Ho'ola Early Phase Clinical Research Center Strategic Plan

	MARCH 2021					JANUARY 2024 (CONSERVATIVE)								JANUARY 2024 (OPTIMISTIC)																				
Operations	Year 1 (F	Y23)	Year 2 (F	Y24)	Year 3	(FY25)	Year 4	I (FY26)	Year	5 (FY27)	5-yea	r Net	Year	1 (FY26)	Yea	ar 2 (FY27)	Yea	ar 3 (FY28)	Year	4 (FY29)	Year	r 5 (FY30)	5-	year Net	Year 1 (Y26)	Year 2 (FY27)	Ye	ear 3 (FY28)	Yea	r 4 (FY29)	Year	5 (FY30)	5-year Net
Patient Enrollment [1]		20		40		75		100		100		335		20		30		45		68		101		264		30	40		55		78		111	314
Av. Reimbursement/patient [2]	\$ 20	,000 ;	\$ 20),000 \$	\$2	20,000	\$	20,000	\$	20,000			\$	30,000	\$	31,500	\$	33,075	\$	34,279	\$	36,465			\$ 4	0,000	\$ 42,000	\$	44,100	\$	46,305	\$	48,620	
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RTRF (Indirect costs) [4]	-	ŝ	\$ 60),000 \$	5 12	20,000	\$2	225,000	\$	300,000	\$ 7	05,000	-		\$	90,000	\$	141,750	\$	223,256	\$	351,629	\$	806,635	-		\$ 120,000	\$	252,000	\$	496,125	\$	694,575	\$ 1,562,700
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UHCC encumbered funds [7]	\$ 2,500	,000 -	-	-			-		-		\$ 2,5	00,000	\$ 2,	,500,000	\$	100,000	\$	100,000	\$	100,000	\$	100,000	\$	2,900,000	\$ 2,50),000	\$ 250,000	\$	250,000	\$	250,000	\$	250,000	\$ 3,500,000
HCC [8]	\$ 500	,000	\$ 500),000 \$	5 50	00,000	\$ 5	500,000	\$	500,000	\$ 2,5	00,000	\$	500,000	\$	500,000	\$	500,000	\$	500,000	\$	500,000	\$	2,500,000	\$ 50	0,000	\$ 500,000	\$	500,000	\$	500,000	\$	500,000	\$ 2,500,000
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Clinical testing pass-through	-		-	-			-		-		-		-		-		-		-		-		-		-		-	-		-		-	-	
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Revenue Subtotal	\$ 5,129	,000	\$ 1,979	9,600 \$	\$ 2,76	50,100	\$ 3,4	43,225	\$3	,615,881	\$ 16,9	27,806	\$5,	,453,800	\$	3,951,900	\$!	5,130,900	\$7,	,014,038	\$ 9	,920,729	\$3	81,471,367	\$ 7,26	L ,500	\$ 5,439,850	\$	8,056,100	\$ 1	0,963,488	\$ 13,	402,234	\$ 45,123,171
Expenditures																																		
Personnel (Clinician) [10]	\$ (1,115	,200) 💲	\$ (1,137	7,504) \$	\$ (1,16	50,254)	\$ (1,1	L83,459)	\$ (1	,207,128)	\$ (5,8	803,546)	\$ ((909,493)	\$	(909,967)	\$	(936,965)	\$ ((800,161)	\$	(852,169)	\$	(4,408,755)	\$ (92	9,493)	\$ (904,967	\$	(931,965)	\$	(885,564)	\$ (940,842)	\$ (4,592,831
Personnel (non-physician) [11]	\$ (903	,560) 💲	\$ (903	3,560) \$	\$ (1,35	55,475)	\$ (1,8	807,300)	\$ (1	,807,300)	\$ (6,7	77,375)	\$ (2,	,002,885)	\$ ((3,256,038)	\$ (3,517,524)	\$ (3,	,805,288)	\$ (4	1,215,881)	\$ (1	16,797,615)	\$ (1,12	5,714)	\$ (2,545,067	\$	(2,630,227)	\$ (2,916,551)	\$ (3,	343,060)	\$ (12,561,620
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Revenue Less Expenses	\$ 1,590	,150 🔅	\$ (671	L,554) \$	\$ (35	55,629)	\$ ((72,534)	\$	151,453	\$ 6	41,886	\$	194,043	\$	(824,105)	\$	76,411	\$ 1,	,858,589	\$4	,302,680	\$	6,434,997	\$ 3,75	,844	\$ 1,609,794	\$	4,292,174	\$	7,003,398	\$8,	951,806	\$ 24,138,721
Running Cash Balance	\$ 1,590	,150 \$	\$ 918	3,596 \$	\$ 56	52,967	\$4	90,433	\$	641,886	\$6	41,886	\$	194,043	\$	(630,062)	\$	(553,651)	\$ 1,	,304,938	\$ 5	607,618			\$ 3,75	,844	\$ 5,364,638	\$	9,656,812	\$ 1	6,660,210	\$25,	612,016	

2021 Assumptions/Comments:

[1] Patent enrollment target of 100 as described in text. Ramp up over 3 years anticipated.

[2] Average reimbursement per patient as described in text. Clinical care reimbursement for imaging and laboratory testing to be billed directly by clinical partners, and not included in budget.

[3] Pharmaceutical industry contract revenue based on anticipated enrollment and average

reimbursement. Pass-through and indirect costs are excluded.

[4] RTRF represents indirect cost funding generated to UH Mānoa ad returned to unit (UHCC). Return based on UH policy estimated at 15% of direct costs, with recovery in following fiscal year. See also explanation in text, below.

[5] Fundraising for this project through philanthropy has exceeded expectations and has led to revised projections. Based on the rate and size of philanthropic commitments over the past 3-4 months, substantial expendable funds should be available for year 1. Subsequent annual

philanthropic support support conservatively estimated.

[6] Based on current endowments, already in place, with 4% annual return on investment. If additional endowments are obtained, additional annual funding will be available for

programmatic support.

[7] Funds currently avaiable at UHCC and encumbered for this initiative.

[8] See explanation in text.

[9] See explanation in text. Represents support for director and clinician investigator from other

grants, including the cancer center support grant (p. 30).

[10] Clinician personnel includes Director (MD), clinician investigator (MD) and pharmacy

director (PharmD). Expenditures include anticipated slary plus UH fringe, calculated at 64%.

Annual cost of living adjustments included.

Office of the Vice President for Research and Innovation

UH Cancer Center Update

Early Phase Clinical Research Center (EPCRC) Business Plan Report

BOR Committee on Research and Innovation February 3, 2022



Background

At the request of Regent Wayne Higaki, the UH Office of the Vice President for Research and Innovation assembled a task force to provide an assessment of the challenges and opportunities facing the UH Cancer Center's new \$13 million Early Phase Clinical Research Center (EPCRC).

UH Cancer Center Task Force Members

- Larry J. Shapiro, MD; CEO, University Health Partners of Hawai'i (Chair)
- ► G. Rick Bruno, MD; VP Patient Care, Queen's Health Systems
- ► Les Chun, MD; CEO, Hawai'i Pacific Health Medical Group
- Aimee Malia Grace, MD, MPH; Director, UH Office of Strategic Health Initiatives

With assistance from:

- ▶ Joe W. Ramos, PhD; Deputy Director, UH Cancer Center
- Clifford C. Martin, MBA, Assoc. Director for Administration, UH Cancer Center

Report Summary

- The EPCRC Task Force determined that there are a number of challenges that UH faces in the operation of the facility under the current business plan, including:
 - Insufficient patient enrollment targets
 - Growth from 20 research subjects in year one to 100 by year five, is quite ambitious for a Phase 1-only program
 - Attainment of 100 enrolled patients goal at year five = average of two patients per day

Report Summary (cont.)

- > Over reliance on philanthropic support
 - EPCRC has secured multi-year financial support for the Hawai'i Cancer Consortium
 - Funding based on heavy reliance of philanthropic support. Economic uncertainties may render current projected levels of giving to be too optimistic
- Operations/logistics needs to be run like a small clinic or outpatient treatment center, rather than a stand-alone sponsored research program
 - Recruiting and funding of treatment personnel, facilities operations, patient recruitment, integration of clinical trials with on-going care and the assumption of fiscal and legal risk may not be sustainable under the current business plan

Report Summary (cont.)

- The EPCRC may not be eligible for clinical trials requiring radiation therapy, cell-based therapies and advanced imaging technologies as they are not currently available at UH Cancer Center.
 - Until such time when the EPCRC is equipped with such costly, but necessary technology, it will have to secure collaborations with an external provider
- Existing competition from local health systems with ties to MD Anderson Cancer Center, Seattle Cancer Care Alliance, etc.
 - These existing associations with well-established and well-equipped cancer center will have an impact on securing grants and contracts, as well as patient flow to the EPCRC

Opportunities

- Expansion of scope to include Phase II, Phase III and other non-cancer clinical trails to increase patient numbers and revenue in order to ensure sustainability. Additional costs and operational complexities should be offset by a corresponding increase in revenue. Dep. Dir. Joe Ramos is working with Queen's and HPH officials to assemble a task force to strengthen the business plan
- Augmentation to a Long-Term Survivor Cohort to provide value-added service to patients, including well-being interventions, functionality assessments and cancer recurrence studies that would complement and not compete with local healthcare systems
- Establishment of an academic division of oncology at JABSOM to help build needed expertise and to fill shortages in specialized areas of cancer care and science to benefit the state.
- Creation of new enterprises and other future growth due to UH Cancer Center's reputation as a center of excellence for cancer care, ex. further leveraging of data from the highly regarded Multi Ethic Cohort Study to become a potential revenue stream



Review of Ho'ōla EPCRC Proposal

Written and prepared by J. Freidenberg



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1. Overview

Ho'ōla EPCRC seeks to address a significant deficiency in cancer care in the state of Hawai'i. Currently, residents of Hawai'i must travel to the mainland in order to participate in an early phase clinical trial. This is impractical for virtually all state residents.

A high level estimate is that 500 Hawai'ians per year are appropriate candidates for an early phase trial. In addition to benefitting cancer patients in Hawai'i, Ho'ōla has the potential to significantly diversify the demographics for early phase clinical trials nationally which in turn will benefit ALL cancer patients.

This engagement asks for an assessment of the budget expenses, volume projections and trial revenue contained in the Ho'ola EPCRC proposal.

The current proposal, including the budget, volume and revenue projections is a good starting point for the plan to launch a new trial clinic. Having said that, to provide feedback that is actionable, it is necessary to make assumptions (recommendations) regarding the strategic positioning of the EPCRC.

The proposal correctly identifies the demographics of the patient population as a significant advantage and rationale for this trial clinic. Trial sponsors will be motivated to bring trials to Ho'ōla in order to access the patient population in Hawai'i. This is particularly true of certain cancers (e.g., breast, liver, nasopharyngeal, pancreatic and stomach cancers) which have disproportionate impact on Asian/Pacific Islanders and particular cancer genomic variants (e.g., EGFR exon 20 insertions). The center can also help address the aggregation of clinical trial data across Asian American, Native Hawai'ians and Pacific Islanders (AANHPI) which can mask important differences across specific AANHPI populations. Patient safety, regulatory compliance and data collection and reporting are required for every successful trial clinic and assumed. Even with all of that, to fully realize the benefit of this opportunity, the trial clinic must also demonstrate an ability to open trials quickly as well as an ability to actually enroll patients in those trials.

The budget recommendations in this assessment assume a commitment to build a clinic that consistently delivers the performance required to annually attract the most scientifically compelling trials.

We see this as a next iteration rather than a divergence from the current proposal.

2. MD Engagement

The active engagement of the referring oncologists (those oncologists who refer patients to participate in clinical trials) is the single most important factor in determining the success of Ho'ōla. Alignment of referral incentives is important to program success. We propose an alternative leadership structure in order to maximize physician engagement and align referral incentives. We believe there is benefit to asking physician leaders to focus on those responsibilities for which they are uniquely qualified. Conversely, there is benefit to tasking administrative leaders with non-clinical responsibilities (revenue cycle, HR, IT, facilities, fundraising, PR, etc.).

It is likely to be very challenging, expensive and time consuming to recruit a full-time oncologist with early phase trial experience (and other experience and aptitude you need) who will relocate to launch a startup clinic under the timeframe proposed.

Therefore, we are recommending that the EPCRC hire a non-MD healthcare executive leader to serve as the CEO. Then utilize existing local oncologists to provide the medical leadership required. This alternative structure engages more local physicians into the success of the clinical trials program and increases the chances the referring physicians will refer eligible patients, provide clinical support to clinical trial patients and foster relationships with industry to grow the program.

We recommend identifying one physician champion at each of the four groups (Queens, HCC, HCH and Kaiser). One of the four would be designated as the CMO and paid by Ho'ōla for 2 days per week. The other 3 would have titles denoting their leadership positions and paid for 1 day per week. All 4 would continue to see patients in their respective clinics.

In the event one or more of the groups is unable to identify an existing oncologist willing to serve in leadership, Ho'ōla and that group can collaborate on a recruitment. A new recruit always takes time to build their panel. By providing monetary support for a new oncologist, the clinic makes the recruitment package more attractive (as does the opportunity to participate in scientifically compelling research), While building their panel, the new physician can help identify eligible patients for clinical trial and can support clinical trial patient care.

In addition to compensation for their administrative and trial clinic time, we recommend additional compensation for each trial for which they serve as the PI.

The job description for the CMO position includes:

- Serving as the dyad partner with the CEO;
- Convening the 4 physician leaders;
- Serving on point for all communication with internal and external physicians;
- Overseeing clinical policies and procedures;
- Supporting the fundraising efforts of the CEO;
- Serving as the PI on some number of trials;
- Weekly office hours in the clinic;
- Represent EPCRC at Research Meetings;
- Meet with trial sponsors; and,
- Participate in Tumor Board.

The job description of the other 3 physician leaders includes:

- Supporting the efforts of the CMO;
- Actively participating in the meetings convened by the CMO;
- Serving on point for communication with MD's in their group;
- Serving as PI on some number of trials;
- Weekly office hours in the clinic; and,
- Participate in Tumor Board.

Another recommendation to enhance physician engagement is to compensate RN's who work in the offices of the referring oncologists for their time. We recommend paying one RN in each of the 4 groups for 4 hours per week. Their responsibilities will include:

- Serve as a Ho'ola champion;
- Assist oncologists with identification, advising, assisting, and enrolling patients in trials; and,
- Serve as a liaison between Ho'ola and the other clinical RN's in the group.

3. Clinical Sequencing

In order to attract biomarker based trials, it is necessary for Ho'ōla to build a database of patients who have had sequencing performed by one of the accredited national labs (Caris, Foundation Medicine, Tempus, etc.). Ideally, all four groups would agree on a preferred lab. In addition to improving the efficiency of the process, one provider will also position Ho'ōla to negotiate a preferred contract with the selected lab. The benefits may include significantly better rates for patients (especially low income patients), obtaining digital results rather than written reports and financial support for Ho'ōla for staff engaged in the sequencing effort (I.e., staff to assist the 4 groups, mine the database and coordinate patient enrollment).

The groups should be encouraged to order sequencing on every patient (patients can of course decline).

This effort should begin immediately. This should not wait until the clinic opens. The sooner there is a functioning database with a critical mass of patients, the sooner trial sponsors will be interested in Ho'ōla.

The development and utilization of the database should be overseen by an IT professional. Expecting busy oncologists to spend time searching the database is unrealistic.

4. Medical Tourism

Ho'ōla has the potential to attract patients from outside the state. While this includes citizens of countries in East Asia, there are more potential patients (not more total population) on the mainland seeking access to promising investigational products in early phase clinical trials.

Success in attracting these patients will boost the number of trials and enrolled patients. Once the clinic is up and running, there are several steps needed to support this effort. In addition to hiring a concierge/navigator to oversee the program, Ho'ōla will need to partner with a company that assists cancer patients who are actively seeking to travel in order to be able to participate in an early phase trial.

5. Fundraising

This engagement does not include as assessment of fundraising targets. However, we believe a successful early phase trial clinic in Hawai'i has the potential to raise significant philanthropy. A program that regularly enrolls patients from out of state (and out of the country) will greatly enhance the fundraising success.

6. Miscellaneous

The plan contemplates utilizing existing regulatory staff. While the existing staff may be well positioned to provide some level of regulatory support, we recommend recruiting a regulatory professional with specific experience with early phase clinical trials and regulations governing compassionate use. There are hundreds of regulations governing early phase trials that do not apply to phase 3 and 4 trials. Having someone with experience with early phase regulatory requirements will enhance the opportunity for success.

7. Summary

The attached budget (revised to reflect our recommendations), has just under \$200K in increased labor costs in year 1. This is partially offset by a projection in financial support from the preferred sequencing lab.

The most significant proposed change to the expenditures is that instead of allocating funding to a fulltime, newly recruited MD, we have more dollars going to oncologists currently working in the community.

We have also revised the revenue projections. Our assessment is that revenue for startup fees and patient enrollment should be higher and have made changes to the budget accordingly. Additionally, we have made changes to the Grants Contracts Worksheet (lines 5 and 6) to reflect ongoing administrative costs related to the annual IRB review, pharmacy fees, study closure fees, etc.

EPCRC assumptions include a relatively hard start date for the program and a scaling of the number of clinical trials and patients on study. This creates financial challenges for the program. In the conservative summary, the program runs in the red during year 2 and year 3 to a total of approximately \$630k. This can be bridged by activating the program in 2024 in advance of the clinic being opened. This will allow for clinical trial opportunities to be identified and the activation process to be started so that the program launches with a handful of protocols and associated revenue streams.

We believe the volume and revenue projections are realistic provided that Ho'ōla is able to 1. Secure the support of referring oncologists, 2. Quickly build a robust database of sequenced patients and 3. Open trials and enroll patients expeditiously. We also believe that all three of these requirements are doable.

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SEQ #	EXPI	LANATION		FY 2024			FY 2025		
			Perm	Temp	Amt	Perm	Temp	Amt	
101-001	SUPPLEMENTAL REQUEST: ADD FUNDS FOR UNIVERSITY (UOH210/MM).	OF HAWAII, HILO						400,000	A
	DETAIL OF GOVERNOR'S REQU TEAM TRAVEL EXPENSES (FY2:	EST:	*****						
102-001	SUPPLEMENTAL REQUEST: ADD POSITIONS AND FUNDS FO HILO (UOH210/MM).)R UNIVERSITY OF HAWA	AII,			3.00		210,000	A

TOTAL BUDGET CHANGES

4.00

4.00

4,007,627 A

-								
BUDGET TOTALS	522.25	7.00	47,428,371	А	526.25	7.00	49,690,749	А
	64.00	0.00	47,227,520	В	64.00	0.00	47,227,520	В
	0.00	0.00	443,962	Ν	0.00	0.00	443,962	Ν
	2.00	0.00	7,474,443	W	2.00	0.00	7,488,856	W

		Monday, M	ay 15, 2023	3:36 pm		LEGISLA BUDGET CO	TIVE BUDGE MPARISON V					Page 1013 o	f 1070
Program II Structure # Subject Co	t: 070302	10 2000000 HET		TY OF HAWA DUCATION &	II, HILO TECHNOLOGY	7							
			HR3	00 CD1						HR3	00 GM		
		FY24	1105	00 CD1	FY25				FY24	1105		FY25	
SEQ #	Perm	Temp	Amt 400,000	Perm	Temp	Amt	A	Perm	Temp	Amt 400,000	Perm	Temp	Amt 400,000 A
EX		OR UNIVERSIT	400,000 Y OF HAWAII, HI	, ,		*****	A		OR UNIVERSI	TY OF HAWAII,		/	
BF	REAKOUT AS	DOES NOT CO FOLLOWS: . (FY24: 400,000						DETAIL OF GC TEAM TRAVE		EQUEST:			
103-001							А			1,700,000			1,700,000 A
AI ***	**********	OR UNIVERSIT	Y OF HAWAII, HII ***********************************			****			OR UNIVERSI			/	****
		VERNOR'S REG ISE PROGRAM											
104-001							А	8.00		198,000	8.00		198,000 A
AI *** LE DF (2) EA (1) (2) 1.0 (1)	EGISLATURE ETAIL OF GO) PERM ASSIS (CH)) PERM ASSIS) PERM INSTI)0 EACH)) PERM ACAI	S AND FUNDS DOES NOT CO VERNOR'S REG STANT PROFES TUTIONAL/AC DEMIC SUPPOF		**************** , #94601F; 1.00 ; 1.00) RT PBB-01 (#9 7F; 1.00)) EACH; 99,000	****		**************** DETAIL OF GC (2) PERM ASSI EACH) (1) PERM ASSI (2) PERM INST 1.00 EACH) (1) PERM ACA	NS AND FUNE ***************** OVERNOR'S R STANT PROFI STANT PROFI ITUTIONAL/A DEMIC SUPPO	DS FOR UNIVERS ***************** EQUEST: ESSOR I-3 (#9460 ACADEMIC SUPP DRT PBA-01 (#946 #94603F, #94604F	**************************************	.00 EACH; 99,0	**********

		Thursday,	May 19, 2022	11:58 ar			TIVE BUDGET MPARISON W					Page 809 o	f 832
Program ID Structure #: Subject Cor	07030	210 2000000 HET		SITY OF HAV	VAII, HILO I & TECHNOL	OGY							
			HB160	0 CD1						HB160	00 GM		
		2022		~	2023			-	2022	. .		2023	
SEQ # 31-001	Perm	Тетр	Amt	Perm 1.00	Temp	Amt 155,040	•	Perm	Тетр	Amt	Perm 1.00	Temp	Amt 155,040 A
TRA SYS (UOI ***** LEG DET (1) P	NSFER-IN TEMWIDE H210/BF). HSLATURI AIL OF GO PERM DIRI	E SUPPORT (L **************** E CONCURS. OVERNOR'S	ND FUNDS FRO IOH900/JC) TO U REQUEST: JNAKEA STEW	JNIVERSITY	′ OF HAWAII,	HILO ******		DETAIL OF G	N POSITION A E SUPPORT (SOVERNOR'S RECTOR - MA	AND FUNDS F UOH900/JC) T ******************** S REQUEST: AUNAKEA STI	O UNIVERSI	TY OF HAWA	AII, HILO ******
100-001						2,280,000	A						2,280,000 A
ADD	FUNDS F		E SITY OF HAWAI			*****		SUPPLEMENT ADD FUNDS I	FOR UNIVER	RSITY OF HAW	WAII, HILO(U	OH210/MM).	*****
LEG	ISLATUR	E CONCURS.						DETAIL OF G OTHER PERS			00)		
		OVERNOR'S ONAL SERVI	REQUEST: CES(2,280,000)										
101-001						800,000	A						400,000 A
ADD	FUNDS F	AL REQUES	E SITY OF HAWA	II, HILO(UOI	H210/BF).	*****		SUPPLEMENT	FOR UNIVER	RSITY OF HAW	VAII, HILO(U	OH210/BF).	*****
LEG	ISLATURI	E DOES NOT	CONCUR.					DETAIL OF G TRAVEL(400.		S REQUEST:			
	AKOUT A	S FOLLOWS: 00,000)							,				
\$400),000 NON-	RECURRING	ł.										