

STRONGER by DEGREES



MEETING AGENDA

Lung Cancer Research Governance Board

Wednesday, June 8, 2016
Conference Room A

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AGENDA
Kentucky Lung Cancer Research Program
Governance Board

Council on Postsecondary Education
Wednesday, June 8, 2016
2:00 PM
Conference Room A

- | | |
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Kentucky Lung Cancer Research Program Governance Board

February 17, 2016
Meeting Minutes

The Kentucky Lung Cancer Research Program Governance Board met Wednesday, February 17, 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), Mark Evers (UK), Joe Graviss (CPE), Amtullah Khan (MAL – videoconference), Don Miller (UofL) and Tim Mullett (UK). Dan Flanagan (CPE) and Rajan Joshi (MAL) were absent.

Others present were: Dianne Konzen (UofL), Elisha Maxson (UK), Milton Pierson (UofL), Nathan Vanderford (UK), Rebecca Bowman (CPE), Shaun McKiernan (CPE), Jay Morgan (CPE), Travis Powell (CPE), Haley Russell (CPE) and Debbie Weakly (CPE staff to KLCRP).

APPROVAL OF MINUTES

Chair Roach called for a motion to approve the minutes of the November 18, 2015 meeting. A motion was made by Don Miller and seconded by Mark Evers. The minutes were approved.

CASH ACTIVITY REPORT

Rebecca Bowman referred to the Cash Activity Report and stated there were no changes since the last meeting.

GOVERNOR'S RECOMMENDED BIENNIAL BUDGET

Shaun McKiernan of CPE's Finance unit was invited to the meeting to update the Board on the Governor's recommended biennial budget. The Tobacco Funds for the Kentucky Lung Cancer Research Fund were reduced from \$4.9 to \$4.7 million in 2016-17 and would then increase to \$5.2 million in 2017-18. The funds for ovarian cancer screening were reduced from \$800,000 to \$775,000 for both years of the upcoming biennium. The only amounts specified in the Governor's budget proposal were for the total funding and the level of Ovarian Cancer Screening Outreach Program funding. If enacted as currently proposed, the net of these changes would result in a \$12,800 reduction in KLCRP funding for the biennium.

Travis Powell stated that the budget recommendation is still early in the process but normally these numbers do not change. Milton Pierson indicated that the grant funds for each institution can be reallocated, but the amounts for the ovarian cancer will remain as

recommended. Rebecca pointed out that the contracts will not be written until after the budget is approved on or before April 15th and the proposals from UK and UofL will be submitted after that time.

GRANT FUNDING REQUEST – UNIVERSITY OF KENTUCKY AND UNIVERSITY OF LOUISVILLE

Chair Roach asked UK to present their grant funds request. Nathan Vanderford gave a brief description of each grant request. Chair Roach called for a motion to approve. A motion was made by Joe Graviss and seconded by Don Miller to approve the grant funds request for the University of Kentucky. The motion was approved.

Chair Roach asked UofL to present their grant funds request. Don Miller gave a brief description of each grant request. Chair Roach called for a motion to approve. A motion was made by Mark Evers and seconded by Tim Mullett. The motion was approved.

MARKETING PLAN UPDATE

Nathan stated that the Marketing Committee had not moved forward with the brochure until the Board had decided on what information to use as a result of the Economic Impact Study. A letter had been sent to the Legislators providing the results of the study and one legislator, Senator Higdon, had requested a copy of the full study. Nathan indicated that the marketing idea of the consultant was radically different than what was planned for the brochure. Mr. Graviss asked what needed to be done to have the most impact and Nathan responded it would depend on the audience. Mr. Graviss stated it was important to stress key points such as the lung cancer program began with minimal funds, investments were made, the program has grown due to those investments, and then point out the return on those investments. Travis stated the format of the brochure was good and now the data needs to be added; it should focus on financial information and include a personal story of the impact of the cancer research. The amount of work to finalize the brochure would be minimal. Mr. Graviss suggested that the necessary information be added to the current brochure placeholders. Nathan indicated they would move forward and may have to reconvene the small group.

SYMPOSIUM – ANNUAL OR BIENNIAL

Nathan referred to the draft agenda included in the meeting materials. He stated it was similar to what has been done in the past and the major focus should be on the poster sessions. He indicated that UK would host the symposium this year and would work with UofL on the logistics of the agenda. Two dates were proposed due to facility availability – September 17 or September 24. Mr. Graviss asked who would be the expected audience and Dr. Miller responded academic faculty from both campuses, university Board members and other interested individuals who support the program, such as legislators.

Mark Evers suggested presenting awards to someone from the House and Senate who have been proponents of the cancer research program and the Board may need guidance from CPE on the recipients. Jay Morgan suggested that a better date for the symposium may be late January when the legislators are in session but Mr. Graviss responded we may not need

to plan around them as long as they are aware the symposium is taking place. Dr. Evers asked if January would be a good time to deliver the brochures and Mr. Graviss suggested that providing them in their own district outside of the session may work better. He felt that if there are legislators who are key proponents of the program and we have a specialist or clinician in that particular district who could meet with them, that may be a better way to distribute the brochure. Travis indicated that CPE could identify some key legislators.

Jason Chesney suggested another idea for the agenda would be for someone who is completing their two-year funding cycle to present their work. Nathan stated that he and other staff will move forward with these suggestions as they plan for the symposium.

OTHER BUSINESS

- Timeline – Rebecca referred to the draft timeline that was provided to the Board members and reported on what needed to be done before the June meeting date was determined. Chair Roach asked for suggestions for the best available time and June 8 was agreed upon for the next meeting date.

Rebecca stated that an annual report is due by statute to the Legislative Research Commission by September 1st. The Center Directors testify to the Legislature in the fall and annual reports are submitted to CPE per the contract. She questioned whether those reports should be sent to LRC and the Governor and would they suffice to meet the statutory requirement or should the deadline for the reports be moved up to mid-August and a separate narrative be sent to LRC and the Governor and keep the annual due date on September 15th. Another question that Rebecca posed was does the Board need to review the annual reports and should a meeting occur before they are sent to LRC and the Governor.

Nathan asked if using the report that is presented when the Directors testify to LRC could be used as the one that is required by statute. Mr. Graviss stated one report outlining the activities and expenditures of the program and used by both institutions should suffice. He indicated the format used the last couple of years seems to be sufficient. Mr. Graviss also asked if the Board approves the document and, if so, when? Nathan indicated the Board does review and approve the reports, therefore, they should be due to the Board in mid-August and a meeting scheduled in late August for approval before submitting to LRC and the Governor by the September 1 deadline. Chair Roach asked for suggestions for an August meeting date and it was decided that the Board would meet on August 31st to approve the annual report. The report would be sent to Board members for review prior to that meeting.

Travis stated that as part of the timeline, the Strategic Plan was to be approved in even years only. Since this is an even numbered year, it should be reviewed at the June meeting for any changes and presented at a meeting in October. Chair Roach

asked for suggestions for an October meeting. Since some Board members were not available in October, a November 9th meeting date was agreed upon.

Rebecca will update the timeline with all changes to be forwarded to Board members and also included as part of each meeting materials per Mr. Graviss' request. Debbie will send out calendar invites for all meetings during the remainder of 2016.

With no further business, the meeting was adjourned at 3:15 pm.

Council on Postsecondary Education
Lung Cancer Research, Tobacco Settlement Fund (6349 fund)
FY16 Cash Activity Report as of May 31, 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	1,279.98									651,502.68
7/25/2015	APA annual audit fee	(7,344.00)									652,782.66
1/4/2016	Tripp Umbach Economic Impact Study	(7,500.00)									645,282.66
4/18/2016	UKRF-Lung Cancer FY16-RIT1 Novel (7/1/16-6/30/2018)				(150,000.00)						
4/19/2016	FY16 appropriation - yet to be received								4,972,500.00		
4/19/2016	FY16 appropriation - JV2T will be completed near FY year end		800,000.00		750,000.00	1,550,050.00	750,000.00	1,122,450.00	4,972,500.00		
5/10/2016	UKRF - Ovarian Screening FY16 - (7/1-6/30/16)		(800,000.00)								
5/25/2016	UKRF - Lung Cancer FY16 Program Funds (7/1-6/30/16)					(1,550,050.00)					
	Cash Balance	30,841.29	-	-	1,207,096.44	-	750,000.00	1,122,450.93			3,110,388.66

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Markey KLCRP Cycle 15 Grant Request

ACTION: Recommend that the Board approve the following revision to a Cycle 15 Grant

Faculty	Title	Initial request (Approved 2/17/16)	Amended request
Ellen Hahn	Radon and tobacco smoke exposure biomarkers of lung cancer risk	\$75,000	\$150,000

**Kentucky Lung Cancer Research Program
Governance Board
June 8, 2016**

2016-18 Budget Allocations

ACTION: Recommend that the Board approve the 2016-18 Budget Allocations for the Markey Cancer Center and the James Graham Brown Cancer Center.

Budget allocations for 2016-18 have been submitted by the University of Kentucky and the University of Louisville for approval and are attached.

FY16 KLCRP appropriation - University of Kentucky

Estimated Estimated
 Account # Name FY17 budget FY18 budget

3049024113	KCTN	384,900	460,100
3049024114	NCI Designation	980,600	1,158,000
3049024115	Administration	30,000	50,000
3049024116	Biospecimen Core	0	0
3049024117	Marty Driesler	0	0
		1,395,500	1,668,100

Kentucky Lung Cancer Research Program FY 17 Budget Proposal - UofL

Description	Item Cost	Initiative Total
NCI DESIGNATION		
<i>Biorepository</i>		
Technical salary (Andrei Smolenkov), 50%	\$ 40,216	
Operating Expenses	\$ 6,567	
<i>Grid Computing Network (outreach)/Molecular Modeling Core</i>		
Jonathan Maguire, 25% salary	\$ 21,722	
<i>Partial Recruitment costs - associate professor/investigator (\$175,000)</i>		
Salary (faculty)	\$ 100,000	
Salary (technical)	\$ 60,000	
Travel	\$ 5,000	
Operating Expenss (including small equipment)	\$ 60,000	
Capital Equipment	\$ 30,000	
<i>Partial Recruitment costs - associate professor/investigator (\$175,000)</i>		
Salary (faculty)	\$ 75,000	
Salary (technical)	\$ 40,000	
Travel	\$ 5,000	
Operating Expenss (including small equipment)	\$ 60,000	
Capital Equipment	\$ 30,000	
		\$ 533,505
FELLOWS		
2 fellows at \$42,000 + 40% fb	\$ 117,600	\$ 117,600
CLINICAL TRIALS NETWORK [remaining UofL funds from this initiative go to the KTCN]		
Manager, Clinical Trials Research (Karen Carter, 50%)	\$ 40,824	
CTO Research Nurse (Jennifer Schoenbachler; 30% salary)	\$ 24,759	
CTO Laboratory Research Coordinator (Belma Kantardzic, 20% salary)	\$ 16,064	
		\$ 81,648
ADMINISTRATION		
<i>JGBCC Sr. Associate Director of Administration</i>		
Milton C. Pierson, 25% salary	\$ 51,122	
BCC KLCRP Coordinator - Diane Konzen (35% salary)	\$ 31,677	
BCC KLCRP Financial Coordinator - Lisa Bentley (50% salary)	\$ 50,049	
		\$ 132,847
EXTERNAL REVIEW OF Investigtor-Initiated GRANT APPLICATIONS		
UofL applications - reviewer honoraria (at \$250 per review)	\$ 20,000	\$ 20,000
EARLY DETECTION		
Two one-year pilot projects @\$62,500	\$ 125,000	\$ 125,000
TOTAL OF ABOVE INITIATIVES		\$ 1,010,600
INVESTIGATOR-INITIATED GRANTS [5 @ \$150,000]	\$ 750,000	\$ 750,000
TOTAL OF ALL INITIATIVES		\$ 1,760,600
INSTITUTION: University of Louisville		
SUBMITTED BY: Milton Pierson		

Kentucky Lung Cancer Research Program FY 18 Budget Proposal - UofL

Description	Item Cost	Initiative Total
NCI DESIGNATION		
<i>Biorepository</i>		
Technical salary (Andrei Smolenkov), 25%	\$ 20,108	
Supplies	\$ 5,467	
<i>Grid Computing Network (outreach)/Molecular Modeling Core</i>		
Jonathan Maguire, 25% salary	\$ 21,722	
<i>Partial Recruitment costs - associate professor/investigator (\$175,000)</i>		
Salary (faculty)	\$ 100,000	
Salary (technical)	\$ 60,000	
Travel	\$ 5,000	
Operating Expenss (including small equipment)	\$ 60,000	
Capital Equipment	\$ 25,000	
<i>Partial Recruitment costs - associate professor/investigator (\$175,000)</i>		
Salary (faculty)	\$ 100,000	
Salary (technical)	\$ 60,000	
Travel	\$ 5,000	
Operating Expenss (including small equipment)	\$ 60,000	
Capital Equipment	\$ 25,000	
<i>Partial Recruitment costs - assistant professor/investigator (\$175,000)</i>		
Salary (faculty)	\$ 75,000	
Salary (technical)	\$ 40,000	
Travel	\$ 5,000	
Operating Expenses (including small equipment)	\$ 60,000	
Capital Equipment	\$ 25,000	
		\$ 752,297
FELLOWS		
2 fellows at \$42,000 + 40% fb	\$ 117,600	\$ 117,600
CLINICAL TRIALS NETWORK [remaining UofL funds from this initiative go to the KTCN]		
Manager, Clinical Trials Research (Karen Carter, 50%)	\$ 40,824	
CTO Research Nurse (Jennifer Schoenbachler; 30% salary)	\$ 24,759	
CTO Laboratory Research Coordinator (Belma Kantardzic, 20% salary)	\$ 32,129	
		\$ 97,712
ADMINISTRATION		
<i>JGBCC Sr. Associate Director of Administration</i>		
Milton C. Pierson, 25% salary	\$ 51,122	
BCC KLCRP Coordinator - Diane Konzen (35% salary)	\$ 31,677	
BCC KLCRP Financial Coordinator - Lisa Bentley (25% salary)	\$ 12,593	
		\$ 95,391
EXTERNAL REVIEW OF Investigtor-Initiated GRANT APPLICATIONS		
UofL applications - reviewer honoraria (at \$250 per review)	\$ 20,000	\$ 20,000
EARLY DETECTION		
Two one-year pilot projects @\$62,500	\$ 125,000	\$ 125,000
TOTAL OF ABOVE INITIATIVES		\$ 1,208,000
INVESTIGATOR-INITIATED GRANTS [5 @ \$150,000]	\$ 750,000	\$ 750,000
TOTAL OF ALL INITIATIVES		\$ 1,958,000
INSTITUTION: University of Louisville		
SUBMITTED BY: Milton Pierson		

Kentucky Lung Cancer Research Program

2014 Strategic Plan Update

Approved by the KLCR Program Governance Board

October 22, 2014

KLCR Strategic Plan Update

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KLCR Strategic Plan Update

Kentucky Lung Cancer Research Program (KLCR Program)

Strategic Plan

Introduction

In 2000, the Kentucky General Assembly passed enabling legislation that created the Lung Cancer Research Fund, a partnership of the Cancer Centers at the University of Kentucky and University of Louisville under the leadership of a Governance Board of the Lung Cancer Research Fund. This legislation required development of research expertise in lung cancer at each Cancer Center, innovative clinical trials to test new lung cancer treatments throughout the Commonwealth, and leveraging this support to lead the centers toward designation as National Cancer Institute recognized Cancer Centers.

The enabling legislation focuses on lung cancer research and complements the mission of the Commonwealth's two medical research universities in helping Kentuckians gain or retain their good health. To accomplish this mission, each university strives to meet the educational, research, and patient care needs of our citizens working cooperatively together as well as with similarly focused organizations throughout the Commonwealth.

The Governance Board set initial strategies and goals for the program, and in 2014 a group of external experts reviewed the progress and accomplishments of the program since its inception. In alignment with that review, the following Strategic Plan Update for 2014 delineates specific goals, objectives, strategies and measurable outcomes and provides a blueprint for the two universities to follow as they continue to build the nation's centerpiece of lung cancer research in Kentucky.

Out of the 2014 program review, this strategic plan update – that will now span the remaining 6 years of the current Tobacco Settlement Funding including an annual review – includes overarching opportunities for gaining additional synergies between the University of Kentucky and University of Louisville. Additionally, in future years, a joint symposium focusing on the lung cancer research will bring together faculty and staff from both universities in a way that will facilitate greater collaboration toward the ultimate goal of reducing the burden of lung cancer in the Commonwealth and reducing the factors – such as smoking and other environmental factors – that contribute to the disease.

KLCR Strategic Plan Update

GOAL 1: Investigator-Initiated Research

“164.476(5)(a) Develop an expertise in the area of lung cancer research.”

The conduct of investigator-initiated, hypothesis-driven research – i.e., independently conceived research approaches and projects developed by scientists from all relevant disciplines - is the primary means by which biomedical research is advanced. Driven by state of the art knowledge and creative synergism present at medical schools, hospitals, universities, research centers, and corporations they represent, these highly trained investigators:

- Review current scientific knowledge and identify critical gaps
- Develop new hypotheses
- Design the most direct pathways to test those hypotheses
- Utilize and develop novel molecular, genetic and cellular approaches in lung cancer research
- Develop and utilize animal models in the analysis of lung cancer
- “Translate” new findings and technologies into innovative clinical applications
- Test the most promising new prevention and treatment strategies in clinical trials

The KLCR Program’s Investigator-Initiated Research Initiative continues to provide valuable financial resources to develop novel concepts and identify new avenues of research in lung cancer. These innovative research projects are by nature the most high-risk/high-reward research approaches generating proof-of-concept/proof-of-principle data that will lead to stronger scientific programs, increased publications and additional extramural funding.

Objectives

In congruence with the 2014 program review, the KLCR Program will focus its attention on the research areas of tobacco control, epidemiology, early detection/screening, and translational research. Further, additional steps will be taken to strengthen synergies and collaborations occurring at and between the University of Kentucky and the University of Louisville. To this end we will:

1. Recruit existing faculty at the front-lines of lung 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.
2. Recruit new faculty both with interests and expertise in cancer that may be applied specifically to the lung cancer focus areas described above.
3. Develop, mentor and focus early stage career investigators and graduate students on lung cancer. This was specifically suggested by the external reviewers and the KLCRP will henceforth ensure that the investigator-initiated grants have a plan in place for the career development of early stage researchers.

KLCR Strategic Plan Update

4. Continue to support a robust research portfolio for lung cancer at and between each university.
5. Develop intra-programmatic linkages within and between both Cancer Centers, and in alignment with the 2014 program review, we will better define complementary focus areas at each Cancer Center.
6. In addition to the overarching annual symposium we will now have, we will also conduct joint seminars between the two Cancer Centers to share research results among lung cancer scientists funded by the KLCR Program as well as through other mechanisms.

Priorities

1. Recruit additional scientists into the lung cancer research program priority areas.
2. Develop more integrated research programs at each Cancer Center, as well as links between universities.
3. Utilize KLCR investigator-initiated grants to leverage current and future cancer research into the area of lung cancer.

Indicators

1. Publications of lung cancer research at each university continue to break new ground in understanding and intervening in the incidence and mortality from lung cancer.
2. Research portfolios mature into well-rounded representations of lung cancer study, with progressive increases in extramural funding.
3. Annual professional meetings for KLCR scientists result in additional collaborative studies.
4. The Markey Cancer Center and the Brown Cancer Center are identified as increasingly prominent lung cancer research and treatment centers.

KLCR Strategic Plan Update

GOAL 2: Research in Early Detection & Prevention

“164.476(5)(a) Develop an expertise in the area of lung cancer research with an immediate focus on early detection and epidemiology and with an ultimate goal of eradication of lung cancer.”

Despite the direct link between tobacco and lung cancer, only 15% of smokers develop the disease. Thus, a fundamental goal is to discover risk factors that predispose a person to lung cancer. Defining high-risk individuals and development of an effective screening methodology will allow earlier detection, when a malignant tumor is small and asymptomatic, when treatment produces a higher cure rate.

Recent technological advances and new tools for screening have led to renewed trials for detecting early stage lung cancers. Correlative explorations of smoking history, compromised lung function, and biomarkers in serum or exhalant are proposed to help pre-define lung cancer risk in otherwise asymptomatic individuals. Establishment of a biospecimen repository is a key resource to facilitate such studies.

In congruence with the 2014 program review, the KLCR Program will focus its attention on the research areas of early detection/screening, and translational research. Further, additional steps will be taken to leverage and continue previous work to advancing phases. To this end we will:

Objectives

1. Conduct screening and early detection research using available and applicable tools in key geographic areas of the state.
2. Develop and conduct studies in dissemination and implementation research of lung cancer screening; including studies of patient and provider education, community awareness, patient care and program implementation.
3. Expand and refine methodologies for risk-factor delineation.
4. Validate the use of methodologies for lung cancer screening.
5. Identify and develop methodologies for lung cancer prevention.
6. Maintain and expand the biospecimen repository for use by lung cancer researchers.
7. Capitalize on partnerships with regional and local hospitals and clinics to build an early detection network where research is integral to the relationship, including studies of implementation and outcomes of lung cancer screening programs in diverse community based settings, socioeconomic and other epidemiologic studies, and treatment of tobacco addiction studies.
8. Link prevention and early detection studies.

KLCR Strategic Plan Update

Priorities

1. Continue development of and conduct of high priority studies in early detection and prevention of lung cancer, including lung cancer screening and treatment of tobacco addiction.
2. Continue the development and validation of biomarker correlates of lung cancer and/or lung cancer risk through advanced molecular surveillance studies.
3. Articulate current standards of surveillance and screening for lung cancer to be included in CME and other CE programs for Kentucky physicians and healthcare professionals.

Indicators

1. The biomarker repositories at the universities are increasing collections and utilization of biospecimens toward the advancement of early detection research.
2. Further development of candidate molecular markers identified for lung cancer susceptibility and/or early diagnosis.
3. Further development of lung cancer preventative measures.
4. Continue development of and conduct of high priority studies in early detection and prevention of lung cancer, including lung cancer screening and treatment of tobacco addiction.
5. Optimal strategies to treat tobacco addiction of lung cancer patients are researched, examined and advanced in clinical trial phases.
6. Community outreach and continuing education programs are supported by advancing topics in lung cancer screening and treatment of tobacco addiction to articulate best practices.

KLCR Strategic Plan Update

GOAL 3: Kentucky Clinical Trials Network

“164.476(5)(b) Establish a statewide clinical trial network to make university-based clinical trials available to the community physician in order to bring the most innovative cancer treatments to all Kentuckians in need of these treatments.”

Improvements in the effectiveness of cancer treatments are accomplished through a series of phased clinical trials: Phase I – identify maximum tolerated doses of new drugs and dose-limiting toxicities; Phase II – test the study drug’s effectiveness in specific cancers; Phase III – compare new treatments or new use of a treatment with approved treatments. All current approved drugs and treatment guidelines are based on clinical trials before they became generally available. Despite that record of success, many people do not know that cancer clinical trials are the means by which cancer research becomes cancer treatment.

Thousands of cancer clinical trials are underway in the United States. The National Cancer Institute, cooperative groups, academic medical centers, community hospitals, physician private practices, and pharmaceutical companies sponsor cancer clinical trials. Of the 1.3 million people who will be diagnosed with cancer this year, only three to five percent will participate in cancer clinical trials.

The University of Kentucky and University of Louisville have worked together to establish the Kentucky Clinical Trials Network (KCTN) to facilitate collaborative participation in trials, to educate patients and physicians about the benefits of clinical trials, and trial availability and to assist physicians with planning and implementing trials.

In accordance with priorities driven by programmatic stakeholders, and in congruence with the 2014 program review, the KCTN will continue to focus on the development and conduct of high-priority clinical trials at qualified partner sites. Further, the KCTN will place an emphasis of its portfolio on the research areas of early detection/screening, treatment of tobacco addiction, and translational research. During this strategic plan period, additional steps will be taken to advance previous work sponsored by KLCRP in early detection of lung cancer.

Objectives:

1. Increase number of Kentuckians with access to and participating in lung cancer clinical trials.
2. Develop and maintain a critical mass of trained professional staff to support multi-site clinical trials.
3. Offer and manage a portfolio of lung cancer clinical trials through the Network.
4. Identify and develop investigator-initiated clinical trials at both universities that can be offered to patients in diverse settings.

KLCR Strategic Plan Update

5. Continually improve the Network's services with input from participating member sites and physicians.

Priorities

1. Efficiently and effectively manages quality clinical trials for the Network.
2. Utilize technologies to engage, manage and conduct network activities.
3. Identify and develop high-priority investigator-initiated interventional and non-interventional clinical trials for the network portfolio, with emphasis on any or all of the following: lung cancer screening, prevention and early detection, treatment of tobacco addiction, and other concepts emerging for lung cancer clinical trials.
4. Develop and offer balanced trial portfolio that aligns with priorities of stakeholders including the Markey Cancer Center, the Brown Cancer Center, KTCN and participating sites. Provide research training and resources to site research teams.
5. Increase number of patient accrual to network trials.

Indicators

1. The Network has a continuing stream of novel therapeutic trials and non-therapeutic trials available to patients, partnering physicians and sites.
2. The network has increasing patient accrual.
3. The Kentucky Clinical Trials Network provides training and information to participating site teams and physicians and their communities, including clinical trial results and availability.
4. Clinical trials are accessible for Kentuckians at sites with commitment to quality conduct of trials in accordance with applicable research regulations and ethical standards.

KLCR Strategic Plan Update

GOAL 4: NCI-Designation as Cancer Centers

“164.476(5)(c) Leverage the resources earmarked for the Lung Cancer Research Project toward the certification of the cancer program at the University of Kentucky and the University of Louisville by the National Cancer Institute as a cancer center[.]”

The Cancer Centers Program of the NCI supports major academic and research institutions throughout the United States to sustain broad based, coordinated, interdisciplinary programs in cancer research. These institutions demonstrate scientific excellence and the ability to integrate a diversity of research approaches to focus on cancer. The NCI and its Cancer Centers Program are dedicated to advancing cancer research to ultimately reduce cancer incidence, morbidity, and mortality.

Designated Cancer Centers receive funds from NCI for scientific infrastructure of the center, including such elements as scientific leadership and administration; shared/core research resources that give ready access to state-of-the-art technologies; and flexible program development funds that help the center and its associated faculty pursue its planned objectives and take immediate advantage of new research opportunities.

The University of Kentucky obtained NCI designation in 2013 and the University of Louisville is pursuing NCI designation. Support from the KLCR Program has provided vital financial resources to both institutions during a critical stage of development. The goal of NCI Designation requires a continued investment in scientific expertise, equipment, space and financial resources.

In alignment with the original mission of the KLCR Program and with the 2014 review, NCI designation will continue to be a priority for both the University of Kentucky and the University of Louisville. As such, we will:

Objectives

1. 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.
2. Develop and maintain diverse cancer research programs with a high degree of inter- and intra-team collaboration.
3. Provide and promote interactive research opportunities.
4. Offer expanded innovative clinical trials, building on combined research underpinnings of the two centers.

KLCR Strategic Plan Update

Priorities

1. Continue to expand the overall research bases at each institution, particularly in Translational and Clinical Research.
2. Increase extramural funding with emphasis on funding from the NCI.
3. Increase NCI multi-project grants including program projects, SPORC grants and NCI cooperative grants.
4. Expansion of research laboratory space.
5. Develop a more broadly inclusive smoking-related cancer program that involves lung, head & neck, pancreas, cervix and bladder cancers.
6. Provide all support necessary to renew and submit an application for NCI designation for the Markey Cancer Center and James Graham Brown Cancer Center, respectively.
7. Continue to develop multidisciplinary clinics for lung cancer patients.

Indicators

1. Maintain/develop 3-5 firmly established NCI-designable cancer research programs at each institution, with an emphasis on translational and clinical research.
2. Grow NCI funding at both institutions in the range of \$15-\$20 million.
3. Meet with, receive and respond to recommendations of an External Advisory Committee.
4. Meet with, receive and respond to recommendations of the NCI Centers Branch Director.
5. Renew/submit P30 application for NCI-designation.

LUNG CANCER TRUST TIMELINE

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

February 17, 2016	<p>Governance Board Meeting 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>Governance Board Meeting 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>Governance Board Meeting 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 15	<p>Submit fiscal year end June 30 detailed expenditure reports by September 15 (77 days after contract fiscal end)</p>
November 9, 2016	<p>Governance Board Meeting Current FY Investigator initiative grants proposed/review; Approve strategic plan (even years only) ; Review institution reports submitted in September</p>