

## **STRONGER** by DEGREES



## **MEETING AGENDA**

### **Lung Cancer Research Governance Board**

Wednesday, August 31, 2016  
Conference Room A

The Council on Postsecondary Education is Kentucky's statewide postsecondary and adult education coordinating agency charged with leading the reform efforts envisioned by state policy leaders in the *Kentucky Postsecondary Education Improvement Act of 1997*. The Council does not discriminate on the basis of race, color, national origin, sex, religion, age, or disability in employment or the provision of services, and provides, upon request, reasonable accommodation, including auxiliary aids and services necessary to afford individuals with disabilities an equal opportunity to participate in all programs and activities.

Kentucky Council on Postsecondary Education, 1024 Capital Center Drive, Suite 320, Frankfort KY 40601, Ph: (502) 573-1555, Fax: (502) 573-1535,  
<http://cpe.ky.gov>

Twitter: <https://twitter.com/cpenews>

Printed with state funds

Facebook: <https://www.facebook.com/KYCPE>

**AGENDA**  
Kentucky Lung Cancer Research Program  
Governance Board

Council on Postsecondary Education  
Wednesday, August 31, 2016  
2:00 PM  
Conference Room A

---

- |  |    |
|--|----|
| 1. Welcome and Call of Roll                    |    |
| 2. ACTION - Approval of Minutes, June 8, 2016  | 3  |
| 3. Cash Activity Report and End of Year Report | 6  |
| 4. ACTION - Annual Report to the Governor      | 8  |
| 5. UK/UofL Lung Cancer Symposium - Update      |    |
| a. ACTION - Adopt Name for Symposium Award     | 31 |
| b. Budget Update                               | 32 |
| c. KLCRP Symposium Draft Agenda                | 33 |
| 6. KLRCP Brochure                              | 34 |
| 7. Suggestions for Board Appointments          |    |
| 8. Review of KLCRP Timeline                    | 36 |
| 9. Other Business                              |    |
| 10. Adjourn                                    |    |
| <b>Next Meeting Date - November 9, 2016</b>    |    |

# Kentucky Lung Cancer Research Program Governance Board

June 8, 2016  
Meeting Minutes

---

The Kentucky Lung Cancer Research Program Governance Board met Wednesday, June 8, 2016, at 2:00 p.m., ET, at the Council on Postsecondary Education, Conference Room A, Frankfort, Kentucky. Chair James Roach presided.

## **WELCOME AND ROLL CALL**

The meeting of the KLCRP Governance Board was called to order by the Chairman, Dr. James Roach. Roll Call was taken and the following members were present: James Roach, (MAL and Chair), Jason Cheney (UofL), Dan Flanagan (CPE), Amtullah Khan (MAL – videoconference), Don Miller (UofL) and Tim Mullett (UK). Rajan Joshi (MAL) was absent.

Others present were: Kris Damron (UK), Dianne Konzen (UofL), Milton Pierson (UofL), Nathan Vanderford (UK), Rebecca Bowman (CPE), Travis Powell (CPE), and Debbie Weakly (CPE staff to KLCRP). Also in attendance was Derrick Campbell with McCarthy Strategic Solutions.

## **APPROVAL OF MINUTES**

Chair Roach called for a motion to approve the minutes of the February 17, 2016 meeting. A motion was made by Don Miller and seconded by Jason Chesney. The minutes were approved.

## **CASH ACTIVITY REPORT**

Rebecca Bowman referred to the Cash Activity Report. She stated that invoices were being received for payment due by the end of the fiscal year. The invoice for the audit, approximately \$7,500, has not been received. The audit report should be ready soon. She also stated that UK has some grant money they can carry forward into the new fiscal year and the interest earnings are currently at \$31,000.

Don Miller inquired about the ovarian screening funds and Travis Powell responded there is no decrease in the funding for the next biennium.

## **AMENDED MARKEY KLCRP CYCLE 15 GRANT REQUEST**

Chair Roach referred to the request from UK for an increase in one of their Cycle 15 grants. Nathan Vanderford made some brief comments on how the budget was written versus the approved request. They are requesting an increase from \$75,000 to \$150,000 over the next 2 years.

Chair Roach called for a motion to approve the grant request. A motion was made by Don Miller and seconded by Jason Chesney. The motion was approved.

### **2016-18 BUDGET ALLOCATIONS**

Chair Roach asked UK to present their budget allocation. Nathan Vanderford made brief comments on each of the projects and indicated he would provide more detail on the request in the future if the Board preferred. Chair Roach called for a motion to approve the 2016-18 budget allocation for UK. A motion was made by Jason Chesney and seconded by Don Miller. The motion was approved.

Chair Roach asked UofL to present their budget allocation. Milton Pierson made brief comments. Chair Roach called for a motion to approve. A motion was made by Tim Mullet and seconded by Don Miller. The motion was approved.

### **SYMPOSIUM UPDATE**

Nathan Vanderford stated that the date for the UK/UofL Lung Cancer Symposium will be October 15, 2016 at the WT Young Library on the UK campus. The keynote speaker will be Dr. John Minna. They hope he will be able to arrive on Friday to have dinner with Board members. Travel plans are still under discussion.

### Award Recipients

Nathan indicated there had been discussion about the awards to be presented to legislators who were key in creating the lung cancer research program. It was suggested that the main award be given to Tim Shaughnessy who was a champion in creating the program with possibly other awards given to Robert Stivers and Rocky Adkins. Tim Mullet also suggested Harry Carloss. Tim also stated that the intent of the award was to provide recognition to someone who has made a difference in the program. Milton Pierson suggested calling the award the Bonnie Sigafus Achievement Award as a memorial to her and recognizing her efforts in promoting the program. Travis stated that it seemed everyone was in agreement to present the award to Tim Shaughnessy and decision on what to call the award could be made at the next meeting.

Chair Roach called for a motion to establish the award. A motion was made by Don Miller and seconded by Tim Mullet. The motion was approved.

Chair Roach called for a motion to present the inaugural award to Tim Shaughnessy. A motion was made by Tim Mullet and seconded by Jason Chesney. The motion was approved.

### Funding

Rebecca indicated there would be approximately \$22,000 available in interest earnings to use as funding for the symposium. Nathan indicated the largest expense would be the speaker fee which would typically be between \$1,500-2,000. There would also be travel expenses for the speaker. With other costs, Nathan projected the symposium expenses

would not exceed \$5,000 and he would develop a budget for the next meeting. Milton indicated this amount was too low and requested to set aside up to \$10,000 for the expenses. Travis reminded Board members that if the symposium were to be an annual event, the interest earnings do not grow at a rapid rate; therefore, the Board would have to seek other funding. He stated that the contract may need to be amended to use these funds and provide for an invoice to be submitted for payment. Chair Roach asked Nathan to proceed with developing the budget and sending to Board members.

Chair Roach called for a motion to allocate up to \$10,000 of interest earnings to be used for the October 15<sup>th</sup> Lung Cancer Symposium at the UK WT Young Library. A motion was made by Tim Mullet and seconded by Don Miller. The motion was approved.

### **STRATEGIC PLAN REVISIONS**

Travis stated that it was required by statute to review the Strategic Plan every two years. A copy of the plan that was revised in 2014 was provided in the meeting materials. He also indicated that the Board was not required to make any changes, but if there were any to be made during the two year interim, they could be made and voted upon at that time. Both UK and UofL indicated they had no changes at this time to the Strategic Plan.

### **KLCRP TIMELINE**

Rebecca pointed out that September 15 is the date when fiscal year end June 30 detailed expenditure reports are due to CPE. She would like to change this date from September 15 to September 1 to coincide with what is required for reporting to the Governor's Office. Everyone agreed with this change and she will make the change on the timeline. Nathan asked if UK and UofL should submit separate or joint reports and Milton indicated that UofL was agreeable to a joint report.

### **OTHER BUSINESS**

Chair Roach stated that he would be resigning from the Board and this would be his last meeting. He stated he appreciated the opportunity to serve on the Board and members thanked him for his service. He provided handouts to the members on cancer bullet points and cancer stem cells.

Chair Roach called for a motion to adjourn. A motion was made by Tim Mullet and seconded by Jason Chesney. The motion was approved and the meeting adjourned at 2:45 pm.

Council on Postsecondary Education  
 Lung Cancer Research, Tobacco Settlement Fund (6349 fund)  
 FY17 Cash Activity Report as of August 15, 2016

Date	Description	Interest	Ovarian	Combined LC Pool	UK Lung Cancer		UofL Cancer		Total Allocation (Calculated)	comment	CASH
					Grants	Programs	Grants	Programs			
	<b>FY16 Carry-Forward Balance as of 6/30/2016</b>	32,938.52	-	-	832,096.44	-	-	0.93			865,035.89
	YTD Interest Earnings as of 8.15.16	328.00									
8/5/2016	AUDIT: LUNG CANCER RESEARCH FUND FY ENDING 6/30/15	(7,488.00)									865,363.89
	FY17 appropriation - yet to be received	4,706,100.00									865,363.89
	Governance Board approved appropriations (June 2016)		800,000.00		750,000.00	1,395,500.00	750,000.00	1,010,600.00	4,706,100.00		
	<b>Cash Balance</b>	25,778.52	-	-	832,096.44	-	-	0.93	-		857,875.89

9

Council on Postsecondary Education  
Lung Cancer Research, Tobacco Settlement Fund (6349 fund)  
FY16 Cash Activity Report as of June 30, 2016

Date	Description	Interest	Ovarian	Combined LC Pool	UK Lung Cancer		UofL Cancer		Total Allocation (Calculated)	comment	CASH
					Grants	Programs	Grants	Programs			
	Final FY15 carryforward balances	44,405.31	-	-	607,096.44	-	-	0.93			651,502.68
	YTD Interest Earnings as of 5.31.16	3,377.21									651,502.68
7/25/2015	APA annual audit fee	(7,344.00)									654,879.89
1/4/2016	Tripp Umbach Economic Impact Study	(7,500.00)									647,535.89
4/18/2016	UKRF-Lung Cancer FY16-RIT1 Novel (7/1/16-6/30/2018)				(150,000.00)						640,035.89
4/19/2016	FY16 appropriation - yet to be received										490,035.89
4/19/2016	FY16 appropriation - JV2T will be completed near FY year end	4,972,500.00									5,462,535.89
5/10/2016	UKRF - Ovarian Screening FY16 - (7/1-6/30/16)		800,000.00		750,000.00	1,550,050.00			4,972,500.00		4,662,535.89
5/31/2016	UKRF - Lung Cancer FY16 Program Funds (7/1-6/30/16)		(800,000.00)								3,112,485.89
8/10/2016	ULRF - Lung Cancer FY16 Program & Grant Funds (7/1-6/30/16)					(1,550,050.00)					
8/21/2016	UKRF - Lung Cancer FY16 - NOVEL FUNCTION OF METASTASIN-1 (7/1/16-6/30/17)				(75,000.00)			(750,000.00)	(1,122,450.00)		
8/29/2016	UKRF - Lung Cancer-ctDNA in Personalized Therapy (7/16-6/18)				(150,000.00)						
8/29/2016	UKRF-Lung Cancer-Connecting Appalachians (7/16-6/18)				(150,000.00)						
	Cash Balance	32,938.52	-	-	832,096.44	-	-	0.93			865,035.89

7

**Kentucky Lung Cancer Research Program  
Governance Board  
August 31, 2016**

**Annual Report to the Governor**

**ACTION:** Recommend that the Board approve the Annual Report to the Governor for the University of Kentucky and the University of Louisville.

Annual reports have been submitted by the University of Kentucky and the University of Louisville for approval and are attached.



UNIVERSITY OF KENTUCKY	OBJECTIVES FROM 2016 STRATEGIC PLAN	GOALS (Including Metrics)	Describe how endpoints have been met?	Challenges to attaining goals/revision of endpoints/timeframe?
<b>GOAL 1: Investigator Initiated Research (KRS 167.476(5)(a))</b>				
	1a. Recruit existing faculty of cancer research to focus on problems in lung cancer.	Up to 5 projects per year.	Call for proposals for Cycle 15 was released on June 25, 2015, 14 letters of intent were received, and 5 applications were funded; this resulted in 3 principle investigator-level faculty engaging in the KLCRP that had previously not done so at Markey. Cycle 16 call for proposals was released on June 30, 2016, 15 letters of intent were received, and applicants are currently writing full proposals which are due October 31, 2016.	Limited model systems; limited scientific appeal because of lack of national funding opportunities; difficult research area.
	1b. Recruit new faculty with interests and expertise in cancer applied to lung cancer problems	Open-ended.	>70 new faculty since 2009. Several recruits have primary and/or secondary interests in lung cancer. We are continuously looking to recruit faculty with lung cancer research and clinical interests.	Limited expertise available nationally; limited model systems; limited funding available; difficult research area.
	1c. Develop, mentor and focus junior investigators/graduate students on lung cancer	Open-ended.	Junior investigators at the MCC have formal and informal mentorship; many junior faculty have a mentorship committee comprised of senior faculty; new training grant mechanisms are being sought and developed as an effort to boost training for predoctoral students, postdoctoral fellows and junior faculty.	Limited senior investigators available for specific mentoring in lung cancer.
	1d. Support a robust research portfolio for lung cancer.	Up to 5 projects per year; diversity of disciplines.	6 active projects as of 7/31/16. Call for proposals for Cycle 16 was issued in June 2016 with projects being funded by July 2017; 4-6 projects are expected to be funded.	Limited number of new investigators focusing on lung cancer research.
	1e. Develop intra-programmatic linkages within/between UK/UofL Cancer Centers	Encourage collaborative projects in each Cycle.	Currently seeking proposals for Cycle 16. The 6 active KLCRP grants are intra- and inter-programmatic in nature and key personnel come from multiple colleges and departments.	Limited number of productively engaged lung cancer investigators especially related to clinician-scientists.
	1f. Conduct annual scientists' seminars to share research results among funded KLCRP scientists.	Seminar exchange program between UK and U of L investigators funded by KLCRP.	Seminars occur on an ongoing schedule. Interested KLCRP-funded investigators are being sought for open seminar dates.	Funds to support travel expenses, etc..
<b>Goal 2: Research in Early Detection &amp; Prevention (KRS 167.476 (5)(a))</b>				
	2a. Conduct screening and early detection research using available and applicable tools in key geographic areas of Ky; Conduct dissemination/implementation lung cancer screening research.	Develop population-based studies especially in eastern Kentucky where cancer incidence and mortality is highest.	A new lung cancer screening research study has been implemented and efforts are already underway to expand the scope of this project statewide. This study will focus on decreasing lung cancer mortality by detecting the disease at an early, treatable stage and by reducing smoking rates. Additionally, a KLCRP Cycle 13 grant being conducted by Dr. Jamie Studts is investigating the impact and need of lung cancer screening shared decision making through a web-based intervention for primary care providers, a vital group of health care providers that are essential for optimal dissemination and implementation of evidence-based lung cancer screening efforts. The Markey Cancer Center has also established a clinical lung cancer screening program that can be leveraged for research purposes going forward.	Cost of off site, population-based studies is exorbitant.
	2b. Expand and refine methodologies for risk-factor delineation	Develop risk-factor models through population-based studies.	Projects testing heavy metals/environmental contaminants (radon, etc.), tobacco use, and other high-risk behavioral factors in correlation to GI and lung cancer are ongoing. MCC biostatisticians are looking at appropriate risk-factor modeling in these projects.	Overwhelming risk factor of smoking and other lifestyle factors.
	2c. Validate the use of methodologies for lung cancer screening	An ongoing goal seeking improved methods.	The new lung cancer screening research study will revisit cost effective and sustainable screening methods. The new study specifically seeks to develop a network of lung screening sites that includes a research platform to contribute to collection of biospecimens from lung cancer screening participants that can be used to improve lung cancer screening models and modalities. The clinical lung cancer screening program at Markey will also seek to address these issues.	CT is still too costly for routine clinical application & risk assessment remains a challenge.
	2d. Identify and develop methodologies for lung cancer prevention	An ongoing goal.	Prevention projects that are ongoing include tobacco cessation programs, detection and elimination strategies for environmental contaminants and other behavior modification. Dr. Ellen Hahn is conducting significant and innovative work in primary care settings evaluating the effects of a combined radon and environmental tobacco exposure reduction intervention to prevent lung cancer. Lung cancer screening in parallel with tobacco cessation programs are also ongoing at Markey.	Overwhelming risk factor of smoking and other lifestyle factors.
	2e. Maintain and expand the biospecimen repository for use by researchers	An ongoing goal.	More than 20,000 biospecimens (many of which come from Appalachian Kentucky patients) are now available.	Limited access to lung tissue; no surgery for advanced stage disease.
	2f. Capitalize on partnerships with regional and local hospitals and clinics to build an early detection network where research is integral to the relationship	Establish collaborations with our affiliate network and expand the network.	There are currently 16 Markey affiliate hospitals and we have a collaboration with Norton Cancer Institute; other affiliate sites are in negotiation. A Markey research network via partner regional hospitals has been launched. MCC faculty and staff have traveled to Affiliate and Research partner facilities to present CMEs on the standards and coverage decisions for lung cancer screening.	Exorbitant expense; regional and local hospitals are cautious about how expenses will be shared.
	2g. Link prevention and early detection studies.	Continually develop initiatives that serve our catchment area.	Education & smoking cessation programs are widely ongoing as mentioned above. A cycle 12 investigator-initiated grant focuses on identifying the "best" smoking cessation strategy for our catchment area. The new lung cancer screening research study will look to incorporate evidence-based tobacco treatment strategies into high quality lung cancer screening programs in order to combine primary and secondary prevention efforts. Further, efforts are under consideration to incorporate radon education efforts as a component of high quality implementation of lung cancer screening programs. Lastly, the clinical lung cancer screening program at Markey will link patients with prevention strategies including smoking cessation and environmental contaminant mitigation.	Most effective prevention means is smoking cessation; early detection is more problematic in expense, specificity & sensitivity.

UNIVERSITY OF KENTUCKY	OBJECTIVES FROM 2016 STRATEGIC PLAN	GOALS (Including Metrics)	Describe how endpoints have been met?	Challenges to attaining goals/revision of endpoints/timeframe?
<b>Goal 3: Kentucky Clinical Trials Network (KRS 167.476 (5)(b))</b>				
3a.	Increase # of Kentuckians with access to and participating in lung cancer CTs	<ul style="list-style-type: none"> <li>Identify studies based on feasibility evaluations of patient populations seen, site capacity to ensure successful accrual.</li> <li>Study portfolio to include study opportunities for all sites.</li> <li>Increase overall program accrual.</li> <li>Increase % patients enrolled at site level.</li> <li>Engage community based cancer clinicians to increase patients served. Assure coverage in every federal congressional district in Kentucky.</li> </ul>	<ul style="list-style-type: none"> <li>Sites have Enrolled 2,274 participants residing in 81/120 counties to KCTN trials, a saturation of 68% of the Commonwealth.</li> <li>Sites located in every federal congressional district in Kentucky.</li> <li>Collaborating with Markey Cancer Center to expand access to trials to selected affiliate centers. Initial trials will focus on high priority trials in early detection and treatment of tobacco addiction at centers in MCC catchment areas.</li> <li>Continue work with research sites, including Academic Centers, Community-based hospitals; experience ranging from vast research enterprises to no existing research program.</li> <li>Sites have established enrollment to trials or increased their previous overall enrollment performance. Data for selected sites that hold accreditation with the American College of Surgeons, Commission on Cancer indicate verifiable numbers of increased participation and access to trials in FY 2015.</li> <li>IIT collaboratively developed, by MCC clinician, behavioral scientist, KCTN Medical Director and Director. Utilizes innovative statistical design, MOST to identify optimal smoking cessation intervention strategy for newly diagnosed patients; pharmaceuticals and high intensity counseling. Funded with KLCRP cycle 12 award, with additional grant awarded by Pfizer. Trial conducted at 10 KCTN sites. Participating sites have increased capacity in smoking cessation counseling as a result of the study provided training on using motivational interviewing as a technique to counsel patients on smoking.</li> </ul>	<ul style="list-style-type: none"> <li>Challenge is reflective of national and international accrual to trials. National average indicates that less than 3% of adult cancer patients are enrolled to studies. However, most KCTN sites average higher than national average as documented by Commission on Cancer evaluation and commendation level achievements for number of patients enrolled.</li> <li>Despite availability of trials, not every patient is offered opportunity to participate by treating clinicians. Obstacles reflective of time burden in busy clinics, resources and staff for both AMCs and community based sites.</li> <li>Progress: Kentucky Cancer Registry (KCR) implemented clinical trial variables in 2013 software release. Data is now available on the total number of Kentuckians participating in clinical trials. In previous years, this Outcome Measurement Difficult: KCR did not collect a data field of clinical trial. For previous and current year, endpoint to measurable metric - against verifiable numbers collected at sites: # lung cancer patients vs/ # lung cancer patients participate in trial.</li> </ul>
3b.	Develop and maintain a critical mass of trained professional staff to support multi-site clinical trials	<ul style="list-style-type: none"> <li>Onboard new site team members.</li> <li>Expand site research teams based on Site Development Plans.</li> <li>Data Management &amp; Project Management Support for CC.</li> <li>Continue on-site training.</li> <li>Offer Continuing Education opportunities for Research Nurses, Study Coordinators and Study Teams, with varying expertise level.</li> </ul>	<ul style="list-style-type: none"> <li>Onboarded new site team members: Training - PI responsibilities, GCP, CFR, SOPs, systems. .</li> <li>Training: <ul style="list-style-type: none"> <li>3 Research nurses achieved certified research professional credentials. 2. 1 new coordinators completed Research Nurse 101 - intensive 10 wk course. 3. Pls, SCs trained in GCP, CFR, SOPs, protocol prior to and ongoing during trials.</li> </ul> </li> <li>Continued development of Coordinating Center to support trials management and central services. <ul style="list-style-type: none"> <li>Clinical Project Data Manager: advanced trainings in Good Clinical Data Management. Develop CEs on data quality in study conduct for study teams &amp; CC.</li> <li>Project Coordinators: online trainings in assistant project management, apply these principles to improve support services to trials and sites.</li> <li>Network Director: advanced sessions in Regulatory Affairs, Quality Systems, Research &amp; Development, Compliance &amp; Enforcement, FDA &amp; OHRP, Capacity Building. Establishes team and program CE goals.</li> </ul> </li> <li>Site Continuing Education (CE) selected spotlight: <ul style="list-style-type: none"> <li>Representatives from ten sites attended the Markey Cancer Center Affiliate Network annual meeting offering CEs. KCTN Coordinating Center team assisted with staffing the meeting and hosted a research information table. KCTN Medical Director moderated a lung cancer screening panel, KCTN Director hosted clinical trials round-tables for dinner and breakfast (most attended table at the event with 22 participants).</li> <li>Presented CME sessions at area centers, "Development of Quality Lung Cancer Screening" and "Practical Lung Cancer Screening CT", "Shared Decision Making", "Treatment of Tobacco Addiction"</li> <li>Representatives from seven KCTN sites attended the annual Human Subjects Protection Regional Conference, sponsored by Cincinnati Children's, UC, UK and Schulman IRB.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Challenges to incorporate research into busy clinic practices is a static problem, physician and nurse time. Challenges with consistency of seamless incorporation of trial consideration for majority of patients seen.</li> <li>Compliance requirements are intensive and require substantial commitments from physicians, nurses, and institutions.</li> <li>Site resources limit FTE dedicated to research.</li> <li>CC team, challenging transition from experience in study conduct role to CRO type services/sponsor role. Application of expertise is substantial and requires advanced trainings in CFR and GCP, CRO services and study oversight, as well as communications.</li> <li>Unique qualifications to support deliverables of program requires continuing professional development and advancing expertise.</li> <li>Due to complexity of systems and operations needed to develop IITs for multi-site conduct and meet regulatory responsibilities, there are limited internal resources to leverage.</li> <li>Compliance, quality and audit requirements are intensive.</li> </ul>
3c.	Offer and manage industry-sponsored lung cancer clinical trials through the Network.	<ul style="list-style-type: none"> <li>Identify studies based on feasibility evaluations of patient populations seen, site capacity to ensure successful accrual.</li> <li>Engage physicians at Markey Cancer Center and Brown Cancer Center to seek referrals for all industry sponsored trials considered.</li> <li>Target studies to include; early and late stage NSCLC, late stage small cell, epidemiologic factors of Kentucky patients.</li> </ul>	<ul style="list-style-type: none"> <li>Participated in global drug trials sponsored by industry.</li> <li>All Markey Cancer Center trials were considered for appropriateness to expand to external KCTN sites.</li> <li>Site Performance Spotlight: <ul style="list-style-type: none"> <li>Private Practice Site is one of lead enrolling sites internationally to therapeutic trial of investigational drug for treatment of advanced stage NSCLC following progression after or intolerance to at least one prior chemotherapy. Site has enrolled five patients, represents ~5% of total number enrolled in US. Senior sponsor representatives visited site and compliment quality of site and KCTN services.</li> <li>KCTN community site hospital only non-AMC site in KY selected to participate in Phase IIa safety and pharmacokinetic study of G1T28 in patients with extensive stage small cell lung cancer with progression during or after first or second-line chemotherapy. Owensboro Health, Mitchell Memorial Cancer Center and UK Markey Cancer Center are only sites in Kentucky participating.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Capacities at several sites limit # of studies feasible for site study portfolio. Many sites participate in limited number of trials at one time due to limited staffing resources. One site does not participate in more than one trial per patient population, despite large volume of patients that could support at least 2 competing trials. Several sites now decline to participate in industry trials as they prefer to conduct trials initiated and led by MCC and BCC investigators.</li> <li>Limited industry trials available that are consistent with the KLCRP Strategic Plan and KCTN priority portfolio.</li> </ul>

UNIVERSITY OF KENTUCKY	OBJECTIVES FROM 2016 STRATEGIC PLAN	GOALS (Including Metrics)	Describe how endpoints have been met?	Challenges to attaining goals/revision of endpoints/timeframe?
3d.	Identify and develop investigator-initiated clinical trials at both UK and UofL that can be offered to patients in diverse settings.	<ul style="list-style-type: none"> <li>Utilize resources and expertise to assist with quality study development; consider factors influence trial success.</li> <li>Identify studies based on feasibility evaluation to ensure trial accrual; patient populations, site capacity.</li> <li>Consider complexity of trial design to identify studies feasible to launch as multi-site.</li> <li>Facilitate development of trials consistent with KLCRP Strategic Plan goals.</li> </ul>	<ul style="list-style-type: none"> <li>Provide trial development support to physicians and scientists. Generated development of six IIT concepts, four advancing to funding awards and development. Trial pipeline focused to highest priority IITs, including therapeutic, early detection and treatment of tobacco addiction. Trial pipeline achieved goals established in the KLCRP Strategic Plan for goals 2a, 2c, and 3 and in accordance recommendations of the KLCRP Review.</li> <li>Central support of Sponsor-Investigators to meet responsibilities as required under Code of Federal Regulations and ethical research principles. KCTN ensures CFR &amp; GCP are considered in all phases of project; development, conduct, archive. Quality Systems to support Sponsor-Investigators substantial responsibilities.</li> <li>Expanded Investigator-Initiated trials previously conducted at a single facility to multi-site participation thus expanding access to trials to patients across Kentucky, without burdensome travel to patient.</li> </ul> <p>Investigator-Initiated Trial Spotlight:</p> <p>1. MOST - Therapeutic Intervention IIT: "Optimization of Smoking Cessation Strategies in Community Cancer Programs for Newly Diagnosed or Recurrent Lung and Head and Neck Cancer Patients": Examines pharmaceuticals for cessation in combination with a high-intensity counseling or SOC to identify an optimal strategy to treating tobacco addiction in cancer patients. Trial funded by KLCRP, with additional grant support awarded from Pfizer.</p> <p>Investigator-Initiated Trial Development Spotlight:</p> <p>KY LEADS Collaborative: Portfolio studies to reduce the burden of lung cancer in Kentucky through development, evaluation, and dissemination of novel community based interventions to promote provider education, survivorship care and prevention and early detection of lung cancer. BMSF 7 million dollar grant awarded to Dr. Jamie Studts, Markey Cancer Center. Studies will be conducted at 10 KCTN sites.</p> <p>Study 2, Survivorship: Aim is to develop and evaluate lung cancer specific survivorship care programs for patients and caregivers. This study includes a training program for nurse navigators and mental health providers.</p> <p>Study 3, Early Detection &amp; Prevention: Study will examine the implementation of quality lung cancer screening at Kentucky centers. This study includes training, resources to support centers capacity development to perform lung cancer screening in accordance with USPTSF, CMS requirements. The study engages the MCC CRI, to facilitate the transmission of case data to the CMS registry required for reimbursement.</p> <p>Study 4. Quality Review of Screening Scans: A subspecialty-trained thoracic radiologist will centrally overread screening scans performed under the KY LEADS C3 to validate the scan interpretation. Clinically significant discrepancies will generate notice and training to local radiologist. This study will increase capacity of local radiologists to assure appropriate interpretation of CT scans prompting clinical evaluations.</p>	<p>Limited number of Investigator-Initiated Trials (IITs). IITs come to us unfunded or modest funding insufficient to sponsor multi-site trial. From KCTN's inception, all IITs conducted via KCTN have required use of KCTN funds to support trial; including regulatory, study drug, monitoring, site payments or full study funding.</p> <ul style="list-style-type: none"> <li>Grant submissions to NIH and other external agencies are challenging, reflective of increased competitiveness in national funding sources. Increased funding for multi-site investigator-initiated trials is needed.</li> <li>Challenges and time effort of Study Chairs to meet CFR responsibilities of Sponsor-Investigator of multi-site trials. Substantial increase in responsibilities over internal only IITs. Sponsor-Investigators must comply with Code of Federal Regulations as both sponsor and investigator.</li> </ul>
3e.	Continually improve the Network's services with input from practicing KY physicians.	<ul style="list-style-type: none"> <li>Expand study portfolio with priorities as defined in the KLCRP Strategic Plan and KCTN physician research interests.</li> <li>Use of Master Services style contract to sustain study initiation timelines.</li> <li>Perform centralized services.</li> <li>Perform site visits to ensure deliverables are consistent with site and study needs.</li> </ul>	<ul style="list-style-type: none"> <li>KCTN Coordinating Center team conducted 105 site visits in FY2015 (Study Interim, Education, Study Support, Monitoring, Quality Review, Development, &amp; Onboarding).</li> <li>KCTN Medical Director &amp; Director conduct site visits to encourage sustained commitments to research and seek feedback regarding support services.</li> <li>Utilize Project Planning Teams to develop trials with unique insight to community based practitioners, while maintaining integrity and scientific value of trials.</li> <li>Utilize study concept feasibility assessments to solicit feedback from community physicians on trials in development.</li> <li>Per site requests, portfolio includes Interventional and Non-interventional trials.</li> <li>Offer menu of centralized support services while site retains autonomy; including budgets, contracts, regulatory, training, patient screening, conduct support. Allows sites to focus efforts on patients.</li> <li>Performed site evaluation to identify process improvements to study conduct performance; improvements observed in quality measures with implementation of operational suggestions. Implemented use of Screening Analysis reports to provide sites with information to guide improved study operations.</li> <li>KCTN Medical Director, &amp; Director participated in media &amp; community events to engage &amp; educate community on participation in trials.</li> </ul>	<p>Due to site diversity, difficult to meet all needs. However, sites experience many of the same challenges in conducting trials;</p> <ul style="list-style-type: none"> <li>Not every patient is offered the opportunity to participate in a trial, despite availability of trials, due to busy clinics and lack of support staff.</li> <li>Several sites experience recurring struggles with sufficient staffing levels and high turnover.</li> <li>Non-Academic Center sites struggle with sustaining sufficient funding to support dedicated research personnel. Study Coordinators are frequently pulled to cover clinic nurse shortages. Burden of incorporating and sustaining clinical trials in non-AMC practices is challenging despite strong commitments.</li> </ul>
<b>Goal 4: NCI-Designation as Cancer Centers (KRS 164.476 (5)(c))</b>				
4a.	Expand the base of cancer research expertise, particularly in translational research.	Recruit both promising young and proven mature scientists.	Recruited >70 new faculty since 2009; diversity of disciplines represented. A heavy emphasis is being placed on translational research especially related to moving Markey basic science into the clinic via novel/unique clinical trials.	Funding for salary support and access to laboratory space.
4b.	Develop diverse cancer research programs with a high degree of inter- and intra- team	At least 3 designated Program Areas.	We have 4 mature program areas: Cancer Cell Biology and Signaling; Cancer Prevention and Control; Drug Discovery, Delivery and Translational Therapeutics; and Genetic Instability, Epigenetics and Metabolism.	Critical mass of faculty with critical mass of NCI funding; collaborations require protected time.
4c.	Provide and promote interactive research opportunities.	30% of grants and publications collaborative.	About 30% of publications are been intra- or inter-programmatic. Nearly 30% of our grants are collaborative between 2 or more Markey investigators.	Protected faculty research time for development of collaborations.
4d.	Offer expanded innovative clinical trials, building on combined research underpinnings of the two centers.	Accrual of at least 10% of patients to innovative clinical studies.	Approx. 6% accrual in calendar year 2015 (data collection is not complete to report on FY 2016); over 50% of patients accrued to clinical studies are residents of Appalachian eastern Kentucky; We are expanding our Affiliate Network to offer clinical trials throughout the state.	Clinical faculty pressed into clinical service; building renewed leadership emphasis on clinical research.

UNIVERSITY OF KENTUCKY										
2016 FISCAL YEAR-ANNUAL REPORT										
	Budget	Budget	Budget	PERSONNEL	FRINGE BENEFITS	TRAVEL	OPERATING EXPENSES	CAPITAL OUTLAY	INDIRECT COSTS	Total
	TOTAL REVENUE 2000-2016	FY2016 Allocations	FY 2017 Allocations							
<b>ADMINISTRATION</b>	\$ 23,247,005.77									
<b>H-1 GRANTS FUNDING</b>	\$ 16,136,871.93									
Program Grants Carry Forward (FY15)	\$ (3,251,888.39)			\$ 2,608,813.31	\$ -	\$ 6,887.96	\$ 628,679.41	\$ 7,507.71	\$ -	\$ 3,251,888.39
H-1 Grants Carry Forward (FY15)	\$ (1,763,847.94)			\$ 1,000,737.63	\$ -	\$ 5,956.00	\$ 619,652.16	\$ -	\$ 137,482.15	\$ 1,763,847.94
Carryforward funds at CPE	\$ (82,096.44)									
H-1 Grants Cycle 16 funding not yet claimed	\$ (750,000.00)	\$ 750,000.00	\$ 750,000.00							
Administration not yet received (FY16 funding to be used in FY17)	\$ (1,550,050.00)	\$ 1,550,050.00	\$ 1,395,500.00	\$ 1,550,050.00						\$ 1,550,050.00
Other Grants/Contracts		\$ -	\$ -							\$ -
<b>TOTAL INCOME</b>	\$ 31,985,994.93	\$ 2,300,050.00	\$ 2,145,500.00	\$ 5,159,620.94	\$ -	\$ 12,843.96	\$ 1,248,331.57	\$ 7,507.71	\$ 137,482.15	\$ 6,565,786.33
GOAL 1: Investigator Initiated Research	\$ 13,540,927.55	\$ 750,000.00	\$ 750,000.00	\$ 270,995.70	\$ 57,110.99	\$ -	\$ 44,778.66	\$ -	\$ 37,321.07	\$ 410,206.42
GOAL 2: Research in Early Detection/Prevention	\$ 2,413,001.01	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
GOAL 3: Kentucky Clinical Trial Network	\$ 5,747,457.78	\$ 427,600.00	\$ 384,900.00	\$ 272,612.06	\$ 82,638.74	\$ 23,659.16	\$ 65,476.44	\$ -	\$ -	\$ 444,386.40
GOAL 4: NCI Designation (Comp Cancer Center)	\$ 6,589,582.99	\$ 1,072,450.00	\$ 960,600.00	\$ 644,963.71	\$ 165,782.10	\$ -	\$ 32,414.75	\$ -	\$ -	\$ 843,160.56
Administration	\$ 1,903,323.11	\$ 50,000.00	\$ 50,000.00	\$ 31,571.11	\$ 8,945.87	\$ 171.52	\$ -	\$ -	\$ -	\$ 40,688.50
Research Support	\$ 584,742.77									\$ 3,251,888.39
Internet Portal	\$ 292,055.72									\$ 1,550,050.00
Epidemiology	\$ 422,410.00									\$ -
Endowed Chair	\$ 492,494.00									\$ -
<b>TOTAL EXPENSE</b>	\$ 31,985,994.93	\$ 2,300,050.00	\$ 2,145,500.00	\$ 1,220,142.58	\$ 314,477.70	\$ 23,830.68	\$ 142,669.85	\$ -	\$ 37,321.07	\$ 1,738,441.88
<b>Balance</b>	\$ -	\$ -	\$ -	\$ 3,939,478.36	\$ (314,477.70)	\$ (10,986.72)	\$ 1,105,661.72	\$ 7,507.71	\$ 100,161.08	\$ 4,827,344.45

H-1  
\$ 1,354,590.03 FY15 carry forward  
\$ 409,257.91 FY15 fund balance  
\$ 1,763,847.94 \$ 409,257.91  
-1353641.52 Balance of H-1 grants carrying forward into FY17 plus balance of fund  
-1353641.52  
\$ (1,353,641.52) variance \$ (1,353,641.52)  
Program funds  
\$ 3,251,888.39 FY15 Carry-forward  
\$ 1,550,050.00 FY16 funding  
\$ (1,328,235.46) FY16 expenses  
\$ 3,473,702.93 sum  
\$ 3,473,702.93 FY16 carry-forward  
\$ 3,473,703 variance  
\$ -

... 20% of Kentucky's Tobacco Settlement funds shall be spent on a collaborative partnership between UK and UofL dedicated to lung cancer research. KRS 164.476

NOTES:

- Total KLCR funding per reconciliations received.
- Cycle 12 grants - \$450,000 was awarded for Cycle 12
- Cycle 13 grants - \$600,000 awarded for Cycle 13 (grants begin 7/1/14)
- Cycle 14 grants - \$600,000 awarded for Cycle 14 (grants begin 7/1/15)
- Administration Carry-forward funding into FY17:
 

	Balance 6/30/16
Kentucky Clinical Trials Network	\$1,055,541
NCI Designation	\$2,145,886
Administration	\$113,872
Early Detection	\$158,404
	\$3,473,703
- Investigator-Initiated Grants Carry-forward funding into FY17
 

Fund	\$267,341.58
Cycle 11 - began 7/1/12	\$18,130
Cycle 12 - began 4/1/13	\$177,898
Cycle 13 - begins 7/1/14	\$446,240
Cycle 14 - begins 7/1/15	\$365,532
KCTN Data Coordinator - taken from H-1 funding	\$78,500
	\$1,353,642

PLEASE INCLUDE THE FOLLOWING ON ALL DOCUMENTS:

INSTITUTION: University of Kentucky/Markey Cancer Center  
 Prepared By: Elisha Maxson, and Nathan L. Vanderford  
 SUBMITTED BY: Nathan L. Vanderford  
 DATE: 8/5/2016

12

**Kentucky Lung Cancer Research Program  
University of Kentucky FY16 Payroll Expenditures**

Acct No	Initiatives by Goal	Role	Individual	FTE %	New/Existing	Salary	Fringe
3048110255	Investigator Initiated Research (G1)	Faculty - Biostatistics Core	Brent Shelton	0.75%	Existing	\$1,498.59	\$338.38
	Investigator Initiated Research (G1)	Lab Technician	Mamta Goswami	75.00%	Existing	\$12,188.00	\$1,078.65
	Investigator Initiated Research (G1)	Graduate Research Assistant	Nathaniel Holcomb	64.08%	Existing	\$15,229.88	\$1,272.04
	Investigator Initiated Research (G1)	Faculty - Clinician Scientist	Susanne Arnold	0.38%	Existing	\$1,106.28	\$228.40
					FYE Payroll Accruals	\$ (146.39)	\$ (12.37)
3048110274	Investigator Initiated Research (G1)	Faculty - Behavioral Scientist	Christina Studts	6.60%	Existing	\$4,445.64	\$1,223.50
	Investigator Initiated Research (G1)	Faculty - Clinician Scientist	Joseph Valentino	1.15%	Existing	\$3,093.12	\$623.94
3048110846	Investigator Initiated Research (G1)	Faculty - Biostatistics Core	Bin Huang	0.25%	Existing	\$302.46	\$86.99
	Investigator Initiated Research (G1)	Database Administrator	Darren Henderson	2.08%	Existing	\$981.00	\$279.42
	Investigator Initiated Research (G1)	Graduate Research Assistant	Deependra Tvaqi	50.00%	Existing	\$13,300.26	\$159.60
	Investigator Initiated Research (G1)	Faculty - Informatics	Eric Durbin	0.25%	Existing	\$318.69	\$82.02
	Investigator Initiated Research (G1)	Data Management Specialist	Grace Pasley	2.08%	Existing	\$789.24	\$240.81
	Investigator Initiated Research (G1)	Faculty - Pharmacy Science	Jeffery Talbert	0.50%	Existing	\$970.02	\$174.78
	Investigator Initiated Research (G1)	Information Technology Manager	Keith Henry	0.50%	Existing	\$538.41	\$166.02
					FYE Payroll Accruals	\$ (327.85)	\$ (2.62)
3048111498	Investigator Initiated Research (G1)	Faculty - Basic Scientist	Amrita Machwe	46.67%	Existing	\$22,422.60	\$7,391.87
	Investigator Initiated Research (G1)	Graduate Research Assistant	Christina Wicker	50.00%	Existing	\$7,104.29	\$1,400.54
	Investigator Initiated Research (G1)	Faculty - Clinician Scientist	Craig Horbinski	0.00%	Existing		\$ (3.94)
	Investigator Initiated Research (G1)	Faculty - Biostatistics	Li Chen	1.00%	Existing	\$1,140.72	\$296.40
					FYE Payroll Accruals	\$90.39	\$8.37
3048111500	Investigator Initiated Research (G1)	Faculty - Basic Scientist	Amrita Machwe	5.33%	Existing	\$2,560.80	\$844.08
	Investigator Initiated Research (G1)	Faculty - Basic Scientist	David Orren	0.50%	Existing	\$502.32	\$135.48
	Investigator Initiated Research (G1)	Faculty - Biostatistics	Emily Dressler	3.00%	Existing	\$3,444.48	\$989.95
	Investigator Initiated Research (G1)	Faculty - Clinician Scientist	Mahesh Kudrimoti	0.50%	Existing	\$2,130.00	\$395.80
	Investigator Initiated Research (G1)	Faculty - Basic Scientist	Tadahide Izumi	0.50%	Existing	\$520.20	\$153.36
3048112384	Investigator Initiated Research (G1)	Faculty - Biostatistics	Chi Wang	4.00%	Existing	\$4,618.92	\$1,261.87
	Investigator Initiated Research (G1)	Faculty - Basic Scientist	Chunming Liu	1.00%	Existing	\$1,560.00	\$380.47
	Investigator Initiated Research (G1)	Faculty - Biostatistics	Heidi Weiss	1.00%	Existing	\$2,310.12	\$497.41
	Investigator Initiated Research (G1)	Graduate Research Assistant	Hong Wang	100.00%	Existing	\$18,826.65	\$2,579.72
	Investigator Initiated Research (G1)	Faculty - Biostatistics	Jinze Liu	1.00%	Existing	\$2,183.64	\$503.64
	Investigator Initiated Research (G1)	Faculty - Clinician Scientist	Sivakumaran Theru	1.00%	Existing	\$1,500.00	\$391.54
	Investigator Initiated Research (G1)	Faculty - Clinician Scientist	Susanne Arnold	1.00%	Existing	\$2,949.96	\$622.39
	Investigator Initiated Research (G1)	Graduate Research Assistant	Yuchen Yang	100.00%	Existing	\$18,975.00	\$2,583.04
					FYE Payroll Accruals	\$657.42	\$58.18
3048112439	Investigator Initiated Research (G1)	Faculty - Biostatistics	Chi Wang	3.00%	Existing	\$3,464.16	\$946.43
	Investigator Initiated Research (G1)	Faculty - Basic Scientist	Chunming Liu	3.00%	Existing	\$4,680.00	\$1,141.35
	Investigator Initiated Research (G1)	Staff - Research Associate	Tianxin Yu	50.00%	Existing	\$20,580.48	\$7,863.10
3048112440	Investigator Initiated Research (G1)	Faculty - Clinician Scientist	Susanne Arnold	0.25%	Existing	\$737.52	\$155.65
	Investigator Initiated Research (G1)	Graduate Research Assistant	Ye Yang	100.00%	Existing	\$23,319.07	\$1,622.93
					FYE Payroll Accruals	\$361.54	\$4.34
3048112542	Investigator Initiated Research (G1)	Clinical Research Assistant II	Emily Shardelow	9.81%	Existing	\$4,743.90	\$1,542.20
	Investigator Initiated Research (G1)	Faculty - Biostatistics	Heidi Weiss	1.00%	Existing	\$2,117.61	\$450.39
					FYE Payroll Accruals	\$31.09	\$10.93
3048112580	Investigator Initiated Research (G1)	Faculty - Biostatistics	Bin Huang	4.00%	Existing	\$4,839.36	\$1,285.65
	Investigator Initiated Research (G1)	Database Analyst	David Rust	5.00%	Existing	\$3,105.00	\$904.10

Acct No	Initiatives by Goal	Role	Individual	FTE %	New/Existing	Salary	Fringe
	Investigator Initiated Research (G1)	Faculty - Informatics	Eric Durbin	1.00%	Existing	\$1,274.76	\$324.56
	Investigator Initiated Research (G1)	Data Management Specialist	Grace Pasley	5.00%	Existing	\$2,630.80	\$802.76
	Investigator Initiated Research (G1)	Faculty - Clinician Scientist	Michael Brooks	2.00%	Existing	\$7,030.68	\$1,420.15
	Investigator Initiated Research (G1)	Faculty - Informatics	Venkata Kavuluru	15.00%	Existing	\$17,282.81	\$4,479.41
	Investigator Initiated Research (G1)	Graduate Research Assistant	Anthony Rios	0.00%	Existing		\$823.00
3048113028	Investigator Initiated Research (G1)	Faculty - Informatics	Venkata Kavuluru	20.00%	Existing	\$18,036.07	\$4,619.04
	Investigator Initiated Research (G1)	Database Analyst	David Rust	5.00%	Existing	\$621.00	\$180.82
	Investigator Initiated Research (G1)	Data Management Specialist	Grace Pasley	5.00%	Existing	\$526.16	\$160.54
3048113044	Investigator Initiated Research (G1)	Faculty - Biostatistics	Brent Shelton	0.25%	Existing	\$499.53	\$130.95
	Investigator Initiated Research (G1)	Faculty - Basic Scientist	Jamie Studts	1.04%	Existing	\$1,443.75	\$378.81
	Investigator Initiated Research (G1)	Staff - Research Associate	Kory Brinker	10.00%	Existing	\$4,103.19	\$1,033.99
3049025842	Investigator Initiated Research (G1)	Faculty - Basic Scientist	David Watt	1.00%	Existing	\$1,828.56	\$403.29
3048111390	Investigator Initiated Research (G1)	Lab Technician	Mamta Goswami	0.00%	Existing	\$55.00	\$4.87
	Investigator Initiated Research (G1)	Graduate Research Assistant	Nathaniel Holcomb	0.00%	Existing	\$135.58	\$12.00
					FYE Payroll Accruals	\$ (236.78)	\$ (20.00)
			<b>Total FTE</b>	<b>7.61</b>		<b>\$270,995.70</b>	<b>\$57,110.99</b>
3049024113	Clinical Trials (G3)	Clinical Research Assistant II	Emily Shardelow	28.50%	Existing	\$8,793.61	\$2,958.66
		Administrative Research Assistant	Joseph Alexander	70.00%	Existing	\$33,416.83	\$13,212.54
		Asst. Director for Clinical Studies	Kristine Damron	55.00%	Existing	\$46,264.21	\$13,068.98
		Data Management Specialist	Lara Sutherland	42.08%	Existing	\$27,199.05	\$8,940.06
		Clinical Research Assistant III	Melinda Dowden-Kruger	100.00%	Existing	\$54,981.12	\$17,566.49
		Clinical Research Assistant III	Michele Hughes	100.00%	Existing	\$60,064.57	\$18,581.17
		Student Employee	Ryan Haas	100.00%	Existing	\$416.00	\$36.81
		Clinical Director	Timothy Mullett	10.00%	Existing	\$39,900.00	\$7,767.63
					FYE Payroll Accruals	\$1,576.67	\$506.40
			<b>Total FTE</b>	<b>5.06</b>		<b>\$272,612.06</b>	<b>\$82,638.74</b>
3049024114	NCI-Designation (G4)	Faculty - Research	Cai Huang	75.00%	Existing	\$68,450.16	\$20,769.10
		Assistant Director of Administration	Carla Repass	73.00%	Existing	\$58,764.25	\$12,691.98
		Graduate Research Assistant	Congcong Xu	20.83%	Existing	\$4,122.14	\$49.46
		Graduate Research Assistant	Daniel Binzel	8.33%	Existing	\$1,987.78	\$23.86
		Assistant Director of Finance	Elisha Maxson	40.00%	Existing	\$27,884.58	\$9,374.37
		Graduate Research Assistant	Erfu Yan	100.00%	Existing	\$2,983.36	\$35.81
		Faculty - Informatics	Eric Durbin	14.85%	Existing	\$19,970.99	\$5,077.87
		Student Employee	Eric Gettler	100.00%	Existing	\$1,639.35	\$56.29
		Staff - Research Associate Senior	Garretson Epperly	35.00%	Existing	\$21,429.84	\$6,583.95
		Graduate Research Assistant	Hongran Yin	20.83%	Existing	\$4,122.14	\$49.46
		Faculty - Behavioral & Community Research	Jamie Studts	10.00%	Existing	\$10,436.64	\$2,426.71
		Staff - Administrative Research Assistant	Jennifer Dolly	100.00%	Existing	\$42,599.20	\$10,529.81
		Faculty - Research	Jing Li	100.00%	Existing	\$92,289.96	\$25,270.48
		Faculty - Biostatistics Core	Jinze Liu	30.00%	Existing	\$33,626.14	\$3,439.31
		Post-Doctoral Scholar	Mario Vieweger	25.00%	Existing	\$10,749.99	\$3,090.73
		Student Employee	Mary Wilson	41.67%	Existing	\$1,021.77	\$57.56
		Faculty - Research	Meenakshi Upreti	17.71%	Existing	\$15,312.45	\$4,458.56
		Faculty - Assistant Director of Research	Nathan Vanderford	25.00%	Existing	\$30,750.00	\$8,252.72
		Faculty - Research	Piotr Rychahou	34.32%	Existing	\$27,638.03	\$8,925.95
		Faculty - Research	Qingding Wang	47.57%	Existing	\$52,652.87	\$14,916.50
		Staff - Statistician	Quan Chen	56.00%	Existing	\$28,108.38	\$6,563.73
		Staff - Statistician Assitant	Rani Jayswal	29.00%	Existing	\$8,223.98	\$2,518.01
		Faculty - Informatics	Sally Ellingson	16.88%	Existing	\$13,733.20	\$4,076.42

Acct No	Initiatives by Goal	Role	Individual	FTE %	New/Existing	Salary	Fringe
		Graduate Research Assistant	Shaoying Wang	20.83%	Existing	\$5,206.08	\$62.48
		Faculty - Informatics	Tamas Gal	52.23%	Existing	\$4,068.41	\$1,298.21
		Faculty - Research	Yadi Wu	50.00%	Existing	\$42,073.92	\$12,374.23
		Post-Doctoral Scholar	Yi Shu	25.00%	Existing	\$9,574.90	\$2,653.58
		Graduate Research Assistant	Zhengyi Zhao	20.83%	Existing	\$5,206.08	\$62.48
					FYE Payroll Accruals	\$337.12	\$92.48
			<b>Total FTE</b>	<b>11.90</b>		<b>\$644,963.71</b>	<b>\$165,782.10</b>
3049024115	Administration (Gx)	Assistant Director of Finance	Elisha Maxson	30.00%	Existing	\$6,971.11	\$2,343.73
		Faculty - Assistant Director of Research	Nathan Vanderford	20.00%	Existing	\$24,600.00	\$6,602.14
			<b>Total FTE</b>	<b>0.50</b>		<b>\$31,571.11</b>	<b>\$8,945.87</b>
		<b>FISCAL YEAR 2016</b>	<b>Total</b>			<b>\$ 1,220,142.58</b>	<b>\$ 314,477.70</b>

Kentucky Lung Cancer Research Program  
University of Kentucky FY16 Capital Expenditures

Accounts	Initiatives by Goal	Equipment	Purchase Amount
3048109368	Investigator Initiated Research (G1)		\$0.00
3048109411			\$0.00
3048111390			\$0.00
3048110255			\$0.00
3048110274			\$0.00
3048110846			\$0.00
3048111498			\$0.00
3048111500			\$0.00
3048111854			\$0.00
3048112542			\$0.00
3048112384			\$0.00
3048112439			\$0.00
3048112440			\$0.00
3048112580			\$0.00
3048113028			\$0.00
3048113044			\$0.00
3048112949			\$0.00
3049025842		\$0.00	
		<b>Total</b>	<b>\$0.00</b>
3049024116	Early Detection ()		\$0.00
3049024117			\$0.00
		<b>Total</b>	<b>\$0.00</b>
3049024113	Clinical Trials (G3)		
		<b>Total</b>	<b>\$0.00</b>
3049024114	NCI Designation (G4)	Lab Equipment	\$7,896.99
		<b>Total</b>	<b>\$0.00</b>
xxxxx	Epidemiology (Gx)		
		<b>Total</b>	<b>\$0.00</b>
3049024115	Administration		\$0.00
		G1	
		G2	
		G3	
		G4	
		<b>Total</b>	<b>\$0.00</b>
xxxxx	Endowed Chair		
		<b>Total</b>	<b>\$0.00</b>
<b>TOTAL</b>			<b>\$0.00</b>



Cycle	Grant	UK Account #	Close Date	Investigator	Budget	Spent in Prior Fiscal Years	Personnel + Fringe	Travel	Operating Expenses	F&A costs	Total Costs	Balance
N/A	Evaluating Quality of Lung Cancer Screening Implementation	3048112949	6/30/2017	Brooks, Michael	\$ 28,248	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 28,248
N/A	KCTN Data Coordinator	3048111854	6/30/2017	Mullett, Tim	\$ 78,500	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 78,500
14	Information Extraction from Diagnostic Narratives to Improve Patient Recruitment Efforts for Lung Cancer Clinical Trials	3048113028 (replaces 3048112580)	6/30/2017	Kavuluru, Venkata	\$ 95,155	\$ -	\$ 24,144	\$ -	\$ -	\$ 2,414	\$ 26,558	\$ 68,597
14	Automated Eligibility Screening Approaches for Lung Cancer	3048112580	6/30/2016	Kavuluru, Venkata	\$ 54,845	\$ -	\$ 46,203	\$ -	\$ 3,656	\$ 4,986	\$ 54,845	\$ -
14	Biomarker Discovery by Interrogating Lung Cancer lipid Metabolome	3048112440	6/30/2017	Fan, Whei-Mei	\$ 150,000	\$ -	\$ 26,201	\$ -	\$ -	\$ 2,620	\$ 28,821	\$ 121,179
14	Scope of 3048112439	3049022582	6/30/2017	Watt, David	\$ 16,000	\$ -	\$ 2,232	\$ -	\$ 4,426	\$ 666	\$ 7,324	\$ 8,676
14	KLF4 as a novel biomarker and tumor suppressor in lung cancer	3048112439	6/30/2017	Liu, Chunming	\$ 134,000	\$ -	\$ 38,676	\$ -	\$ 5,155	\$ 4,383	\$ 48,214	\$ 85,786
14	Harnessing Advanced Genomic and Bioinformatics Technologies for in-depth Molecular Characterization of Lung Adenocarcinoma	3048112384	6/30/2017	Wang, Chi	\$ 150,000	\$ -	\$ 62,460	\$ -	\$ -	\$ 6,246	\$ 68,706	\$ 81,294
13	A Single-Arm Phase II study of thorascopic lung cancer staging with the use of intraoperative ultrasound at the time of definitive resection	3048102542	5/31/2017	Martin, Jeremiah	\$ 150,000	\$ -	\$ 8,896	\$ -	\$ -	\$ 890	\$ 9,786	\$ 140,214
13	Disseminating LCS through shared decision making: A web-based CE intervention for primary care providers	3048113044	3/31/2018	Studts, Jamie	\$ 150,000	\$ -	\$ 7,590	\$ -	\$ -	\$ 759	\$ 8,349	\$ 141,651
13	II Trial of Induction Chemotherapy and Low-Dose	3048111500	7/31/2017	Arnold, Susanne	\$ 150,000	\$ 13,721	\$ 11,676	\$ -	\$ -	\$ 1,168	\$ 12,844	\$ 123,435
13	Biomarkers for Carcinogenesis related to Tobacco	3048111498	6/30/2017	Izumi, Tadahide	\$ 150,000	\$ 55,499	\$ 39,851	\$ -	\$ 8,841	\$ 4,869	\$ 53,562	\$ 40,939
12	Automated Identification of Lung Cancer Patients Eligible for Clinical Trial Rec	3048110846	12/31/2015	Durbin, Eric	\$ 150,000	\$ 118,427	\$ 18,059	\$ -	\$ 3,655	\$ 2,172	\$ 23,886	\$ 7,688
12	Nucleotide excision repair and lung cancer in Appalachian Kentucky	3048110255	3/31/2016	Mellon, Isabel	\$ 150,000	\$ 110,840	\$ 32,781	\$ -	\$ 2,565	\$ 3,535	\$ 38,882	\$ 278

Cycle	Grant	UK Account #	Close Date	Investigator	Budget	Spent in Prior Fiscal Years	Personnel + Fringe	Travel	Operating Expenses	F&A costs	Total Costs	Balance
12	Optimization of Smoking Cessation Strategies in Community Cancer Programs for Newly	3048110274	3/31/2017	Valentino, Joe	\$ 240,000	\$ 37,240	\$ 9,386	\$ -	\$ 13,188	\$ 2,289	\$ 24,862	\$ 177,898
11	Building the infrastructure for a comprehensive lung cancer data source	3048111390	6/30/2015	Mellon, Isabel	\$ 25,754	\$ 25,788	\$ (49)	\$ -	\$ -	\$ (5)	\$ (54)	\$ 21
11	MRP2 expression: Regulation by arsenic and effects on treatment outcomes in lung cancer	3048109411	6/30/2015	Vore, Mary	\$ 100,000	\$ 99,903	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 97
11	Mechanism of Redox Injury	3048109368	6/30/2017	St Clair, Daret	\$ 73,344	\$ 51,592	\$ -	\$ -	\$ 3,293	\$ 329	\$ 3,622	\$ 18,130
<b>TOTALS</b>					<b>\$ 2,017,598</b>	<b>\$ 513,008</b>	<b>\$ 328,107</b>	<b>\$ -</b>	<b>\$ 44,779</b>	<b>\$ 37,321</b>	<b>\$ 410,206</b>	<b>\$ 1,094,383</b>

**Kentucky Lung Cancer Research Program  
Annual Report FY2016**

**INSTITUTION:** James Graham Brown Cancer Center, University of Louisville  
**Prepared By:** Diane K. Konzen  
**SUBMITTED BY:** Diane K. Konzen  
**DATE:** August 17, 2016

**Kentucky Lung Cancer Research Program  
FY2016**

	FROM STRATEGIC PLAN 2010	GOALS (Including Metrics)	Describe how endpoints have been met?	Challenges to attaining goals/revision of endpoints/timeframe?
<b>GOAL 1: Investigator Initiated Research (KRS 167.476(5)(a))</b>				
1a.	Recruit existing faculty in cancer research to focus on problems in the areas of tobacco control, lung cancer epidemiology, early detection/screening of lung cancer, and translational lung cancer research	Up to 5 projects per year	<ul style="list-style-type: none"> <li>• 5 new grants awarded for Cycle 15 (including two to new, externally recruited faculty members (PI's on one grant) and one new faculty member who was promoted from within (PI on one grant)</li> <li>• 10 active (KLCRP) projects (5 each from Cycles 14 and 15)</li> <li>• Cycle 16 funding will be announced in late August</li> <li>• Additional recruitment to lung cancer research is underway (6 junior faculty and 4 senior faculty at UofL are beginning work on lung cancer research; continuing lung cancer projects are creating new interest, especially among post-doctoral fellows and junior faculty - in both basic and clinical research) (In addition, see 1b., below)</li> </ul>	Limited scientific interest in this area (although it is growing); open ended
1b.	Recruit new faculty with interests and expertise in cancer that may be applied specifically to the lung cancer focus areas described above.	Open-ended	<ul style="list-style-type: none"> <li>• 3 new faculty were recruited to the JGBCC in FY2016 (two of whom as primary faculty, while one was a postdoctoral fellow at UofL): - Donghan Lee, Ph.D. (from Max Planck Institute, Göttingen, Germany) , - Joseph Kouokam, Ph.D. (from University of Louisville), and - John P. Wise, Sr., Ph.D. (from University of Southern Maine).</li> <li>• Additional recruitment is underway: including two faculty who will be recruited through a grant from the Leona M. and Harry B. Helmsley Charitable Trust; two faculty who are to be recruited through funds from the Kosair Charities; as well as the recruitment of three epidemiologists (who will round out, with one to lead, the Prevention &amp; Control Program)</li> </ul>	Limited expertise available nationally; open ended
1c.	Develop, mentor and focus early stage investigators/graduate students on lung cancer.	Open-ended	<ul style="list-style-type: none"> <li>• 6 junior investigators, 3 postdoctoral fellows and 4 UofL graduate students were being mentored on lung cancer in FY2016</li> <li>• In addition, from various schools in the region, 17 high school research interns and 16 college undergraduate summer research interns were mentored in lung cancer in FY2016</li> </ul>	Limited investigators available to mentor in lung cancer; open-ended
1d.	Support a robust research portfolio in lung cancer at/between each University.	Up to 5 projects/year; spread across disciplines	<ul style="list-style-type: none"> <li>• Ten active projects (funded by KLCRP)</li> <li>• Thirty cancer grants were received in FY2016: National Cancer Institute grants were awarded to 4 faculty [Beverly, Frieboes, Miller, and Yaddanapudi]; thirteen National Institutes of Health (NIH) grants to 12 faculty [Arteel, Chen, Deng, Kosiewicz, Rai, Roman, Schaner-Tooley, Shirwan, States, Taylor, Tse, and Yan (2)]; plus twelve additional grants were awarded (1 x Elsa U. Pardee Foundation; 1 x Cemptra Pharmaceuticals; 1 x Young Survival Coalition; 1 x Research to Prevent Blindness; 1 x the Biomedical Development Corporation, 1 x Hyundai Hope on Wheels; 1 x Regulation Directive Medical Physics LLC; 1 x the Veterans Administration Medical Center; 1 x the US-Israel Binational Ag &amp; Dev Fund; and 3 from the KY Science &amp; Engineering Forum) - 21 of these grants were pursuant to Investigator-Initiated grants and nine were independent of the program</li> <li>• 469 scientific papers were published by JGBCC investigators - 42 resulting from Investigator-Initiated grants and 6 resulting from Early Detection pilot projects</li> </ul>	Limited scientific appeal; open ended; low funding rate from the NCI

20

**Kentucky Lung Cancer Research Program  
FY2016**

	<b>FROM STRATEGIC PLAN 2010</b>	<b>GOALS (Including Metrics)</b>	<b>Describe how endpoints have been met?</b>	<b>Challenges to attaining goals/revision of endpoints/timeframe?</b>
1e.	Develop intra-programmatic linkages within/between UofL/UK Cancer Centers	Encourage collaborative projects in each Cycle and/or in national funding each year	<ul style="list-style-type: none"> <li>• One National Cancer Institute (NCI) grant funded which includes an investigator from the UK/Markey; as well as one to UK/Markey which includes a UofL investigator</li> <li>• UofL JGBCC faculty continue to invite UK/Markey speakers to present at and attend seminar programs and vice versa</li> <li>• New joint research projects continue to be discussed and preliminary research undertaken both internally and with UK/Markey researchers</li> <li>• 2 joint projects are being discussed for potential submission to this Cycle [Cycle 16] of KLCRP funding, and one project is being discussed for potential submission to the National Institutes of Health within the next year</li> </ul>	Distance between institutions
1f.	Conduct annual scientists' seminars and separate poster sessions to share research results among funded KLCRP scientists	seminar exchange orogram between UK and UofL investigators	Seminars as investigators are available to talk at scheduled events Scientist Seminar to be held at Markey this October; plan to hold these Seminars annually alternately at Markey Cancer Center and Brown Cancer Center	Distance between institutions
<b>Goal 2: Research in Early Detection &amp; Prevention (KRS 167.476 (5)(a))</b>				
2a.	Conduct screening and early detection research using available and applicable tools in key geographic areas of Ky	Ongoing	<ul style="list-style-type: none"> <li>• The old mobile mammography van, which went all over the state of KY, has been replaced with a new van that allows screening for 7 forms of cancer: breast, cervical, colon, lung, prostate, skin and head/neck.</li> <li>• Project testing radiation exposure and ways to combat same and their consequences continues [funded by the National Aeronautics &amp; Space Administration (NASA)]. This project has spawned a number of new research projects in and associated with the Brown Cancer Center</li> <li>• 3 additional active projects (one funded by KLCRP; and 2 by the NIH on two separate grants)</li> <li>• 4 additional projects are in the feasibility phase</li> </ul>	Limited expertise available; open ended
2b.	Develop/conduct studies in dissemination and implementation research of lung cancer screening	Open ended; any is good, more is better	• 1 project is being planned and a funding application will be submitted to the National Institutes of Health within the next year	
2c.	Expand and refine methods for risk-factor delineation	Ongoing	• 2 projects are underway (but as yet unfunded)	Overwhelming risk factors of smoking
2d.	Validate the use of methods for lung cancer screening	Ongoing	<ul style="list-style-type: none"> <li>• 1 project (unfunded as yet) by Garbett [Use of plasma thermograms for the diagnosis of very early lung cancer]</li> <li>• Development of a radio-labeled aptamer as a diagnostic imaging agent</li> </ul>	CT too costly for routine application and results disputed; need improved method(s)

**Kentucky Lung Cancer Research Program  
FY2016**

	<b>FROM STRATEGIC PLAN 2010</b>	<b>GOALS (Including Metrics)</b>	<b>Describe how endpoints have been met?</b>	<b>Challenges to attaining goals/revision of endpoints/timeframe?</b>
2e.	Identify and develop methodologies for lung cancer prevention	Ongoing	<p>Multiple projects are underway, including:</p> <ul style="list-style-type: none"> <li>• Development of a novel 'vaccine' against lung cancer (this project received a currently active R21 grant from the National Cancer Institute, and the investigators are working with and organizing a consortium with researchers at Harvard University to continue the work and take it to the next level)</li> <li>• Development of a lung cancer 'breath test' continues using identified biomarkers for very early detection of the disease (a V Foundation grant was received for this project)</li> <li>• Identification of a potential new lung cancer biomarker (work continues)</li> <li>• Correlation of the presence of human papillomavirus (HPV) with the onset/presence of lung cancer</li> </ul>	Overwhelming number of smoking risk factors
2f.	Maintain and expand the biospecimen repository for use by lung cancer researchers	Ongoing; more is better	<ul style="list-style-type: none"> <li>• Reorganization and expansion of the Biorepository continues</li> <li>• 608 specimens from 56 lung cancer participants were collected and available in FY16 (where lung cancer is the primary site) <ul style="list-style-type: none"> <li>- 20 malignant tumors</li> <li>- 18 normal adjacent tissues</li> <li>- 25 whole blood samples</li> <li>- 399 plasma samples</li> <li>- 116 serum samples</li> <li>- 16 buffy coats</li> <li>- 6 FFPE blocks</li> <li>- 8 bronchial lavages</li> </ul> </li> <li>• 219 lung cancer samples were distributed <ul style="list-style-type: none"> <li>- 9 malignant tumors</li> <li>- 8 normal adjacent tissues</li> <li>- 25 whole blood samples</li> <li>- 163 plasma samples</li> <li>- 8 bronchial lavages</li> <li>- 6 FFPE blocks [FFPE = formaldehyde fixed-paraffin embedded]</li> </ul> </li> </ul>	Limited access to lung tissue; no surgery for advanced stage disease.
2g.	Capitalize on partnerships with regional and local hospitals and clinics to build an early detection network where research is integral to the relationship	Target at least 5 participating institutions	<ul style="list-style-type: none"> <li>• 3 active sites (UofL)</li> <li>• KCTN (see UK report)</li> <li>• JGBCC partnered with Kentucky One Health, greatly expanding (27) the number of potential sites available throughout the state; in addition a second site for the JGBCC opened late last fiscal year at Jewish Northeast)</li> </ul>	Limited tools available; developing partnerships
2h.	Link prevention and early detection studies	Any is good, more is better	<ul style="list-style-type: none"> <li>• Majority of education &amp; smoking cessation courses and studies are provided through the KY Cancer Program, and many are held each year</li> <li>• a major study is under discussion, but no project implemented to date</li> </ul>	

**Kentucky Lung Cancer Research Program  
FY2016**

	FROM STRATEGIC PLAN 2010	GOALS (Including Metrics)	Describe how endpoints have been met?	Challenges to attaining goals/revision of endpoints/timeframe?
<b>Goal 3: Kentucky Clinical Trials Network (KRS 167.476 (5)(b))</b>				
3a.	Increase number of Kentuckians with access to and participating in lung cancer clinical trials	<ul style="list-style-type: none"> <li>Identify studies based on feasibility of patient populations seen</li> <li>Increase program accrual</li> <li>Expand number of Kentucky counties with patients seen</li> </ul>	<ul style="list-style-type: none"> <li>33 active clinical trials in lung cancer are available at the JGBCC</li> <li>&gt;45% of JGBCC patients were accrued to available lung cancer trials</li> <li>a new location was added late in the last fiscal year (Medical Center Jewish Northeast), broadening the area in which JGBCC trials are available</li> <li>Working to make all JGBCC trials available through the KCTN</li> <li>Study on the avoidance of clinical trials by some sectors of the population (especially in Kentucky) is in the feasibility/discussion phase</li> </ul>	While many trials are available, identifying those appropriate to the KY population is more difficult. Despite trial availability, not all appropriate patients offered opportunity to participate in a trial by treating clinicians. Obstacles reflect national problem of time availability in clinics and lack of support staff.
3b.	Develop and maintain a critical mass of trained professional staff to support multi-site clinical trials	<ul style="list-style-type: none"> <li>Increase data management &amp; project management support for cancer center</li> <li>Increase number of clinical faculty in the area</li> </ul>	<ul style="list-style-type: none"> <li>Biostatistics Core now has 3.5 FTE biostatisticians</li> <li>JGBCC has attained a critical mass of trained professional staff; however, as the number of patients continues to grow, recruitment for additional positions is underway (with the addition of two additional clinical sites this is an on-going process)</li> </ul>	Availability of trained professionals in this area is limited nationally
3c.	Offer and manage industry-sponsored lung cancer clinical trials through the Network.	See UK report	JGBCC continues to develop, coordinate and participate in, clinical trials to be made available to all patients who qualify for them	
3d.	Identify and develop investigator-initiated clinical trials at both UK and UofL that can be offered to patients in diverse settings.	See UK report	JGBCC continues to develop investigator-initiated clinical trials to be made available to all patients who qualify for them. A couple examples follow: <ul style="list-style-type: none"> <li>Beta-glucan's Immuno-modulatory Effect on Non-Small Cell Lung Cancer</li> <li>Protocol for the Cancer Database and Specimen Repository at the JGBCC</li> <li>Micro-Nano Device for Exhaled Breath Analysis</li> <li>Optimization of Smoking Cessation Strategies in Community Cancer Programs for Newly Diagnosed or Recurrent Lung and Head and Neck Cancer Patients (UK) and at least one other trial is planned in lung cancer for 3rd quarter FY17</li> </ul>	Limited number of Investigator-Initiated Trials
3e.	Continually improve the Network's services with input from practicing KY physicians.	See UK report	Input received continuously, especially from our partner institutions, and is discussed/implemented	
<b>Goal 4: NCI-Designation as Cancer Centers (KRS 164.476 (5)(c))</b>				
4a.	Expand the base of cancer research expertise, particularly in translational research, with the recruitment of both promising young scientists and established investigators working at the front lines of cancer research	Recruit both promising young and proven mature scientists	<ul style="list-style-type: none"> <li>Three new faculty recruited in FY2016 (1 with primary appointment in another department), all of whom are members in the four research programs</li> <li>2 post-doctoral fellows were retained and promoted to junior faculty positions (with another to be promoted in early FY17)</li> <li>JGBCC continues to offer high school (17 in FY16) and early college undergraduate students (16 in FY16) an opportunity to work on and develop an interest in lung cancer research</li> </ul>	Funding for salary support and recruitment packages, and - especially in the two years - availability of laboratory space

**Kentucky Lung Cancer Research Program  
FY2016**

	FROM STRATEGIC PLAN 2010	GOALS (Including Metrics)	Describe how endpoints have been met?	Challenges to attaining goals/revision of endpoints/timeframe?
4b.	Develop and maintain diverse cancer research programs with a high degree of inter- and intra- team collaboration	Develop/maintain at least 3 NCI-designable program areas	<ul style="list-style-type: none"> <li>• After review and discussion, the 'developing' developmental biology program was folded into an existing program; thus there are 4 mature program areas with continued focused recruitment into each. JGBCC members in these programs are responsible for the following:</li> <li>• In addition to the resubmission of the multi-project P01 submitted by Mitchell et al. in this fiscal year, an additional multi-project program P01, an application specific to lung cancer, is under discussion for submission to the National Cancer Institute</li> <li>• A SPOR multi-project clinical &amp; basic research funding application is under discussion for submission to the NIH</li> </ul>	Critical mass of faculty with NCI funding
4c.	Provide and promote interactive research opportunities	30% of grants and publications collaborative; grow NCI funding	<ul style="list-style-type: none"> <li>• 37% of funded grants to JGBCC faculty are interactive</li> <li>• 42.9% of JGBCC faculty publications are interactive</li> <li>• The Center Director, all faculty and the program leaders are involved</li> <li>• UofL is the <i>only</i> institution to have been awarded 'the trifecta' of grants to support the translation of research into viable commercial products:               <ul style="list-style-type: none"> <li>- JGBCC at UofL is one of only 3 US institutions selected as a Research Evaluation &amp; Commercialization Hub (REACH) by the NIH (3/2015), which will provide \$3 million over 3 years, matched by \$3.1 million from UofL, to significantly advance UofL's ability 'to take a great idea to the marketplace'</li> <li>- UofL received the Coulter Translational Research Partnership (2011), a \$5 million grant to fund promising projects in order to move innovative technologies to clinical application through commercialization, and</li> <li>- UofL received the \$300,000 three-year National Science Foundation grant (4/2015) to create an Innovation Corps (I-Corps) Site to strengthen the innovation ecosystem in the region and nationally through networking and training opportunities</li> </ul> </li> </ul>	Availability of faculty time to develop collaborations
4d.	Offer expanded innovative clinical trials, building on combined research underpinnings of the two centers	Accrue at least 10% of patients to innovative clinical studies	<ul style="list-style-type: none"> <li>• &gt;45% of JGBCC patients were accrued to lung cancer trials in 2015</li> <li>• Continuing move to expand the number of affiliates (with two added in the last fiscal year) including the newly opened (late in FY15) JGBCC at the Jewish Northeast Medical Center</li> <li>• Centralized the clinical research office</li> <li>• One investigator (KLCRP funded in the early phase) received federal approval for and continues a clinical trial on a drug he discovered</li> <li>• An additional d KLCRP funded investigator is looking toward federal approval to implement a clinical trial in the next fiscal year</li> <li>• Two investigator-initiated funded grants are moving toward clinical trials</li> </ul>	Insufficient clinical faculty for number of clinical trials - clinicians are being recruited to a number of positions; an emphasis on clinical research continues



**Financial Report  
Annual FY 2016  
07/01/2015 - 06/30/16  
University of Louisville**

	<b>Total Revenue FY2000-2015</b>	<b>ExpendituresFY20 00-2015</b>	<b>Encumbrances</b>	<b>Balance</b>
Investigator-Initiated Grants	15,803,481.16	13,979,733.14	\$ 1,574,411.16	\$ <b>249,336.86</b>
NCI Designation	8,479,982.02	7,015,927.91	\$ 1,255,465.00	\$ 208,589.11
Early Detection	2,176,739.00	1,201,395.89	\$ -	\$ 975,343.11
Fellows	1,545,172.45	1,090,354.96	\$ 225,000.00	\$ 229,817.49
Clinical Trials	1,799,996.56	\$ 1,721,872.24	\$ 78,124.32	\$ -
Administration	1,341,750.62	\$ 947,501.53	\$ 168,545.00	\$ 225,704.09
<b>TOTALS</b>	<b>\$ 31,147,121.81</b>	<b>\$ 25,956,785.67</b>	<b>\$ 3,301,545.48</b>	<b>\$ 1,888,790.66</b>

Kentucky Lung Cancer Research Program  
FY 2014-2015

		Qtr 1 FY2016 Report (7/1/15 - 9/30/15)								
			PERSONNEL	FRINGE BENEFITS	TRAVEL	OPERATING	CAPITAL OUTLAY	F&A	Total Expense	Balance
KLCR Program Title	Total Revenue FY2000-2016	Expenditures FY2000-2015								
Investigator Initiated Grants	15,803,481.16	13,337,622.07	\$ 83,261.90	\$ 26,373.36	\$ 347.89	\$ 21,200.33	\$ -	\$ 12,728.49	\$ 143,911.97	2,321,947.12
NCI Designation	8,479,982.02	6,289,046.78	\$ 67,676.03	\$ 20,142.04	\$ 1,265.60	\$ 10,323.02	\$ -	\$ -	\$ 99,406.69	2,091,528.55
Early Detection	2,176,739.00	1,132,895.89					\$ -	\$ -	\$ -	1,043,843.11
Fellows	1,545,172.45	1,039,744.93	\$ 21,330.75	\$ 8,002.81	\$ -	\$ -	\$ -	\$ -	\$ 29,333.56	476,093.96
Clinical Trials	1,799,996.56	1,534,294.14	\$ 36,368.93	\$ 11,125.76	\$ -	\$ -	\$ -	\$ -	\$ 47,494.69	218,207.73
Administration	1,341,750.62	814,834.06	\$ 25,432.58	\$ 6,992.43	\$ -	\$ -	\$ -	\$ -	\$ 32,425.01	494,491.55
<b>TOTALS</b>	<b>31,147,121.81</b>	<b>24,148,437.87</b>	<b>234,070.19</b>	<b>72,636.40</b>	<b>1,613.49</b>	<b>31,523.35</b>	<b>-</b>	<b>12,728.49</b>	<b>352,571.92</b>	<b>6,646,112.02</b>

		Qtr 2 FY2016 Report (10/1/15 - 12/31/15)								
			PERSONNEL	FRINGE BENEFITS	TRAVEL	OPERATING	CAPITAL OUTLAY	F&A	Total Expense	Balance
KLCR Program Title	Total Revenue FY2000-2016	Expenditures FY2000-Qtr 1 2016								
Investigator Initiated Grants	15,803,481.16	13,481,534.04	\$ 67,600.77	\$ 19,169.38	\$ 1,295.81	\$ 44,060.00		\$ 13,212.65	\$ 145,338.61	2,176,608.51
NCI Designation	8,479,982.02	6,388,453.47	\$ 81,163.54	\$ 24,142.81	\$ 1,455.63	\$ 19,600.03	\$ 55,922.89		\$ 182,284.90	1,909,243.65
Early Detection	2,176,739.00	1,132,895.89							\$ -	1,043,843.11
Fellows	1,545,172.45	1,069,078.49	\$ 11,311.50	\$ 3,919.98					\$ 15,231.48	460,862.48
Clinical Trials	1,799,996.56	1,581,788.83	\$ 36,218.40	\$ 11,102.65					\$ 47,321.05	170,886.68
Administration	1,341,750.62	847,259.07	\$ 25,432.60	\$ 6,369.58		\$ 1,000.00			\$ 32,802.18	461,689.37
<b>TOTALS</b>	<b>31,147,121.81</b>	<b>24,501,009.79</b>	<b>221,726.81</b>	<b>64,704.40</b>	<b>2,751.44</b>	<b>64,660.03</b>	<b>55,922.89</b>	<b>13,212.65</b>	<b>422,978.22</b>	<b>6,223,133.80</b>

		Qtr 3 FY2016 Report (1/1/16 - 3/31/16)								
			PERSONNEL	FRINGE BENEFITS	TRAVEL	OPERATING	CAPITAL OUTLAY	F&A	Total Expense	Balance
KLCR Program Title	Total Revenue FY2000-2016	Expenditures FY2000-Qtr 2 2016								
Investigator Initiated Grants	15,803,481.16	13,626,872.65	\$ 57,906.62	\$ 16,029.65		\$ 84,254.47		\$ 15,819.13	\$ 174,009.87	2,002,598.64
NCI Designation	8,479,982.02	6,570,738.37	\$ 140,703.86	\$ 37,811.35	\$ 190.87	\$ 36,043.71	\$ 1,837.50		\$ 216,587.29	1,692,656.36
Early Detection	2,176,739.00	1,132,895.89							\$ -	1,043,843.11
Fellows	1,545,172.45	1,084,309.97	\$ 4,488.69	\$ 1,556.30					\$ 6,044.99	454,817.49
Clinical Trials	1,799,996.56	1,629,109.88	\$ 34,384.22	\$ 11,079.84					\$ 45,464.06	125,422.62
Administration	1,341,750.62	880,061.25	\$ 22,438.12	\$ 7,006.54					\$ 29,444.66	432,244.71
<b>TOTALS</b>	<b>31,147,121.81</b>	<b>24,923,988.01</b>	<b>259,921.51</b>	<b>73,483.68</b>	<b>190.87</b>	<b>120,298.18</b>	<b>1,837.50</b>	<b>15,819.13</b>	<b>471,550.87</b>	<b>5,751,582.93</b>

		QTR 4 FY2016 Report (04/01/16 - 6/30/16)								
			PERSONNEL	FRINGE BENEFITS	TRAVEL	OPERATING	CAPITAL OUTLAY	F&A	Total Expense	Balance
KLCR Program Title	Total Revenue FY2000-2016	Expenditures FY2000-Qtr 3 2016								
Investigator Initiated Grants	15,803,481.16	13,800,882.52	\$ 98,964.58	\$ 27,517.64	\$ 3,242.10	\$ 33,157.39		\$ 15,968.91	\$ 178,850.62	1,823,748.02
NCI Designation	8,479,982.02	6,787,325.66	\$ 136,765.62	\$ 37,734.37	\$ 6,220.13	\$ 47,678.39	\$ 203.74		\$ 228,602.25	1,464,054.11
Early Detection	2,176,739.00	1,132,895.89					\$ 68,500.00		\$ 68,500.00	975,343.11
Fellows	1,545,172.45	1,090,354.96							\$ -	454,817.49
Clinical Trials	1,799,996.56	1,674,573.94	\$ 36,218.44	\$ 11,079.86					\$ 47,298.30	78,124.32
Administration	1,341,750.62	909,505.91	\$ 22,688.67	\$ 7,556.95		\$ 7,750.00			\$ 37,995.62	394,249.09
<b>TOTALS</b>	<b>31,147,121.81</b>	<b>25,395,538.88</b>	<b>294,637.31</b>	<b>83,888.82</b>	<b>9,462.23</b>	<b>88,585.78</b>	<b>68,703.74</b>	<b>15,968.91</b>	<b>561,246.79</b>	<b>5,190,336.14</b>

Kentucky Lung Cancer Research Program  
FY 2014-2015

			PERSONNEL	FRINGE BENEFITS	TRAVEL	OPERATING	CAPITAL OUTLAY	F&A	Total Expense	Balance
--	--	--	-----------	-----------------	--------	-----------	-------------------	-----	---------------	---------

		Annual FY2016 Report (7/1/15 - 6/30/16)										
KLCR Program Title	Total Revenue FY2000-2016	Expenditures FY2000-2016	PERSONNEL	FRINGE BENEFITS	TRAVEL	OPERATING	CAPITAL OUTLAY	F&A	Total Expense	Encumbrances	Balance	
Investigator Initiated Grants	15,803,481.16	13,979,733.14	\$ 307,733.87	\$ 89,090.03	\$ 4,885.80	\$ 182,672.19	\$ -	\$ 57,729.18	\$ 642,111.07	\$ 1,574,411.16	\$ 249,336.86	
NCI Designation	8,479,982.02	7,015,927.91	\$ 426,309.05	\$ 119,830.57	\$ 9,132.23	\$ 113,645.15	\$ 57,964.13	\$ -	\$ 726,881.13	\$ 1,255,465.00	\$ 208,589.11	
Early Detection	2,176,739.00	1,201,395.89	\$ -	\$ -	\$ -	\$ -	\$ 68,500.00	\$ -	\$ 68,500.00	\$ -	\$ 975,343.11	
Fellows	1,545,172.45	1,090,354.96	\$ 37,130.94	\$ 13,479.09	\$ -	\$ -	\$ -	\$ -	\$ 50,610.03	\$ 225,000.00	\$ 229,817.49	
Clinical Trials	1,799,996.56	\$ 1,721,872.24	\$ 143,189.99	\$ 44,388.11	\$ -	\$ -	\$ -	\$ -	\$ 187,578.10	\$ 78,124.32	\$ -	
Administration	1,341,750.62	947,501.53	\$ 95,991.97	\$ 27,925.50	\$ -	\$ 8,750.00	\$ -	\$ -	\$ 132,667.47	\$ 168,545.00	\$ 225,704.09	
<b>TOTALS</b>	<b>31,147,121.81</b>	<b>25,956,785.67</b>	<b>1,010,355.82</b>	<b>294,713.30</b>	<b>14,018.03</b>	<b>305,067.34</b>	<b>126,464.13</b>	<b>57,729.18</b>	<b>1,808,347.80</b>	<b>\$ 3,301,545.48</b>	<b>\$ 1,888,790.66</b>	

**Kentucky Lung Cancer Research Program  
Personnel Report  
FY2016 Report (7/1/15- 6/30/16)**

Acct No	Initiatives by Goal	Role	Individual	FTE %	New/Existing	Salary	Fringe
GB150024A1	NCI -Designation						
		Postdoctoral Associate	Traci Kruer	100%	Existing	\$ 37,760.04	\$ 15,833.94
		Biostatistician	Jianmin Pan	77%	Existing	\$ 59,636.85	\$ 17,861.11
		Director Biostatistics	Shesh Rai	32%	Existing	\$ 60,469.19	\$ 11,704.76
		Research Scientist	David Ban	100%	New	\$ 36,974.66	\$ 8,281.83
		Tissue Biorepository Manager	Andrei Smolenkov	100%	Existing	\$ 61,883.04	\$ 20,426.13
		Biomedical Engineer	Christopher Worth	100%	Existing	\$ 63,314.04	\$ 20,404.74
		Graduate Research Assistant	Zinal Chheda	40%	New	\$ 13,047.62	\$ 1,534.50
		Research Technologist II	Cameron Conway	100%	New	\$ 12,616.89	\$ 3,949.96
		Research Scientist	Mark Doll	30%	New	\$ 10,266.42	\$ 3,149.09
		Graduate Research Assistant	Bindu Hegde	100%	New	\$ 4,000.00	\$ 443.00
		Associate Professor	Donghan Lee	25%	New	\$ 16,666.65	\$ 4,019.85
			<b>Total</b>			<b>\$ 376,635.40</b>	<b>\$ 107,608.91</b>
GB150024	Administration				<b>Existing</b>		
		KLCRP Coordinator	Diane Konzen	35%	Existing	\$ 24,371.90	\$ 7,049.90
		Sr. Assoc. Director, Administration	Milton Pierson	25%	Existing	\$ 40,973.51	\$ 9,176.04
		KLCRP Financial Coordinator	Courtney Jenkins	74%	New	\$ 13,556.60	\$ 5,252.69
		KLCRP Financial Coordinator	Caroline Wheat	50.00%	New	\$ 21,224.56	\$ 6,446.87
			<b>Total</b>			<b>\$ 100,126.57</b>	<b>\$ 27,925.50</b>
GB150024B1	Early Detection Program		<b>None</b>				
						\$ -	\$ -
						\$ -	\$ -
			<b>Total</b>			<b>\$ -</b>	<b>\$ -</b>
GB150024E1	Lung Fellowship Program						
		Fellow	Sobha Bodduluri	100%	Existing	\$ 10,019.25	\$ 4,077.04
		Fellow	Arokyia Papu John	100%	Existing	\$ 27,111.69	\$ 9,402.05
						\$ -	\$ -
						\$ -	\$ -
						\$ -	\$ -
			<b>Total</b>			<b>\$ 37,130.94</b>	<b>\$ 13,479.09</b>
GB150024C1	Clinical Trial Program						
		Mgr., Research Nursing	Karen Carter	50%	Existing	\$ 54,282.90	\$ 14,508.49
		Lab Research Coordinator	Melissa Hall	50%	Existing	\$ 27,391.42	\$ 9,379.93
		Clinical Research Coordinator	Belma Kantardzic	50%	Existing	\$ 31,067.40	\$ 10,204.81
		Clinical Research Nurse	Jennifer Schoenbachler	50%	Existing	\$ 32,282.47	\$ 10,294.88
			<b>Total</b>			<b>\$ 145,024.19</b>	<b>\$ 44,388.11</b>
				<b>Annual</b>		<b>\$ 658,917.10</b>	<b>\$ 193,401.61</b>
				<b>FY 2016</b>		<b>\$ 852,318.71</b>	

## Investigator Initiated Grants

June 30, 2016

FY16 Expenses

Cycle	Grant	Uoof Account #	Close Date	Investigator	Budget	Previous Expense	Personnel + Fringe	Travel	Operating Expenses	F&A costs	Commitments	Total Costs	Balance
7	Effect of Estrogen on Polycyclic Aromatic Hydrocarbon-Mediated	OGMB071063	11/30/2013	Gupta, Ramesh	\$ 150,000	\$ 144,876	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 5,123.73
9	Visualization of Hypoxias and Angiogenesis	OGMB091526	10/31/2011	Li, Xiao-feng	\$ 150,000	\$ 145,773	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 4,226.53
9	Novel Small Molecule Inhibitors of Choline Kinase	OGMB091527	10/31/2011	Clem, Brian	\$ 150,000	\$ 149,425	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 574.56
9	Role of GPR30m: A Novel Estrogen Receptor G-Protein	OGMB091529	10/31/2011	Jala, Venkatakrishna	\$ 150,000	\$ 150,390	\$ -	\$ -	\$ -	\$ (390)	\$ -	\$ (390)	\$ (0.01)
9	The Role of Novel Ras Effecto, RASSF2	OGMB091531	10/31/2011	Donninger, Howard	\$ 75,000	\$ 74,641	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 358.96
9	Identification and Testing of Small Molecule Inhibitor to Sphingosine Kinase I	OGMB091534	10/31/2011	Wattenberg, Brian	\$ 75,000	\$ 72,052	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 2,948.32
9	Exosomal microRNA Profiles for Diagnosis	OGMB091547	10/31/2011	Gercel-Taylor, Cicek	\$ 150,000	\$ 103,720	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 46,279.54
10	Combined Orally Administered Beta-Glucan	OGMB101369	11/30/2012	Yan, Jun and Kloecker, Goetz	\$ 150,000	\$ 149,040	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 959.74
10	The Role of Rev-1 in Carcinogen induced Lung Cancer	OGMB101372	11/30/2012	McGregor, W. Glenn and States, J. Christopher	\$ 150,000	\$ 150,000	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
10	Stable isotope-resolved Metabolomics	OGMB101380	11/30/2012	Fan, Teresa	\$ 150,000	\$ 117,053	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 32,947.46
10	Controlled Inhibition of the Glycolytic Pathway	OGMB101383	11/30/2012	Chesney, Jason	\$ 150,000	\$ 144,693	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 5,307.15
10	Activation of the Par-4 Extrinsic Pathway	OGMB101407	11/30/2012	Gupta, Ramesh	\$ 150,000	\$ 146,413	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 3,587.34
11	The Role of MiR-301a in NF-kB Activation and Lung Cancer	OGMB120493	4/30/2014	Li, Yong	\$ 150,000	\$ 144,304	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 5,696.00
11	New Approaches for Eliminating Lung Cancer	OGMB120510	4/30/2014	Yaddanapudi, Kavitha	\$ 150,000	\$ 149,775	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 225.26
11	Activating Bax as a Therapeutic Strategy	OGMB120516	5/1/2012	Li, Chi	\$ 150,000	\$ 92,890	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 57,109.91
11	Beta-glucan Modulates Differentiation and Function	OGMB120517	7/1/2012	Ding, Chaulin	\$ 150,000	\$ 150,274	\$ -	\$ -	\$ -	\$ (274)	\$ -	\$ (274)	\$ 0.35
11	Targeting Sphingolipid Metabolism in Lung Cancer	OGMB120518	4/30/2014	Wattenberg, Brian	\$ 150,000	\$ 149,228	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 771.62
12	Small Molecule Inhibitors of Pro-Inflammatory Cytokines	OGMB130366	3/1/2013	Donninger, Howard	\$ 150,000	\$ 64,626	\$ 11,724	\$ 161	\$ 64,137	\$ 7,602	\$ -	\$ 83,625	\$ 1,748.87
12	Metabolic Stress Adaptation by MIF Family Members	OGMB130397	3/1/2013	Mitchell, Robert	\$ 150,000	\$ 149,917	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 82.56
12	Tight Junction Protein, Claudin 9 as Novel Mediator	OGMB130407	3/1/2013	Sharma, Rajesh	\$ 150,000	\$ 74,075	\$ 25,789	\$ 1,379	\$ 10,145	\$ 3,730	\$ -	\$ 41,043	\$ 34,881.63
12	Exploiting the Stressed Out Nature of Cancer Cells	OGMB130409	3/1/2013	Bates, Paula	\$ 150,000	\$ 143,019	\$ 4,007	\$ -	\$ 2,215	\$ 622	\$ -	\$ 6,844	\$ 136.65
12	Regulation of MicroRNA's in Lung Adenocarcinomas	OICB130438	3/1/2013	Klinge, Carolyn	\$ 150,000	\$ 100,373	\$ 33,386	\$ -	\$ 5,998	\$ 3,938	\$ -	\$ 43,322	\$ 6,305.50
12	Investigation of the Role of PFKFB3 in EMT and Metastasis	OGMB130420	3/1/2013	Yalcin, Abdullah	\$ 150,000	\$ 52,830	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 97,169.76
13	The N-end Rule Ubiquitination Pathway as Novel Driver	OGMB140472	3/1/2014	Beverly, Levi	\$ 150,000	\$ 138,956	\$ 9,875	\$ -	\$ 273	\$ 1,015	\$ -	\$ 11,163	\$ (118.96)

Cycle	Grant	UofT Account #	Close Date	Investigator	Budget	Previous Expense	Personnel + Fringe	Travel	Operating Expenses	F&A costs	Commitments	Total Costs	Balance
13	Analysis of Cancer Metabolites in Exhaled Breath for Diagnosis	OGMB140460	3/1/2014	Fu, Xiao-An and Bousamra, Michael	\$ 150,000	\$ 47,602	\$ 55,673		\$ 10,206	\$ 6,588		\$ 72,467	\$ 29,931.30
13	Understanding the Prognostic significance of Circadian Disruption	OGMB140436	3/1/2014	Sephton, Sandie	\$ 150,000	\$ 62,305	\$ 31,577	\$ 116	\$ 19,455	\$ 5,115		\$ 56,263	\$ 31,432.49
13	Joint Probabilistic Models for Early Diagnosis of Malignant	OGMB140428	3/1/2014	El-Baz, Ayman	\$ 150,000	\$ 3,752	\$ 6,163			\$ 616		\$ 6,779	\$ 139,469.14
13	Co-targeting 6-Phosphofructo-2-Kinase Fructose 2,6 Bis	OGMB140456	3/1/2014	Telang, Sucheta	\$ 150,000	\$ 19,994	\$ 34,329		\$ 14,083	\$ 4,841		\$ 53,253	\$ 76,753.30
14	Transcription Factor c-MAF in Lung Cancer-associated Macrophages	OGMB150435	6/1/2015	Yan, Jun	\$ 150,000	\$ -	\$ 9,857		\$ 9,717	\$ 1,957		\$ 21,530	\$ 128,469.91
14	Targeting the Anaphase Promoting Complex as Lung Cancer Chemotherapy	OGMB150446	6/1/2015	States, J Christopher	\$ 150,000	\$ 2,214	\$ 12,548	\$ 3,229	\$ 6,327	\$ 2,166		\$ 24,271	\$ 123,515.11
14	Dietary Supplement Indole-3-Carbinol in Lung Cancer Therapy and Prevention	OGMB150463	6/1/2015	Zhou, Heshan Sam	\$ 150,000	\$ -	\$ 35,767		\$ 14,363	\$ 5,013		\$ 55,143	\$ 94,856.76
14	Naturally Occurring Methyltransferase Mutations and Their Role in Promoting Lung Cancer	OGMB150447	6/1/2015	Schaner-Tooley, Christine	\$ 150,000	\$ 9,151	\$ 68,339			\$ 6,834		\$ 75,173	\$ 65,676.26
14	Role of Neutrophils in Crystalline Silica-Mediated Lung Cancer Promotion	OGMB150494	6/1/2015	Bodduluri, Haribabu	\$ 150,000	\$ -	\$ 52,722		\$ 25,282	\$ 7,801		\$ 85,805	\$ 64,194.86
15	Novel small molecule inhibitors of the Ras Oncoprotein for Lung cancer	OGMB160425	6/1/2016	Clark, Geoffrey	\$ 150,000		\$ 2,696		\$ 474	\$ 317		\$ 3,487	\$ 146,513.01
15	Regulation of Glucose Utilization by Estradiol in Lung Cancer	OGMB160444	6/1/2016	Imbert-Fernandez, Yoannis	\$ 150,000	\$ -	\$ 1,017			\$ 102		\$ 1,119	\$ 148,880.89
15	Characterization of AF1q in Carbon Nanotubes (CNT) Induced Lung Cancer	OGMB160465	6/1/2016	Tse, William	\$ 150,000	\$ -						\$ -	\$ 150,000.00
15	In vivo investigation of particulate $\beta$ -glucan in lung cancer mouse model	OGMB160514	6/1/2016	Guo, Haixun	\$ 150,000	\$ -	\$ 1,356			\$ 135		\$ 1,491	\$ 148,508.82
15	Inhaled IL-10 for prevention and therapy of lung cancer	OGMB160490	6/1/2016	Li, Qingsheng	\$ 150,000	\$ -							\$ 150,000.00
<b>TOTALS</b>					<b>\$ 5,550,000.00</b>	<b>\$ 3,103,361.80</b>	<b>\$ 396,823.91</b>	<b>\$ 4,885.80</b>	<b>\$ 182,675.19</b>	<b>\$ 57,728.98</b>	<b>\$ -</b>	<b>\$ 642,113.88</b>	<b># \$ 1,804,524.32</b>

**Kentucky Lung Cancer Research Program  
Governance Board  
August 31, 2016**

**Lung Cancer Symposium Award**

**ACTION:** The Board will recommend and approve the name of the Lung Cancer Symposium Award.

During the June 8, 2016 Lung Cancer Board meeting, an award was established to be presented at the Lung Cancer Symposium to a legislator who was key in creating the lung cancer research program. It was suggested and approved that the inaugural award be presented to Tim Shaughnessy with the name of the award to be decided upon at the August 31, 2016 meeting.

### KLCRP Symposium Budget

Personnel	\$3,063
Symposium Supplies	\$200
Abstract Book Printing	\$450
Award	\$250
Poster Presentation Material	\$1,900
Symposium Food	\$2,637
Speaker fees	\$1,500
<b>Total Costs</b>	<b>\$10,000</b>





## **AGENDA**

**University of Kentucky Markey Cancer Center and University of Louisville Brown Cancer Center  
Lung Cancer Symposium**

**October 15, 2016**

**WT Young Library, University of Kentucky**

<b>8:30 a.m. – 9:00 a.m.</b>	<b>Registration and Poster Setup</b>
<b>9:00 a.m. – 9:05 a.m.</b>	<b>Welcome</b>
<b>9:05 a.m. – 10:05 a.m.</b>	<b>Lung Cancer Research at Markey*</b>
<b>10:05 a.m. – 10:15 a.m.</b>	<b>Break</b>
<b>10:15 a.m. – 11:15 a.m.</b>	<b>Lung Cancer Research at Brown*</b>
<b>11:15 a.m. – 12:30 p.m.</b>	<b>Poster Session</b>
<b>12:30 p.m. – 1:30 p.m.</b>	<b>Lunch</b>
<b>1:30 p.m. – 2:00 p.m.</b>	<b>Awards</b>
<b>2:00 p.m. – 3:00 p.m.</b>	<b>Keynote Speaker</b> <b>John D. Minna, MD</b> <b>Professor, Internal Medicine and Pharmacology</b> <b>Director, Hamon Center for Therapeutic Oncology Research</b>  <b>“Molecular Pathogenesis of Lung Cancer with Translation to the Clinic”</b>
<b>3:00 p.m. – 3:15 p.m.</b>	<b>Wrap-up</b>

**\*Presentations given by three research groups for a total of 20 minutes each (presentations and questions).**

## Expert care, close to home helped save Vickie's life

Vickie Duff experienced a cough for months and after several treatments without improvement, she knew something more serious was happening.

She met with a physician who recommended a chest X-ray which led to additional tests and referral to another physician. The examinations confirmed Duff's worst fears – she had stage III lung cancer.

She sought multiple opinions about what to do next. With the thoughtful guidance of her cancer doctor, she opted to have surgery to remove the cancer in her lungs.

As soon as she woke up from the surgery, she felt better. "I knew it was out of me," she said. "I felt great."



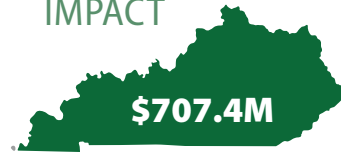
After undergoing chemotherapy for six months after her surgery, Duff celebrated the end of her treatment with family and friends. She's been cancer free for five years.

"They told me the life expectancy for my cancer; it was five years or so," Duff recalled. "But I knew there were survivors out there who had lived long past that. I want to be one of them."

Duff is one of many Kentuckians who have survived lung cancer thanks to the high-quality cancer care available throughout the state. As the collaborative work of the Kentucky Lung Cancer Research Program continues, more Kentuckians like Duff will have access to groundbreaking therapies that might represent their best hope for successful treatment.

## KLCRP Economic Impact Since 2001

**TOTAL ECONOMIC IMPACT**

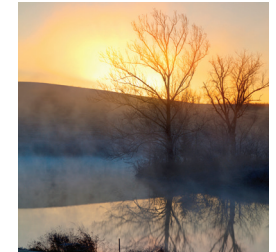


**\$24M** in state and local tax revenue

The **combined return on investment** as a result of dedicated funding support for KLCRP is **\$11.34 per dollar invested or leveraged.**



## Kentucky Lung Cancer Research Program



 University of Kentucky

UNIVERSITY OF **LOUISVILLE.**

 **Kentucky Council on Postsecondary Education**

**Contact the Kentucky Lung Cancer Research Program**

Travis Powell, JD  
[travis.powell@ky.gov](mailto:travis.powell@ky.gov)  
 502-573-1555

## History and summary

Kentucky has the highest rate of lung cancer incidence and mortality as well as the highest smoking rates in the country.

To address this critical problem, the Kentucky Legislature established the Kentucky Lung Cancer Research Program (KLCRP) in 2001 using funds from the Tobacco Master Settlement Agreement.

The KLCRP was launched as a collaboration between the Markey Cancer Center at the University of Kentucky and the James Graham Brown Cancer Center at the University of Louisville. It is governed by a nine-member board consisting of representatives from both universities, members of the Council on Postsecondary Education and members-at-large.

KLCRP provides critical funding that:

- Develops robust academic cancer centers that lead cancer research and clinical education efforts at the state institutions.
- Funds competitive research grants that focus on understanding the causes of lung cancer and to study new treatments.
- Supports translational clinical research studies through the Kentucky Clinical Trials Network, which facilitates the development and implementation of clinical trials throughout the Commonwealth via partnerships with regional hospitals and clinics.



## Kentucky Clinical Trials Network

The KLCRP has established the Kentucky Clinical Trials Network (KCTN), an alliance of university and community-based physicians conducting promising clinical trials focused on the prevention, early detection and treatment of lung cancer throughout the Commonwealth. The KCTN portfolio includes trials initiated by physicians at the Markey Cancer Center and Brown Cancer Center as well as national and global trials, allowing patients and participating sites to have earlier access to innovative therapies. KCTN members include a multidisciplinary team of health care professionals, including pulmonologists, medical oncologists, radiologists, surgeons and behavioral scientists.

**“With the Kentucky Clinical Trials Network, we are simply tearing down a roadblock that allows all Kentuckians the opportunity to fight their battle with cancer with all weapons available at their disposal, including clinical trials.”**

– Adam D. Lye, MD

Medical Director, HMM Cancer Care Center

KCTN Principal Investigator, KCTN Portfolio Committee

The KCTN study portfolio is governed by an advisory committee, which includes representatives from KCTN member sites, including the Markey Cancer Center and the Brown Cancer Center.

KCTN sites are conveniently located in every federal congressional district in the Commonwealth, allowing patients access to research opportunities while remaining at home under the direct care of their trusted local physicians.



KCTN sites have enrolled more than 2,200 participants in studies in 80 of 120 counties, or 67 percent of the state.

## Research

Through investigator-initiated competitive grants and programmatic funding, KLCRP researchers are leading the way in conducting state-of-the-art lung cancer research that spans the areas of tobacco control, lung cancer epidemiology, early detection/screening of lung cancer and translational lung cancer research.

Examples of this research include development of novel early detection breath and blood tests as well as novel imaging assessments of lung nodules, techniques that could greatly increase lung cancer survival rates. Significant work is also ongoing to address the smoking prevalence in the state through policy work and stakeholder capacity



building as well as studies on the implementation of strategic treatment of tobacco dependence in patients with lung cancer. Decreasing smoking rates in the state could dramatically impact lung cancer incidence rates and improve the treatment outcomes of patients with lung cancer.



# LUNG CANCER TRUST TIMELINE

February, June, August, November Governance Board 2016 meeting months

February 17, 2016	<p><b>Governance Board Meeting</b> Investigator initiated grants proposed/review; Governor recommended Biennial budget review; Review suggested year timelines working document; Begin discussion about strategic plan updates (Last plan updated October 2014; required to be updated every two (2) years)</p>
March – April	<p>Council staff and institutions will respond as requested to the Auditor of Public Accountants while they conduct the required audit of all expenditures from the lung cancer research fund.</p>
May 31	<p>Institutions submit a biennial budget request to Council staff detailing administrative, grant, and individual initiative costs.</p>
June 1	<p>Institutions submit an invoice to Council staff for current fiscal year Board approved Investigator initiated grants and administrative costs (Processing is contingent on receiving prior year annual report, budget for future FY, and cash availability)</p>
June 8, 2016	<p><b>Governance Board Meeting</b> Current FY Investigator initiative grants proposed/review; Approve upcoming institution biennium budgets; discuss strategic plan revisions (if any)</p>
June – July	<p>Once state budget is approved, Council staff and institutions complete with signatures the contract for the fiscal biennium. This contract has a separate line for each state fiscal year (FY17 and FY18).</p>
August 22	<p>Center Directors and Institution representatives work together to create an annual executive summary outlining the activities and expenditures of the preceding first year. The Center annual reports will be completed by this time to support the executive summary.</p> <p>Circulate to board members at least one week in advance of August 31 so they may review, make comments to prepare report for approval at the August 31 meeting .</p>
August 31, 2016	<p><b>Governance Board Meeting</b> Current FY Investigator initiative grants proposed/review; Review institution reports submitted in September; Discuss strategic plan</p> <p>By statute: The Governance Board of the Lung Cancer Research Project shall submit an annual report to the Governor and the Legislative Research Commission by September 1 each year for the preceding fiscal year, outlining its activities and expenditures.</p>
September 1	<p>Submit fiscal year end June 30 detailed expenditure reports by September 1 (62 days after contract fiscal end)</p>
November 9, 2016	<p><b>Governance Board Meeting</b> Current FY Investigator initiative grants proposed/review; Approve strategic plan (even years only) ; Review institution reports submitted in September</p>