due to the significant structural changes that will occur. Rated as “Outstanding” in the 2017 competitive renewal review, commitment from the state, university and clinical partners was received well by the reviewers. A reorganization will be seen as lack of commitment, especially from the state, but also from the university, should the reorganization be allowed to take place.

Center Director: This is the most important element within the “Six” which will be affected by this proposed reorganization. The following is quoted from the afore mentioned NCI review:

The Center Director is rated outstanding. Dr. Holcombe has complete authority over all resources at the Center, which includes research space, faculty recruitment and appointment of members, and all Cancer Center revenue and all financial matters. His direct control and authority over the entire cancer programs at the Center and shared resources as well as clinical trials infrastructure ensures that the Center remains mission focused. The impact of the new center director is palpable and there is confidence that under his leadership the Center will continue to address its challenges and create opportunities to reach its strategic goals. Dr. Holcombe is highly qualified for this position.

Guidelines on the Center Director have recently changed to emphasize importance of the authority of the director. Authority must be seen as “superior to that of department chairs.” A reorganization will be seen as a demotion of the current director authority, which is equivalent to that of a Dean at UH.

Overall, the review of the Six Essential Elements will suffer in the next renewal, as a result of this reorganization, putting NCI-designation in jeopardy. There has been only one NCI-designated Cancer Center to lose its designation in the last 20 years, and that was University of Vermont. Their loss of NCI-designation was based precisely on the same issues the legislature is proposing—a reorganization that is not befitting to the established guidelines used for consideration of NCI-designation. NCI-designation brings with it the ability to apply for grants not available to other institutions. Moreover, this designation also lends credibility to the institutional resources necessary for research grants awarded by NCI, and more broadly, by NIH and other federal agencies. It is well known that 85% of all NCI extramural funding is awarded to the 71 NCI-designated Cancer Centers. The remaining ~1,000 cancer centers in the US seek the remaining 15% to support cancer research programs at their institutions. A reorganization and loss of NCI-designation will result in the UH Cancer Center being among the lower 15%.

Cancer Center Administrative Leadership: Cancer Center Administration, which I am privileged to lead over the past two and a half years, has made huge improvements to operations and management of the facility over the past couple of years. In recognition of these efforts, this team, consisting of leaders in the area of fiscal, communication, grants management, human resources, community outreach, facilities, philanthropy, and clinical research operations, was awarded the Governor’s 2019 State Team of the Year. The award declaration stated:

Your team, comprised of various administrative offices, invested valuable time and your combined talents to improve the efficiency and operational productivity of your individual units. This resulted in employee work satisfaction, cost savings, and achievement of key mission-based objectives. Your team helped revitalize the Cancer Center with robust community outreach to educate the public about cancer prevention, renewed an active collaboration with community organizations, and reinforced the need for cancer research. In addition, by employing a rigorous budget review process, your team reduced annual expenditures by over \$2 million.

A critical and defining moment occurred when the National Cancer Institute (NCI) recognized the unique contributions of the UH Cancer Center and rewarded your efforts by continuing the NCI-designation. For Hawai’i, this means that family and friends will have access to cutting-edge cancer treatments and the highest quality of cancer care. Due to your extraordinary teamwork and tireless dedication, the UH Cancer Center has flourished as an academic unit and service organization.

A reorganization, frankly, belies this achievement and offers little incentive for a continued upward trajectory already in place.

In summary, HB 2564 will be detrimental to the UH Cancer Center and to the people of Hawai’i. I therefore request that the legislature cancel such measures that may be before you.

Sincerely,

Clifford C. Martin, MBA

Associate Director for Administration at the University of Hawaii Cancer Center



American Cancer Society
Cancer Action Network
2370 Nu`uanu Avenue
Honolulu, Hawai`i 96817
808.432.9149
www.acscan.org

House Committee on Lower and Higher Education
Representative Justin Woodson, Chair
Representative Mark Hashem, Vice Chair
Representative Sean Quinlan, Vice Chair

LATE

House Committee on Health
Representative John Mizuno, Chair
Representative Bert Kobayashi, Vice Chair

HB 2564 – RELATING TO THE UNIVERSITY OF HAWAII
Cory Chun, Government Relations Director – Hawaii Pacific
American Cancer Society Cancer Action Network

Thank you for the opportunity to provide comments on HB 2564, which creates the cancer research unit within the University of Hawaii medical school. While we appreciate the Legislature’s intent of reducing costs to the State, we do have concerns on the proposed measure.

One of the major criteria used by the National Institutes of Health (NIH) in determining whether a cancer center can be recognized by the National Cancer Institute (NCI) and receive support from P30 grant funding is institutional commitment.¹ The specific criteria for the commitment is as follows:

“Commitments of parent institutions to the Cancer Center generally include the following:

- An organizational status for the Cancer Center that is comparable or superior to that of departments.
- Funding from the institution and consortium partners.
- Research, clinical, and administrative space and positions.
- Measures that ensure other institutional leaders (deans, hospital presidents, and department chairs) will provide the long-term stable support necessary to accomplish strategic Cancer Center objectives.
- Joint control, at a minimum, with department chairs over faculty recruitments to the Cancer Center.

¹ See <https://grants.nih.gov/grants/guide/pa-files/PAR-20-043.html> <accessed on 2-6-2020>

- A well-defined plan for a change in directorship and for continuing institutional commitment to support of the Cancer Center.
- Recognition of participation in team science in institutional policies, including those related to promotion and tenure.
- A commitment to facilitate clinicians to participate in clinical trials
- A commitment to facilitate research by clinician scientists.
- Authority of the Center Director:
 - As comparable or superior to that of department chairs, with appointments to decision making committees relevant to the Cancer Center and formally codified authorities.
 - Over specific research and resource space and equipment dedicated to the Cancer Center for the enhancement of center research capabilities.
 - Over inpatient and outpatient clinical research facilities and the appointment and evaluation of individuals critical to linking oncology care to clinical research.
 - Over faculty appointments to the Cancer Center, and of their periodic review for continued membership.
 - Over central discretionary funds (e.g., philanthropic funds, facilities and administrative costs, and clinical revenues).
 - In consortium centers, Director oversight for integration of scientists in collaborating institutions into the research Programs of the center and CCSG-supported shared resources.”

Our concern with this measure is that by placing the University of Hawaii Cancer Center (UHCC) within the John A. Burns School of Medicine for organizational and cost reduction purposes, the measure may unintentionally affect the UHCC’s designation as a National Cancer Institute cancer center. It is unclear whether the director will maintain the same authority that is required for NIH grant funding under the P30 core grants or whether placing the center under the authority of medical school jeopardizes that requirement by placing that authority in the dean of the medical school. This measure may also affect requirements for researchers and clinical staff as well.

Should the UHCC lose its designation as an NCI designated cancer center it would not be eligible for NIH grant funding and support grants. 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 urge the committee to consider these issues on this measure.

Thank you for the opportunity to provide comments on this important matter.

LATE

HB-2564

Submitted on: 2/6/2020 2:00:53 PM
Testimony for LHE on 2/7/2020 2:00:00 PM

Submitted By	Organization	Testifier Position	Present at Hearing
Mary Suzanne Palumbo	Individual	Oppose	No

Comments:

I am writing this in strong opposition to HB2564, which merges the University of Hawaii Cancer Center (UHCC) with the John A. Burns School of Medicine (JABSOM).

I have a long association with JABSOM. My late husband, Nicholas E Palumbo, DVM was professor Emeritus at the medical school. He was on the faculty at JABSOM in the 1960's, when it was a started under Dean Cutting. I have seen the medical school evolve close up. And we have much of which to be proud.

In recent years, I have had the opportunity to get to know the workings of the UH Cancer Center. As recent president of the Friends of the Cancer Center, a community group that promotes and supports and advocates for the UHCC, I have seen Dr Holcombe and his staff work close up. Dr. Randall Holcombe has brought world wide attention to the research of cancer diagnostics and treatment to the Pacific Rim in ways that have rapidly eclipsed previous directors. On a personal level, Dr Holcombe helped to guide me through my own personal battle with breast cancer. He has recently regained National Cancer Institute certification for UHCC. The faculty and staff have worked long and hard to regain this accreditation. The NCI designation is only given to 71 facilities in the country. The NCI designation allows us to attract faculty and staff throughout the world. Recent additions to the staff include two researchers with clinical appointments in Honolulu. These two women, Dr. Jessica Rhee and Dr. Jami Fukui, are the only two breast cancer specialists in Hawaii. They, and researcher-physicians with like status, are essential to allowing people like myself to get competent and specialized treatment in the state of Hawaii.

The foolhardy merger of UHCC and JABSOM will result in the loss of NCI designation. It will let millions of research dollars go elsewhere. And we will lose our amazing faculty and research staff presently working at UHCC. Please oppose this merger. There is no cost savings, there is no reason except ego to pursue this merger.

Many thanks for your time and service to our community

Sue Sylvester Palumbo, DVM

The Cat Clinic, Inc

[Honolulu, HI](#)

Ph [\(808\)284-3765](#)

Sent from my iPad

LATE

HB-2564

Submitted on: 2/6/2020 2:13:14 PM

Testimony for LHE on 2/7/2020 2:00:00 PM

Submitted By	Organization	Testifier Position	Present at Hearing
Diane T. Ono	Individual	Oppose	Yes

Comments:

Dear Chairs Woodson and Mizuno, Vice Chairs Hashem, Quinlan, and Kobayashi, and Members of the Committees:

I am writing as a long time supporter of the UH Cancer Center in strong **OPPOSITION to HB2564** which would place the UH Cancer Center into the John A. Burns School of Medicine.

My support of UH Cancer Center dates back to 1997, 23 years ago when my daughter Mari Galihier was diagnosed with acute lymphocytic leukemia at the age of four. Mari was treated successfully for 2-1/2 years through a clinical trial administered by the UH Cancer Center. I decided back then, during her treatment, that I would never forget the important life-saving work of the UH Cancer Center. After all, it has been through cancer research that childhood leukemia became a curable disease. The incredible progress made is a direct result of how research scientists brought together chemistry, pharmacology and quantitative data from clinical trials to turn childhood leukemia from what was once an absolute death sentence to one where children are now being cured at the rate of 85-90% -- all within my lifetime.

Over the years, my support has been as an advocate in the community, as an ambassador on the Friends of the UH Cancer Center board as well as financially as a donor through UH Foundation. I will do whatever I can to support and preserve this great institute, the UH Cancer Center, because of what it means to the people of Hawai'i and beyond.

What makes our UH Cancer Center premier in the field of cancer research is its National Cancer Institute (NCI) designation. It is one of only 71 cancer centers that hold this designation.

I had the opportunity to serve on the UH Search Advisory Committee which resulted in the hiring of Dr. Randall Holcombe at a time when the Cancer Center was embroiled in controversy with its NCI designation at risk. Dr. Holcombe's work and leadership over the several years he has been the Director at the Cancer Center is masterful. Through his leadership, there is now an environment of collaboration and cohesiveness among the research scientists. Dr. Holcombe has built bridges among the key stakeholders in the community, namely, the hospitals in our state where cancer patients are treated.

The Multiethnic Cohort which is a 25-year long population study has resulted in the publication of over 600 papers. Our Cancer Center's research is known worldwide.

Additionally, through Dr. Holcombe's oversight, in the few years he's been in Hawai'i, the UH Cancer Center administrative team won the Governor's Award for Team of the Year in 2018. The award recognized Dr. Holcombe and his team for their role in streamlining UH Cancer Center finances and with renewing the NCI designation. A key component in the renewal of UH Cancer Center's NCI designation is the Director's authority. Director Holcombe presently reports directly to the Provost; he should NOT be reporting to the dean of the medical school. Director Holcombe's authority cannot and should not be diluted in any way.

Presently, UH Cancer Center is in the best position I have seen in my years of support. The cliché comes to mind – if it ain't broke, don't fix it. Please do not meddle with the present organization of the UH Cancer Center as an autonomous institute at the University of Hawai'i at Manoa.

Respectfully submitted,

Diane T. Ono

3731 Pukalani Place

Honolulu, HI 96816

HB-2564

Submitted on: 2/6/2020 2:29:31 PM

Testimony for LHE on 2/7/2020 2:00:00 PM



Submitted By	Organization	Testifier Position	Present at Hearing
Pallav Pokhrel	Individual	Oppose	No

Comments:

Dear Chairs Woodson and Mizuno, Vice Chairs Hashem, Quinlan, and Kobayashi, and Members of the Committees:

I am writing as an Associate Professor in the UH Cancer Center to voice my **OPPOSITION to HB2564** which would place the UH Cancer Center under the John A. Burns School of Medicine.

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 and graduate students. Research is secondary. Our Central mission is cancer research that will impact 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 a different goal and different culture.

I strongly believe that there is no advantage for faculty, staff, or students from the proposed merger. Faculty already move freely between the two organizations. We have faculty that teach in JABSOM and serve on many JABSOM committees already. And we already share a number of resources from conference rooms to the security personnel.

Thus, for the reasons above I am strongly **AGAINST HB2564**. It is an attempt to solve a problem that doesn't exist and will instead cause many unintended costs and consequences.

Thank you,

Pallav Pokhrel, PhD

Associate Professor

Cancer Prevention Program

University of Hawaii Cancer Center



UNIVERSITY OF HAWAI'I
CANCER CENTER

February 6, 2020

Dear Chairs Woodson and Mizuno, Vice Chairs Hashem, Quinlan, and Kobayashi, and Members of the Committees:

I am writing as an Associate Professor at the UH Cancer Center to express my adamant **OPPOSITION to HB2564** which would place the UH Cancer Center into the John A. Burns School of Medicine.

This change would result in loss of our NCI-designation which would have disastrous effects for the Cancer Center, its faculty, and the entire community. Under Dr. Randall Holcombe's current leadership and authority, every aspect of the Cancer Center has improved. Being re-designated by the NCI allows us to recruit faculty of the highest caliber to conduct high quality research for the benefit of those in Hawaii, the Pacific, and beyond. By placing the Cancer Center into the medical school, Dr. Holcombe's authority and ability to lead the Cancer Center effectively would be weakened.

UH Cancer Center currently has a very good working relationship with the medical school and many Cancer Center faculty have faculty appointments in the medical school, including me, so the proposed change in this bill is not necessary to foster better collaboration.

As Medical Director of the Clinical Trials Office, I oversee the clinical trials infrastructure for our entire network which includes the major hospital systems and oncology private practices. The cancer clinical trials we offer and administer directly to the community impacts the entire state. I am excited about our plans to open an Early Phase Clinical Trials Unit and be able to offer the most novel agents to treat cancer that would not be available to our residents without this new facility. The success of this Unit would only be possible under the leadership of Dr. Holcombe with his extensive experience and in his current role as Director with his current level of authority. The failure to create such a unique Unit in Hawaii would be a tragic disservice to our residents who would have to continue to travel to the mainland to access these most novel treatments and place significant burdens on patients and their families.

The future of UH Cancer Center is very bright under Dr. Holcombe's current leadership and authority. This was also recognized by our recent External Advisory Committee site visitors. Placing the Cancer Center in the medical school would undo all the impactful work that has been done under Dr. Holcombe's leadership. Therefore, I strongly **OPPOSE HB2564**. Thank you for your consideration.

Jessica Rhee, MD, MS
Associate Professor, UH Cancer Center
Medical Director, UH Cancer Center Clinical Trials Office
Associate Professor, Department of Medicine, John A. Burns School of Medicine

February 6, 2020

LATE

Dear Members of the Committee:

I am an Associate Researcher in the UH Cancer Center and I am writing to express my **strong opposition to HB2564**. This bill proposes to establish an organized research unit for cancer research within the University of Hawaii John A. Burns School of Medicine. I have been a faculty member at the UH Cancer Center since 2008.

The UH Cancer Center has a critical role in serving the needs of our community and catchment area. The Cancer Center is one of only 71 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. As a very accomplished medical oncologist and visionary leader, Dr. Holcombe, as the Director of the UH Cancer Center has been a key component of this accomplishment. Reorganizing the research unit, and having the UH Cancer Center within UH JABSOM would jeopardize the NCI designation and important research and clinical advancements that have been accomplished under Dr. Holcombe's leadership. Furthermore, as the mission of the UH Cancer Center is very different from JABSOM, the leadership of both entities should require different expertise. Dr. Hedges, as the Dean of JABSOM, has limited experience with the cancer research and care, thus it is not ideal for him to hold a leadership position overseeing the UH Cancer Center. Also, the proposed reorganization would detract from Dr. Hedges' primary responsibility to educate our future medical doctors.

I request that the committee members consider the negative consequences and limited benefit of the proposed reorganization and oppose HB2564.

Sincerely,

Lenora WM Loo, PhD
Associate Researcher

LATE

The House Committee on Lower and Higher Education & Committee on Health

February 7, 2020 (2pm)

Personal Letter AGAINST HB 2564

Re-organization of the University of Hawaii Cancer Center

within the UH John A Burns School of Medicine

Dear Chairs Woodson and Mizuno, Vice Chairs Hashem, Quinlan, and Kobayashi, and Members of the Committees:

The content of this brief letter represents testimony AGAINST the bill HB 2564 (and SB 2575) to reorganize the UH Cancer Center within the UH JABSOM Medical School.

This message is simple. The designation from the National Cancer Institute (NCI) as a recognized Cancer Center is based on being an independent entity under a Director assigned to lead the Cancer Center and only the Cancer Center. Many of the novel and experimental treatments offered to the citizens of Hawaii are available due to the University of Hawaii Cancer Center's efforts as it currently exists under the NCI. I would not want to be the senator or the representative that would have to share with their constituents, "I made the decision that led to limiting cancer treatment opportunities to the citizens of Hawaii". There is no guarantee that these treatments would continue if a new structure is implemented.

As a resident of the state of Hawaii and as noted above, I do not support bill HB 2564 (and SB 2575).

Best regards,
Carol J Boushey
145 Waokanaka Place
Honolulu, HI 96817
cjboushey@live.com

LATE

February 6, 2020

House Committee on Lower and Higher Education Hearing on House Bill 2564

February 7, 2020, 2:00 pm, Conference Room 309

I am not an employee of the University of Hawaii Cancer Center, however I am aware of the efforts of the Cancer Center. The consideration of HB 2564 the House Committee on Lower and Higher Education on Friday, February 7th is of concern to me as I think it would have a significant negative impact on the Cancer Center.

The following are applications of the flawed logic contained in this bill. Hopefully, the lack of wisdom and flawed logic of these suggestions does not escape the members of this committee, and that same skepticism is be applied to the consideration of this bill.

The University of Hawaii School of Architecture and Department of Urban and Regional Planning are adjacent to the University of Hawaii Schidler Business College. The main entities involved in process of planning, designing and constructing buildings are businesses. Therefore, the School of Architecture and Department of Urban and Regional Planning should be part of the Schidler Business College.

"Placing resources devoted to training and educating of urban planners, architects and construction managers conducting building-related research in an integrated university organizational structure as opposed to stand-alone and "duplicative" organizations will foster a unified strategic vision. "Unified" leadership will allow better coordination with Hawaii's private construction-related developers and businesses in the construction community and with other state agencies." (This paragraph was written in the same spirit as HB 2564, based on lines 19-21 from page 2 and lines 1-4 from page 3)

Along with urban planners, architects and construction managers, medical device engineering firms, biotech and pharmaceutical research firms, hospitals and health insurance providers that are all involved in the health arena are also businesses. Perhaps any University of Hawaii academic programs that deal with those areas of inquiry should also be transferred to the University of Hawaii Schidler Business College.

If the logic of these suggestions that comes directly from HB 2564 leaves one scratching one's head, perhaps it is because the underlying assumptions of HB 2564 are ill-conceived.



James Donahue

Resident of the State of Hawaii



UNIVERSITY OF HAWAII
CANCER CENTER

LATE

HAWAII TUMOR REGISTRY
701 ILALO ST, 4TH FLR, HONOLULU, HI 96813

To: To Whom It May Concern
Fax: (808) 586-6381

From: Brenda Y. Hernandez, PhD
Fax: (808) 587-0024
Phone: (808) 586-9750

Re: Testimony regarding HB 2564

Number of page(s): 2 including cover

Warning: This message is intended only for the use of the individual or entity to which it is addressed and contains information that is protected by State statute and is confidential or privileged. If the reader of this message is not the intended recipient, or the employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly forbidden by law. If you have received this communication in error, please notify us immediately by telephone and return the original to us at the above address via the US Postal Service. Thank you for your kokua.

I am writing in opposition to HB2564, which would place the UH Cancer Center within the John A. Burns School of Medicine. I serve as an Associate Professor of the UH Cancer Center and Principal Investigator of the Hawai'i Tumor Registry (HTR). The HTR is responsible for public health surveillance of all cancers diagnosed in the state of Hawai'i. The HTR has successfully operated under the University of Hawai'i Cancer Center since 1973 when it became a funded registry of the National Cancer Institute Surveillance, Epidemiology and End Results (SEER) Program. As one of eighteen SEER registries nationwide, the HTR serves as a critical resource for cancer research and cancer control activities in Hawai'i and the U.S. The HTR's operations are closely aligned to the current mission of UH Cancer Center, which is to reduce the burden of cancer through research, education, patient care and community outreach. The HTR has greatly benefited from operating within a self-standing Cancer Center and has consistently received national and international recognition for its excellent performance. Dr. Randall Holcombe has provided tremendous support to the HTR and has demonstrated visionary leadership for the UH Cancer Center.

Mahalo,

Brenda Y. Hernandez, MPH, PhD

The House Committee on Lower and Higher Education & Committee

February 7, 2020 (2pm)

LATE

Individual Testimony **AGAINST HB 2564**

Re-organization of the University of Hawaii Cancer Center
within the UH John A Burns School of Medicine

Dear Chairs Woodson and Mizuno, Vice Chairs Hashem, Quinlan, and Kobayashi, and Members of the Committees:

I herein submit my individual testimony **AGAINST** the bill **HB 2564 (and SB 2575)** to reorganize the UH Cancer Center within the UH JABSOM Medical School.

The faculty of the UH Cancer Center, are working tirelessly to help the people of Hawaii. Our goals are to reduce the burden of cancer on the people in the state by improving cancer prevention, diagnosis, treatment, and education. The current organization with our Director reporting to the Provost and having flexibility to control space, faculty hires, and budget is essential to preserve our National Cancer Center Designation. The NCI designation is critical for researchers like us to maximize the possibility to secure research funding. The NCI designation is also very important to attract and keep high caliber faculty colleagues to maintain our research competitiveness. Our current director, Dr. Randall Holcombe MD, MBA, is clearly an excellent Director with outstanding leadership abilities and achievements.

For the reasons above, I am strongly **AGAINST HB2564 (and SB 2575)**.

Thank you,

Lang Wu, PhD
Assistant Professor
UH Cancer Center

LATE

Fax: 808-586-6381

Date: 02-06-2020



This is Peiwen Fei, a Professor and basic cancer Researcher at the University of Hawaii Cancer Center, and I have worked here since 2011. I am opposed to Bill HB2564.

The University of Hawaii Cancer Center is one of 71 NCI designated cancer centers in the U.S. Given the small size of our center, this is a big achievement and one that UH and Hawaii can be proud of. The NCI requires that the Cancer Center director have strong authority over the decisions made at the Center, including on budgets, space and faculty/staffing. Therefore, Bill HB2564 that would reduce the authority of the UHCC director would severely hurt our competitiveness and threaten our NCI designation.

Aloha Chairs Woodson and Mizuno, Vice Chairs Hashem, Quinlan, and Kobayashi, and Members of the Committees:

I herein submit my individual testimony **AGAINST** the bill **HB 2564 (and SB 2575)** to reorganize the UH Cancer Center within the UH JABSOM Medical School.

My name is Claire Hughes. I am a member of the UH Cancer Center's Native Hawaiian Community Advisory Board. Like you, I have worked, for my entire professional and retirement life to improve health for all citizens of Hawai'i, not just for Native Hawaiians. While the intent of bill **HB 2564 (and SB 2575)** may be to help the UH Cancer Center and Hawai'i's people, I am testifying against Bill HB 2564. I believe, strongly, **HB 2564 (and SB 2575)** would not benefit our efforts to decrease the cancer burden within Hawai'i's citizens and communities, for the following reasons:

- Under the leadership of Dr. Randall Holcombe, our new director, the Cancer Center has made much progress in strengthening the Center's research programs and improving the Center's relationships with communities. And, for the first time, under Dr. Holcombe's leadership, the Native Hawaiian community has a voice in the content and direction of research conducted at the Center. The Native Hawaiian Advisory Board recently reviewed an organoid research proposal to be conducted in the soon-to-be renovated annex.

- The proposed changes in **HB 2564 (and SB 2575)** will jeopardize future renewal of the NCI-designation (P30 grant), as it would require demotion of the director. The level of authority of the director's is an important criterion for evaluation the Center's NCI-designation (P30 grant). The NH Advisory Board of the UH Cancer Center was invited to attend the recent UHCC External Advisory Committee meeting. We learned that the reason the NCI originally renewed the Cancer Center grant for 3 instead of 5 years, was due to multiple changes in the Center's leadership. Currently, because of significant progress made during the last 3 years, the NCI awarded the Center a fourth year on its funding grant and, will provide a fifth year, if this progress is sustained. The extension and the subsequent grant renewal is because of Dr. Holcombe's leadership, the outstanding faculty, and the autonomy of the UH Cancer Center.

- Since arriving, three years ago, Dr. Holcombe has turned the Center around, addressing its deficit and, successfully building community engagement initiatives that benefit Hawai'i, significantly. The Cancer Center, will work closely with Hawai'i hospitals to make new cancer treatments available to Hawai'i patients, transforming and improving cancer care in Hawai'i. In my opinion, based on many years working with the UH Cancer Center, Dr. Holcombe has brought in new energy and ideas and, has proven to be the ideal person to initiate innovation and build clinical research in cancer.

In my 30+ years of collaborating with the UH Cancer Center, I see the Center poised to realize-greater potential for the people of Hawai'i. I urge you to not change the administrative reporting of the UH Cancer Center. As any change would greatly jeopardize the progress made in the past 3 years. Mahalo.

HB-2564

Submitted on: 2/6/2020 8:03:34 PM

Testimony for LHE on 2/7/2020 2:00:00 PM



Submitted By	Organization	Testifier Position	Present at Hearing
Gertraud Maskarinec	Individual	Oppose	No

Comments:

Dear Members of this Committee,

As a Professor of Epidemiology at the Cancer Center for the last 25 years, my experience has convinced me that the independent status of the Cancer Center and its Director are crucial to its success. As the mission of JABSOM and the Cancer Center are very different, it takes a dedicated leader like Dr. Holcombe with a strong background in oncology to move the research into the right direction. Although I greatly appreciate collaborations with faculty members at JABSOM, the specialized goals of the Cancer Center with a focus on extramural research projects and training of future investigators require the leadership of a dedicated individual who is capable of recognizing new developments in oncology and to initiate activities to bring these innovations to Hawaii. Therefore, this person needs full authority to appoint faculty members and to control the center's resources.

Sincerely,

Gertraud Maskarinec, MD, PhD

Professor and Associate Director of Research Education