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FOCAS APPALACHIA: A CERVICAL CANCER PREVENTION PROGRAM FOR THE WOMEN OF THE KENTUCKY RIVER AREA DEVELOPMENT DISTRICT

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CAPSTONE PROJECT PAPER

A paper submitted in partial fulfillment of the
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Project Narrative

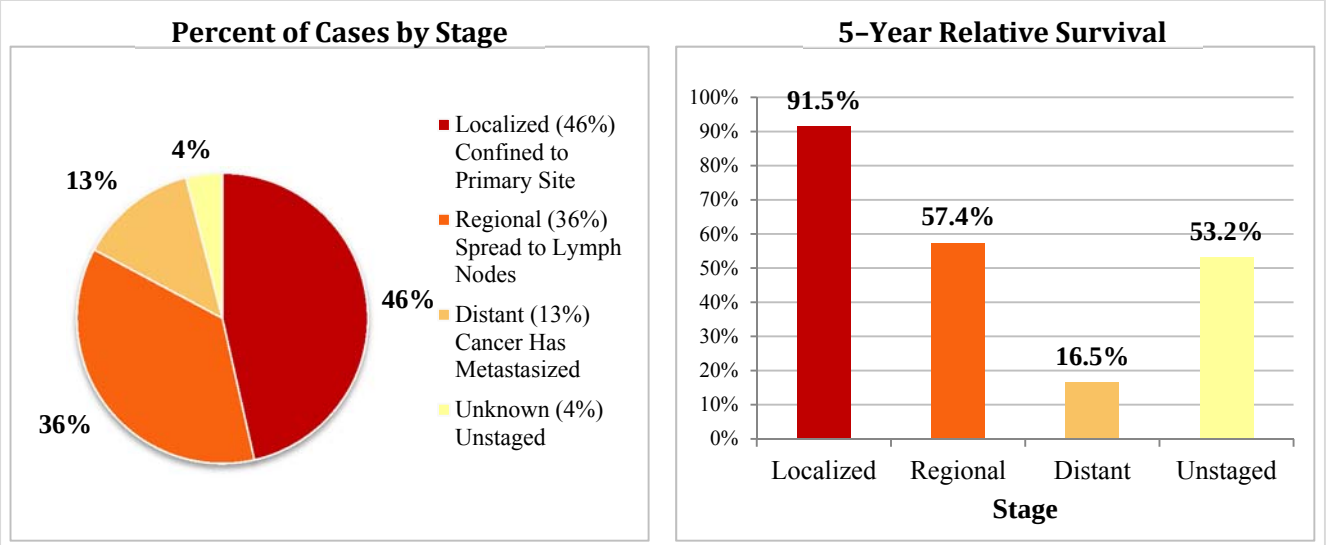
A. Target Population and Need

Cervical cancer is one of the few preventable cancers through routine human papillomavirus (HPV) vaccination and screening/early detection via the Pap test.[1] Compared to other cancers affecting only women, cervical cancer has a very low incidence rate, with just 7.7 cases diagnosed per 100,000 women in the United States (U.S.) annually.[2] In rather stark contrast, the annual incidence of breast cancer among women is 124.8 cases per 100,000, the annual incidence of ovarian cancer is 12.1 cases per 100,000, and the annual incidence of uterine cancer is 25.1 cases per 100,000.[2] However, as described below, there are noted disparities in 5-year survival from cervical cancer as well as incidence of the disease and screening behaviors among specific populations.

The percentage of cases by stage at diagnosis for cervical cancer among U.S. women is nearly equal when comparing localized cervical cancers to combined regional and distant cancers: 46% of cases are diagnosed at the local stage, and 49% of cases are diagnosed at the regional and distant stages. However, the 5-year relative survival rates are vastly different as highlighted in Figure 1 below.[2]

Specifically, when cervical cancer is diagnosed at the localized stage, over 90% of women are alive five years after diagnosis.[2] However, when cervical cancer is diagnosed at the more advanced regional stage, only approximately six out of 10 women are alive after five years, and when cervical cancer is diagnosed at the distant stage, nearly 85% percent of women die within five years of diagnosis.[2] These drastic differences in 5-year relative survival rates demonstrate the importance of screening and early detection.

Figure 1. Percent of Cases and 5–Year Relative Survival by Stage at Diagnosis: Cervical Cancer



SEER 18 2005-2011. All Races. Females by SEER Summary Stage 2000

Although cervical cancer is an uncommon cancer, ranking 14th in frequency of cancers affecting women, it was once the number one cause of cancer-related mortality among women in the U.S.[3,4] The primary reason for this tremendous turnaround in incidence and mortality was the introduction of the Pap smear into gynecologic clinical practice in the 1940s. This simple, routine screening procedure stops the natural progression of the disease by allowing for prompt and comparatively simple medical intervention when a precancerous lesion is found. The Pap smear is unarguably one of the greatest public health successes.[5] Its profound impact is further realized by disparities that exist in geographic regions where screening is not accessible and rates of the malignancy are still elevated. In developing countries, this disease is still the leading cause of cancer-related death among women.[3]

Unfortunately, the benefits of the Pap smear have not extended ubiquitously to all parts of even developed countries. Disparities in cervical cancer incidence still exist in the U.S. For example, in Kentucky, a primarily rural, medically-underserved, lower socioeconomic state, the 5-year incidence rate of cervical cancer (2009-2013) of 8.7 cases diagnosed per 100,000 is higher

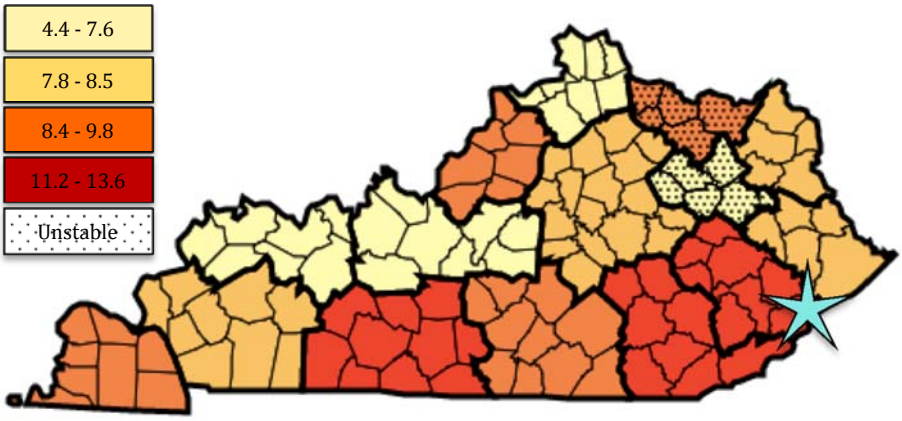
than the national rate at 7.7.[7] According to data presented by the Centers for Disease Control and Prevention (CDC), this incidence rate is among the top five highest rates in the nation.[6]

Within the state of Kentucky, the Kentucky River Area Development District (KRADD) – comprised of eight Appalachian economically-distressed counties (Breathitt, Knott, Lee, Leslie, Letcher, Owsley Perry, and Wolfe) – experiences the highest incidence of cervical cancer in the state with an age-adjusted, 5-year rate of 13.6 cases per 100,000 (2009-2013).[7] This rate is more than 1.75 times higher than the national average.[7] As cervical cancer is a preventable cancer through guideline-recommended HPV vaccination and routine Pap test screening, this high incidence rate reflects the disparate underutilization of HPV immunization and cervical cancer screening in this region. Related specifically to screening, Kentucky and the U.S. have similar screening rates, 74.5% and 75.2%, respectively; however, in the KRADD, only 68.2% of women are screening within U.S. Preventive Services Task Force (USPSTF) recommendations.[8,9] Current USPSTF recommendations advise screening via the Pap test in women age 21 to 65 every 3 years or, for women age 30 to 65 who want to extend the screening interval, screening with both Pap test cytology and HPV testing every 5 years.[10] Notably, previous research has

Figure 2.

Age-Adjusted Invasive Cancer Incidence Rate in Kentucky

Cervix Uteri, 2009-2013
By Area Development District
Age-Adjusted to the 2000 U.S. Standard Million Population
KY Rate: 8.7 / 100,000



All rates per 100,000
Data accessed February 10, 2016. Based on data released November 1, 2014.

found that while the prevalence of *any* HPV type is similar between Appalachian women and non-Appalachian non-Hispanic white women, the prevalence of high-risk HPV is *higher* among Appalachian women, 33.5% vs. 26.9%, respectively.[11]

The high incidence rate of cervical cancer in the KRADD reflects the underutilization of Pap test screening and a lack of follow-up care after abnormal cytology results.[41] The underutilization of screening and lack of follow-up care reflect the barriers to screening and treatment in this region. Barriers to cancer screening in Appalachia have been extensively researched and are well documented. Appalachian women have cited barriers that are consistent with three main categories of influences on cancer screening: personal, professional, and systemic.[12] These influences align with the barrier-predictive factors of the PRECEDE/PROCEED framework: predisposing, enabling, and reinforcing. Personal influences are predisposing factors including attitudinal and knowledge barriers. Specifically regarding cervical cancer screening, a study published in the *Journal of Community Health* (2013) found that the majority of Appalachian women who were non-compliant with Pap test screening recommendations thought Pap tests were "too embarrassing" and were afraid of cancer being found.[12] Other predisposing barriers include privacy concerns, reluctance to interact with a male physician, lack of perceived need for screening, and fear of subjecting oneself to medical scrutiny because of concurrent overweight/obesity or being a smoker, health characteristics that are also disproportionately prevalent in this region.[12-14]

The KRADD has been cited as the epicenter of traditional Appalachian Mountain culture.[15] With its tight-knit, rural communities and traditional Christian values, the often co-occurring cognitive characteristic, and predisposing barrier, of fatalism may be common in this

region.[16,17] A recent study from the University of Kentucky's (UK) Rural Cancer Prevention Center (RCPC) found that a fatalistic attitude – a perceived lack of control over destiny or fate – toward cervical cancer may discourage Appalachian women from taking action to prevent the disease.[18] Negative beliefs about the inevitability of developing cancer, and that cancer is a death sentence, may prevent individuals from participating in proactive health measures.[16,18]

Systemic influences or enabling factors pose structural or environmental barriers to cancer screening. In the KRADD, these barriers include lack of insurance, low socioeconomic status, fewer female providers, limited transportation and long travel time to services along with challenging topography, and health professional shortage—four of the eight KRADD counties are designated health provider shortage areas for primary medical care.[12,13,19,32] These systemic barriers along with the aforementioned predisposing factors—collectively the physical and social determinants of health of this region—contribute to myriad health disparities disproportionately prevalent in this region.[12,20]

In addition to the elevated incidence rate of cervical cancer, this district is noted for high rates of poverty, unemployment, disability, obesity, respiratory disease, and smoking (Table 1).[8,9] In 2014, the percentage of high school graduates in the KRADD was 14 percentage points less than the state's percentage of graduates, and the median household income was just over half of the nation's median household income.[8,9]

Table 1. Demographic and Health Behavior Characteristics at the District, State, and National Levels (2014)

	KRADD	Kentucky	Nation
Health Behavior or Outcome			
Women aged 18+ who had a Pap test within the past 3 years (%)	68.2	74.5	75.2
Women aged 40+ who had a mammogram within the past 2 years (%)	64.6	74.4	73.0
Adults aged 50+ who ever had a sigmoidoscopy or colonoscopy (%)	55.9	69.7	69.3
Adults who are current smokers (%)	33.6	26.4	18.1
Adults who are obese (%)	38.0	31.6	29.6
Adults aged 65+ who had all their natural teeth extracted (%)	40.7	23.9	15.1
Adults who reported good or better health (%)	62.3	75.7	83.3

Premature deaths (years lost per 100,000 population)	15,592	9,436	7,562
Heart disease deaths (per 100,000 population)	322	205	193
Demographic			
High school graduation (%)	69	83	82
Median household income	$27,179	$43,039	$53,046

Within the eight counties that make up the KRADD, disparities in sociodemographic and other health behaviors and outcomes exist as well as noted in Table 2; the prevalence of these indicators at the state level is provided for comparison purposes.[8,9,21] Notably, these eight counties rank in the bottom 15 of Kentucky's 120 counties. Both annual and 5-year age-adjusted cervical cancer incidence and mortality data are unstable at the county level.

Table 2. Demographic and Health Behavior Variables at the County Level

	Breathitt	Knott	Lee	Leslie	Letcher	Owsley	Perry	Wolfe	Kentucky
Demographic									
Population	13,409	15,892	7,594	10,918	23,359	4,508	27,597	7,214	4,413,547
Female (%)	50.0	50.3	44.6	50.5	50.6	51.2	50.5	50.5	50.8
Non-Hispanic white (%)	97.2	97.5	95.0	98.1	97.8	97.4	95.7	97.8	85.4
Rural (%)	81.5	100	100	100	100	100	74.1	100	41.6
Children in poverty (%)	44.0	44.0	45.0	38.0	37.0	55.0	36.0	50.0	26.0
Unemployment rate (%)	11.9	13.2	12.6	13.9	13.4	10.9	12.0	12.8	8.2
Rank of 120	114	113	101	111	105	120	118	119	NA
Health Behavior or Outcome									
Adult smoking (%)	30.9	32.2	40.7	39.2	29.8	38.7	33.3	38.7	26.4
Access to exercise options (%)	17	30	79	100	58	55	59	37	89
Adult obesity (%)	43	41	30	40	38	37	38	33	30
Mammography screening (%)	31	49	38	39	50	43	48	51	69
Age-adjusted mortality*	775	543	687	638	598	693	739	693	445
Child mortality^	159	83	n/a	111	46	n/a	91	n/a	65
Motor vehicle crash deaths	49	40	38	38	41	42	37	42	20
Drinking water safety# (%)	83.3	62.0	82.3	0.0	27.4	0.0	0.0	0.0	10.9

* Per 100,000 population, if under age 75
^ Per 100,000 population
# Percent of the population exposed to water exceeding a violation in the past year

Although the KRADD is an economically distressed region with various access-to-care issues, it has an existing healthcare infrastructure that can support the implementation of a wide-scale community-level program. According to the 2015 Comprehensive Economic Development

Strategy (CEDS) of the KRADD, its healthcare industry has become one of the region's strongest and fastest growing economic sectors in recent years.[22] This strategic document identifies the weaknesses and strengths of the region that both preclude and support developmental initiatives in its key sectors. This document also serves as a community needs assessment as it provides economic, educational, infrastructural, and environmental analyses. Identified key strengths include the Mountain Comprehensive Health Corporation, regional hospitals, the district health department and local health centers (there are 256 healthcare establishments in the eight constituent counties), and media sources; weaknesses include a lack of preventive health and mental health services, a lack of drug rehabilitation treatment facilities, and a lack of transportation services.[22]

Although the CEDS document reports preventive health services as a deficiency of the KRADD, there is a strong network of organizations with the mission and capacity – through their resources and available services – to implement and support community-wide health initiatives. The Kentucky River District Health Department (KRDHD), along with its eight affiliate local county health centers, provides a variety of preventive health programs and is the central promoter and advocate of positive health in the region. For example, a notable program with the goal of reducing the burden of breast and cervical cancer is Ladies Health Days, hosted by the KRDHD through its local health centers at multiple time points throughout the year. Information and promotional gifts that raise breast and cervical cancer awareness and promote screening are given to program participants. In addition, each woman receives a physical exam including a breast exam, a Pap smear, and age-appropriate lab work; charges are based on income. The KRDHD provides financial support for mammography services and for follow-up of abnormal Pap tests and mammograms.

The KRDHD is able to amplify its mission through its strong partnership with the UK's Prevention Research Center (PRC), known locally as the Rural Cancer Prevention Center (RCPC). Through funding and support from the CDC and the Appalachian Regional Commission (ARC), RCPC aims to prevent cancer morbidity and mortality and its related disparities among KRADD residents through health initiatives, including the "1-2-3 Pap" intervention, a high school-based HPV vaccination project, the Cervical Cancer-Free Kentucky Initiative, and colorectal cancer screening with fecal immunochemical testing. Currently, the RCPC is developing the UK Appalachian Cancer Patient Navigation Project for the Appalachian region by creating a structured guideline for patient navigation training, establishing training programs in five Appalachian states, and coordinating services with CDC-funded breast, cervical, and colorectal cancer screening sites in the region.[23] KRDHD, through its close geographic proximity and shared mission, is able to provide RCPC the patient population and organizational structure needed to develop and implement their research-based interventions and programs. Together, the capacity of each organization is mutually bolstered to effectively and cooperatively promote positive health outcomes in the KRADD.

The KRDHD is well positioned through its experience, extensive network of partners (evidenced by attached letters of support), and sustainable infrastructure to expand its programmatic offerings by implementing a wide-scale cervical cancer intervention program. The KRDHD will be adapting a National Cancer Institute (NCI) Research-tested Intervention Program (RTIP) to increase cervical cancer screening rates in the KRADD. Specifically, the Forsyth County Cancer Screening Project (FoCaS) combines community outreach and clinic in-reach strategies to effectively reach its target population at multiple levels.[24] With culturally

thoughtful and logistic adaptations, this intervention is ideally suitable to the KRADD population through its design and methodology.

B. Program Approach

The high incidence of cervical cancer in the KRADD demonstrates the evident need for the implementation of an impactful, sustainable cervical cancer prevention program. FoCaS is a RTIP that was implemented in Forsyth County, North Carolina. It was one of six programs funded by the NCI's "Public Health Approaches to Breast and Cervical Cancer" research initiative in the early 1990s.[24] The FoCaS Project was designed to identify barriers to breast and cervical cancer screening faced by low-income women and healthcare providers and ultimately address these barriers in a comprehensive program designed to improve participation in screening.[24]

This program, by combining both clinic in-reach and community outreach strategies, is designed to reach participants at multiple socioecological levels, as strategies at the individual, interpersonal, community, and organizational levels were thoughtfully conceived to affect greater change. The theoretical framework for the community-based intervention comprised multiple models including the PRECEDE-PROCEED model for planning, the Health Belief Model for identifying and addressing barriers, social learning theory in using lay health educators to deliver educational components and promote self-efficacy in program participants, and the PEN-3 model to ensure cultural appropriateness and sensitivity in program development.[24]

In the original iteration of FoCaS, program participants were medically underserved women, predominately African-American, age 40 and older residing in Winston Salem and Greensboro, North Carolina.[24] The FoCaS Project comprised four phases implemented over a 4-

year period. In phase 1 of the project, local healthcare providers and women residing in the intervention and control cities, Winston Salem and Greensboro, respectively, were surveyed to identify perceived barriers; these identified barriers were used to inform the intervention. The program's Community Advisory Board was also formed during this initial planning year. During phase 2, the clinic in-reach and community outreach interventions were delivered to the intervention communities over a 2.5 year period. Clinic in-reach activities included training for healthcare practitioners, visual prompts in exam rooms, posters and literature in exam rooms, an abnormal test results protocol, one-on-one counseling sessions for women with abnormal test results, patient navigation for follow-up/treatment services, and personalized follow-up letters. Community outreach activities included targeted mailings, one-on-one educational sessions in women's homes, a church program, mass media, and a Women's Fest Event, a community party with food, educational classes, prizes, and information booths. Table 3 further categorizes these intervention strategies by their level in the socioecological model. Phase 3 of the project began at the end of the intervention's delivery and included a follow-up survey of women in both the intervention and control groups. In phase 4, the intervention was delivered to the comparison city as cervical cancer screening rates significantly increased in the intervention city from 73% to 87% (compared to a decline in screening rates in the comparison city from 67% to 60%).[24]

Table 3. Intervention Strategies by Targeted Socioecological Level

	Targeted Socioecological Level		
Strategy	**Individual/Interpersonal**	**Community**	**Organization**
In-reach (clinic-based)	• Training for health care practitioners • One-on-one counseling sessions for women with abnormal test results • Personalized follow-up letters • Chart reminders/visual prompts in exam rooms • Posters and literature in exam rooms	• Monthly classes led by community health workers	• Patient navigation for follow-up/treatment services • Abnormal test protocol

Outreach (community-based)	• Targeted mailings • One-on-one educational sessions in women's homes • Informational centers	• Women's Fest with food, educational classes, prizes, information booths • Church program • Mass media

The FoCaS Project is one of nine cervical cancer intervention programs listed in the NCI's RTIP database.[25] According to the project's RTIPs scores, which measure the program's research integrity, intervention impact, and dissemination capability, the cervical cancer screening component of the intervention had broad impact. The RE-AIM framework, which evaluates a program's translatability into action, measured this program's reach—the absolute number, proportion, and representativeness of individuals who are willing to participate in a given initiative, intervention, or program—at 100%.[25]

The purpose and methodology of the FoCaS Project are translatable to the KRADD region as the target population of the FoCaS Project and the women on the KRADD share common determinants of health and health mediators, including low socioeconomic status and poor rates of cancer screening.[8,9,24] The significance of religious faith is also shared between both groups. The FoCaS Project included a faith-based community strategy in its outreach plan which is translatable to the proposed iteration of the program as research has shown middle-aged Appalachian women view churches as acceptable environments for promoting positive health behavior.[27,28] The proportion of Appalachian residents reporting church affiliation is higher than that observed nationally,[27] and more than one-third report weekly church attendance.[26,27]

Race is a key difference between FoCaS participants and KRADD residents. The majority of FoCaS participants were African American (79.5%); Forsyth County is 57.7% non-Hispanic White, while the KRADD is 97.1% non-Hispanic, White. The rural-urban environmental context is another significant difference between Forsyth County and the

KRADD: Forsyth County is 7.3% rural; the KRADD counties average to 94.5% rural.[29] These differences between the intervention city and the KRADD will necessitate strategic adaptation to ensure cultural appropriateness and relevance, as well as logistic feasibility, before the program is fully implemented in the KRADD. Implementation in the KRADD will bring specific challenges associated with rurality, which include distrust of the medical community,[30,31] cultural barriers such as fatalism,[16-18] limited transportation, topography and weather-related challenges, and a lack of accessibility to essential services due to geographic isolation and poverty.[14,32]

To address these challenges and to create practical solutions, as well as make appropriate program adaptations, the KRDHD will work closely with the Community Advisory Board (CAB) of the RCPC, which will also serve as the official CAB of the Appalachian iteration of FoCaS. This CAB is composed of members who work within the KRADD District Health Department (KRDHD) and the local health centers. This CAB also includes representatives from WellCare of Kentucky, ACS, and KCP. Local media is represented by two members, a city councilman from the *Jackson Times Voice* Newspaper and a radio morning show co-host of WHAS Radio. Finally, a prominent parishioner of Maple Street Church of God represents the faith-based community. This variety of representation ensures a balanced community perspective and provides expertise in the multiple fields that comprise an intervention's successful implementation. Table 4 identifies CAB members by name and affiliated organization and includes the rationale for involvement.

Table 4. Community Advisory Board Membership and Rational for Involvement

Member and Affiliate Organization	Rationale for Involvement
Renee Cooper ***Retired Health Educator***	Insight as a former community health educator; knowledge of community beliefs and perceived barriers
Karen Cornett, RN ***Kentucky River District Health Department***	Knowledge of inner workings of district health department; insight into needed cultural and logistic adaptations per local context; to advise on program planning and participant recruitment and retention

Darlene Deaton, RN ***Kentucky River District Health Department***	Knowledge of inner workings of district health department; insight into needed cultural and logistic adaptations per local context; to advise on program planning and participant recruitment and retention
Susan Oliver ***Lee County Health Center***	Knowledge of local health center operations and patient population; to advise on program planning and participant recruitment and retention
Andrea Smith ***Wolfe County Health Center***	Knowledge of local health center operations and patient population; to advise on program planning and participant recruitment and retention
Vivian Payne ***Lee & Owsley County Health Centers***	Knowledge of local health center operations and patient population; to advise on program planning and participant recruitment and retention
Sherry Whitaker ***Knott County Health Center***	Knowledge of local health center operations and patient population; to advise on program planning and participant recruitment and retention
Sharon Godsey ***WellCare of Kentucky***	Provider of Managed Care Services and psychosocial services; potential liaison between patient and physician
Candace Teague ***American Cancer Society***	Local linkage to a nationwide, community-based cancer organization; connection to information on cancer, local resources, patient service programs; potential future funding sources
Ashley Dunaway ***Kentucky Cancer Program***	Expertise in cancer-related disparities; potential future funding sources; knowledge of services available
Tonya Neace ***Maple Street Church of God***	Represents faith-based community; provides insight into faith-based component of program; assist in coordinating programmatic church events
Harold Gayheart ***City Councilman, Jackson, KY*** ***Jackson Times Voice Newspaper***	Expertise in media messaging and dissemination; ensure dissemination of accurate information to the public; municipal leader with political influence
Chas Kincaid ***WHAS Radio, Hazard, KY***	Local radio personality; expertise in media messaging and dissemination; ensure dissemination of accurate information to the public

For the first six months of the project, the Program Manager and Program Coordinator will meet bi-weekly with the CAB for initial program planning. Initial program planning will specifically involve adapting FoCaS to create an Appalachian iteration of the original program. As the intervention impact of FoCaS for breast cancer screening was low reaching according to its RTIPs scores,[25] the breast cancer screening component of the program will not be rigorously implemented. The importance of breast cancer screening and early detection, including awareness of mammography screening guidelines, will be taught during a clinic-based, monthly educational session. Lessons learned from our cervical cancer screening project may be used to inform a future programmatic iteration focused on improving breast cancer screening rates among KRADD women.

Program adaptions will be logistic and cultural and will not detract from the evidence base of the original program. Program materials, including brochures, mailings, educational literature, and media messaging will be adapted for cultural appropriateness and relevance to our target population. Media imagery will be modified to be more representative of the KRADD and its residents. These adaptations align with consumer information processing (CIP) theory, which indicates that when health information is available and easy to process, individuals can be guided to engage in health protective behaviors, such as preventive screening.[11] Program materials tailored to reflect Appalachian culture and attitudes may promote identification with and relatability to the program's campaign among KRADD women and lead to increased program uptake and adherence.

Each program activity listed in Table 3 will be reviewed and logistically planned by the CAB and Program Manager and Program Coordinator. The outreach strategies of the program intervene at the individual and community levels. At the individual and interpersonal levels, one-on-one counseling sessions in women's homes will be conducted by lay Community Health Workers (CHW) of Kentucky Homeplace, a program developed by the UK's Center for Excellence in Rural Health (CERH) with the mission to provide access to medical, social, and environmental services.[34] These home visits alleviate the barrier of transportation in this geographically-isolated and impoverished region and allow women who are restricted to their homes due to physical or mental handicaps to access the program. CHWs will be demographically similar to program participants (i.e., married, middle-aged, middle-to-lower socioeconomic status), with no professional healthcare background.[36] CAB member Renee Cooper, a retired health educator, and the Program Manager and Program Coordinator and will train the CHWs on cervical cancer, Pap tests, screening guidelines, navigation to follow-up

services, and the intervention protocol, including home visit procedures and tailoring content to participants' identified barriers.[36]

Effective training of CHWs will be critical to the program's successful attainment of its intended outcomes. NCI supports the use of lay patient navigators in medically underserved areas to provide guidance and support to an individual with abnormal cancer screening results or with a cancer diagnosis.[41] Research has shown that patient navigation is an effective method to reduce disparities in cancer care.[41] CHWs will be critical in navigating patients with abnormal results to follow-up care as they will provide personal advocacy, local knowledge, and assistance from the lay perspective to help patients overcome barriers to follow-up care.[41] However, as beneficial as patient navigation is in eliminating barriers to care and providing patient support, it may confound a program's implementation process as there can be variance in CHW communication and deviation from the implementation protocol.

Previous research regarding cervical cancer care in Appalachia has shown that patient navigators feel equipped to handle the logistical barriers reported by patients.[41] Navigators are familiar with the terrain of health facilities and can assist in scheduling and bringing patients to their appointments. Navigators are also equipped to handle barriers related to payment for services. They are able to help patients understand how payment works and complete many of the tasks related to securing payment for care on the behalf of patients. However, findings also indicate that lay navigators may not be well-equipped to help patients address barriers related to uncertainties about cervical cancer and its treatment.[41] Navigators may help patients evaluate their uncertainty by using certain and uncertain knowledge strategically and privilege some forms of uncertainty over others to reframe patients' perceptions of abnormal Pap test results, which may perpetuate misinformation and misunderstanding of cervical cancer.[41] Uncertainty

management strategies will be included in CHW training. CHWs will be trained to defer to medical personal when they lack particular knowledge so they do not use incorrect or misapplied information to help patients overcome uncertainity.[41] The project team will use this research to inform the creation of unique scripts that address barriers related to uncertainty to assist CHWs in delivering consistent and medically accurate information.

The Program Manager and Program Coordinator will monitor CHW implementation of the program for fidelity and adherence to scripts and evidence-based strategies. CHWs will go into the homes of women who are unable to attend the community-based educational classes. The sessions will be scheduled in advance at a time that is convenient for participants. CHWs will use a flip-chart with colorful images and bulleted statements to explain what happens during a Pap smear; CHWs will also explain the etiology of cervical cancer and that cervical cancer is preventable through routine screening and early detection. For women with age-eligible children, the CHWs will also promote HPV vaccination and arrange for vaccination services as appropriate.

In order to further disseminate the program message into the community, a direct mail technique will also be used. The project will mail postcards to all age-eligible women – as identified by county voter registration or drivers' license lists – on a bimonthly basis that provide basic information on cervical cancer with messaging created with the Stages of Change as its basic framework. Given that assessment of each woman's stage of change is not feasible in this mass mailing strategy, stage-directed messaging will begin with the pre-contemplative phase, proceed to the contemplative phase during the next bimonthly mailing period, and then proceed to the preparation and action phases during the next mailing periods. These postcards, as well as birthday cards, newsletters and brochures to address barriers to cervical cancer screening are

examples of outreach at the individual level. All direct mail will be linguistically and culturally adapted by the CAB and Program Manager and Program Coordinator. Medical-accuracy will be reviewed by CAB members and registered nurses Karen Cornett and Darlene Deaton.

At the community level, outreach strategies include a mass media campaign, informational centers, a church program, and a community-wide Women's Fest. In its media campaign, the original program used radio public service announcements (PSAs), newspaper articles and advertisements, and bus posters. The Appalachian iteration of FoCaS will bolster its media campaign by creating a television PSA advertising the program and will use social media to promote and maintain the program. Program messaging will also be disseminated through print and radio media. As the KRADD does not have public transit, the bus posters, an original piece of the media campaign, will transformed into billboard advertisements in the Appalachian iteration of the program. CAB members and media experts Chas Kinkead and Harold Gayheart will use their professional experience and knowledge of the KRADD viewership to inform media and billboard messaging.

Informational centers, another community outreach strategy, will be located throughout the KRADD in doctors' offices, beauty shops, grocery stores, social service agencies, and banks. Based on the strategy of point-of-purchase marketing, these informational centers will be designed as point of purchase displays, structured to increase awareness, educate, and promote health-protective action. These displays will contain contact cards and program brochures advertising the program and addressing common barriers to screening and perceptions of cervical cancer. These centers will be checked on a bi-weekly basis and will be continually supplied with new information by CHWs. Information provided will be medically-accurate and culturally

appropriate to the target population and will be reviewed by the complete CAB and Program Manager and Program Coordinator.

CAB member Tonya Neace, lifelong parishioner of Maple Street Church of God and breast cancer survivor, will inform faith-based messaging and assist in coordinating the church program. FoCaS utilizes three church-based strategies. The first strategy seeks to establish a partnership between the program and a local church. Local churches will be sent a letter requesting their partnership with the program. If interested in participating in the program, ministers will appoint church liaisons who will, using their knowledge of their respective congregations, select the most appropriate program format(s) (of three options) to be implemented in their church. Church liaisons may choose to: (1) have an informational center displayed in their church, (2) schedule a CHW-conducted workshop to be held in their church, and/or (3) become trained to lead their own congregation's workshop.

The second church-based strategy includes program inserts in church bulletins. These inserts will be mailed to local churches and include scriptures and religious imagery as a means to promote preventative cancer screening. The third strategy specifically addresses cancer and health fatalism. The church program will conclude with a session called "Healthy Spirits" which will allow participants to leave the workshop on an inspirational note. Scriptures from the bible, inspirational poems, and positive sayings will be used to strongly emphasize that preventative health measures, including cancer screenings, are God's way of assisting human beings toward wellness.

To celebrate and educate the women in the KRADD, the program will hold an annual "Women's Fest," a large-scale, community-wide party with food, educational classes, prizes, and information booths. The fest will be held in a local park and will be an inclusive, all-day event

with live entertainment and guest speakers, including cervical cancers survivors of all disease stages and healthcare professionals from the community. This event will raise awareness and motivate participation in health protective screening. The KRDHD will showcase their offered services and community-wide and statewide partnerships.

The clinic in-reach strategies also intervene at multiple levels of the socioecological model and address provider, system, and patient barriers to screening.[24] At the organizational level, visual prompts will be put in exam rooms, e.g., "Have you screened today?"; electronic medical record flags will be instituted; an abnormal test protocol will be implemented that includes a referral/navigation process for managing the care of women with abnormal test results and a tracking system; posters and literature to inform patients of the importance and benefits of screening will be distributed in waiting areas and exam rooms and will be reviewed for medical accuracy. Monthly educational classes led by CHWs will target the individual and community influences on behavior. These monthly educational classes will focus on multiple aspects of health and encourage the uptake other positive health behaviors in addition to cervical cancer screening. The curriculum will include an added component to address the importance of HPV vaccination for age-eligible adolescents and will work to dispel common misconceptions related to the vaccine (i.e., vaccination promotes promiscuity; vaccination precludes the need for screening). This effort will be directed to program participants who themselves are age-eligible to receive the vaccine and to participants who can influence/mediate the actions of the adolescents/young adults in their lives (i.e., daughters, sons, nieces, nephews).

The educational classes will also include a series on smoking cessation and prevention. The series will be led by the KRDHD facilitators of the Cooper Clayton Method to Stop Smoking Program. Smoking is a known cofactor to the development of cervical cancer.[37,40]

Findings suggest that that HPV infection alone may not be sufficient to cause cervical cancer; other cofactors, such as smoking, in conjunction with HPV infection, may increase the risk of progression from cervical HPV infection to invasive cervical cancer.[40] Findings also suggest that smokers maintain cervical HPV infections significantly longer and have a lower probability of clearing an infection than women who never smoked.[40] Therefore, the elevated prevalence of HPV infection and smoking in Appalachia may synergistically contribute to the significant disparity of cervical cancer incidence in this region. Efforts to promote smoking prevention and cessation may assist in reducing the incidence of cervical in the long term, as well as reducing other smoking-related morbidities.

Clinic-based strategies also target the individual and interpersonal levels of behavior. Healthcare providers will receive continuing education credits for attending in-service trainings on cultural sensitivity and techniques to integrate cervical cancer screening in primary care settings. Clinic staff will be trained on instituting electronic medical record flags to indicate to providers a potential screening opportunity, personalizing letters for follow-up testing for women who have abnormal results, and employing the abnormal test protocol. Clinic staff will alert CHWs to all abnormal Pap test results. CHWs will contact patients to provide support and facilitate navigation through the follow-up and treatment process to reduce system barriers.

The Appalachian iteration of the program will include two additional clinic-based, organizational strategies. The rurality of Appalachia – geographic isolation and low population density, challenging topography, poverty, lack of transportation – are noted barriers to screening and accessing health services.[14,22,32] The Appalachian iteration will include a mobile Pap clinic to overcome these barriers. A female Advanced Practice Registered Nurse (APRN) will perform the screening exams. The inclusion of a female healthcare provider addresses the barriers of

embarrassment and female provider scarcity that have been cited as barriers to screening in this region.[32] These two specific additions to the programmatic approach allow for a more effective reach of the target population in the KRADD.

In Appalachia, challenges with adapting and implementing evidence-based programs are noted; evidence-based programming itself has been viewed as a barrier to health promotion in this region.[33] Logistic and cultural adaptations are needed to meet the unique needs of this rural, economically-distressed area. Previous researchers in Appalachia have made a range of adaptations to meet constituent needs; this adaptability, however, jeopardizes intervention fidelity.[33] To preemptively address the challenges of evidence-based program implementation in this region, the project team and CAB will draw upon the experience of Dr. Kate Geddens, an assistant professor at UK who focuses her research on health communication to eliminate cancer health disparities and developing partnerships with community-based organizations for intervention delivery. Her ongoing project "Connecting Appalachians to Lung Cancer Screening: Leveraging Social Networks to Reduce Lung Cancer" is highly relatable to the cervical cancer screening needs of this region and will be helpful in informing recruitment and retention strategies as program recruitment and retention are also known challenges of this region.[33]

Once the program is logistically and culturally adapted for the KRADD, focus groups of women residing within the KRADD will be conducted to provide feedback regarding cultural relevance, feasibility of intervention activities, and salience of program messages. Feedback will be analyzed for salient themes by Dr. Geddens and incorporated into the implementation plan accordingly. The program will be pilot-tested with a select sample of women (N=10-15) inclusive of the target population. These women will be recruited from local churches and will participate in all program activities. Pilot-testing will reveal if FoCaS has been appropriately

adapted for full implementation in the KRADD and will demonstrate the program's success in reaching its intended outcomes.

After six inceptive months of rigorous program planning and successful piloting, the Appalachian iteration of FoCaS will be implemented in its first site, the KRDHD, the district-level health department in Perry County. The KRDHD is the best equipped health department in the KRADD and will house the Program Manager and Program Coordinator who will be on-site during the implementation of the program. This oversight will ensure that the program is being implemented with fidelity, which is a critical assurance during the program's first few months of implementation. Program implementation will begin with implementing the clinic in-reach strategies. Healthcare providers and staff will be trained on the objectives of the intervention, current cervical cancer screening guidelines, and program procedures, including implementing the abnormal test result protocol and cultural sensitivity. Waiting areas and exam rooms will be stocked with programmatic literature. Once KRDHD is prepared to implement its clinical interventions, recruitment of program participants will begin. The mass media campaign, comprising print, social, television, billboards, and radio media, will be launched. Informational centers will be set up throughout Perry County. The media campaign and informational centers will advertise the program's one-on-one home counseling sessions and mobile Pap clinic. Participants will be able to self-refer into the program by contacting KRDHD directly. CHWs will conduct the monthly educational classes in KRDHD. Local churches will be contacted for their participation in the program and the church-based program will be delivered to all churches that provide their partnership. At the end of the program, the Women's Fest will be held to reinforce the program's message in a dynamic, inspirational way. Through concluding the program with the Women's Fest, a celebration of women and empowerment, it is intended that

program participants will be motivated to continue participating in cervical cancer screening and other health protective behaviors.

After six months of successful implementation in KRDHD and the Perry County community, the program will be extended to the local health centers and communities of Breathitt County and Owsley County, with long-term goals of offering the program in the remaining five KRADD counties. Breathitt County and Owsley County were selected as the next two counties to receive the program due to particular health disparities at the county level; for instance, Breathitt County has the poorest rate of mammography screening which may imply a poorer rate of cervical cancer screening (this data is not available at the county level). Owsley County has the worst health ranking in the state of Kentucky, is poorest county in the KRADD, and an extremely high prevalence of smoking. This increased prevalence of smoking is relevant to cervical cancer screening as smoking is a risk factor associated with increased risk of developing cervical cancer. Routine screening is, therefore, even more critical in this population.[36]

Figure 3.
KRADD Counties to Receive Intervention

It its projected this program will reach 700 women and lead to the screening of 400 women in its 2.5 year implementation period. “Reach” will be defined as the number of women who participate in at least one program activity: attend a church workshop, an educational class, the Woman’s Fest; respond to the media campaign/informational centers through self-referral into the program, and will include the number of women who are screened for cervical cancer

and who also report their reason for obtaining screening was a result of the FoCaS program. It is expected that a number of screened women will require follow-up treatment of abnormal test results. KRDHD will provide linkages and referral services to its existing partner organizations including Appalachian Regional Healthcare, WellCare, LKLP Transit, and Middle KY Transportation. Health department and health center staff, as well as CHWs, will assess program participants' health insurance status to triage participants to appropriate payment options for their screening and subsequent follow up care as needed.

At the end of this grant period, KRDHD plans to sustain the FoCaS program through additional grant funding awarded through ACS and KCP. KRDHD will expand the full program into the remaining five KRADD counties (Lee, Leslie, Letcher, Knott, and Wolfe). Upon the successful implementation of the program and the attainment of program outcomes across the entire KRADD, KRDHD will appeal to the Kentucky Department for Public Health for an increase in its annual funding allocation to establish the program as a permanent line item in its community outreach and prevention budget. The Appalachian FoCaS model may also be disseminated to other district and county health departments outside the KRADD.

C. Performance Measures and Evaluation

In order to support the achievement of the intervention's outcomes, the program will be evaluated throughout its implementation to assure adherence and fidelity to the implementation plan. Routine surveillance of program activities with collection of relevant performance measure data will ensure that the program is proceeding as planned and is on track to meet its intended outcomes. Performance measure data will be used for continuous quality improvement throughout the duration of the program and to ensure to funders that the program is on track to achieve its outcomes. The Program Manager and Program Coordinator will be responsible for

conducting implementation evaluations of all program components, and with the expertise of a UK biostatistician, the Program Manager will also conduct the outcome evaluation of the program.

Each program activity, listed in the program's logic model (see Appendix A), yields quantifiable performance measure data, which represent yielded outputs. In addition to collecting performance measure data, during the pilot-testing phase of the program and at intervals throughout its live implementation, the Program Manager and Program Coordinator will monitor program activities through direct observation to ensure activities are being implemented with fidelity according to the intervention protocol.

Effectively and properly training the individuals who will conduct the intervention through their direct interaction with program participants is critical to the program meeting its intended outcomes. During the six month planning phase of the project, healthcare practitioners, clinic staff, and CHWs will receive all necessary program training. The Program Manager will monitor the Program Coordinator's first two training sessions with healthcare providers and clinic staff to ensure all clinical procedures have been taught consistently and appropriately. Healthcare providers and clinic staff will participate in mock clinical scenarios during training sessions, which will be observed by the Program Manager and/or Program Coordinator. Any deviations from the implementation protocol will be corrected and re-practiced until properly conducted. The number of individuals trained, including healthcare practitioners, clinic staff, and CHWs, will be tracked. All program trainees will receive pretest and posttest assessments to gauge knowledge learned from the training sessions. Questionnaires will also be given to program trainees to rate and reflect on the quality of training received. Questionnaire and posttest

data will reveal to the Program Manager if all components of the training sessions were properly delivered to participants.

To monitor the clinic in-reach strategies of the program, the Program Manager, who is based in the KRDHD, will conduct observations of clinical programmatic procedures, conduct medical chart reviews, and will ensure the facility is properly displaying programmatic literature. Performance measure data from the clinic in-reach strategies include number of posters, visual prompts, and literatures dispersed/displayed; number of monthly educational classes taught and number of attendants; number of women screened for cervical cancer; number of personalized follow-up letters mailed; and number of patients who received one-on-one counseling for abnormal test results and were navigated to follow-up care.

In addition to the collection of key performance measure data, both quantitative and qualitative assessments will be used to evaluate the implementation of the program's clinic in-reach activities. The Program Manager and Program Coordinator will observe the first two monthly educational classes delivered by each CHW. This will ensure that CHWs are implementing the educational classes with fidelity according to the intervention protocol at each session. The Program Coordinator will then continue to monitor every other monthly class session to assess for maintained implementation fidelity. Program participants will be given pretests before the educational classes and posttests at their conclusion to assess changes in knowledge, attitude, self-efficacy, and perceptions of barriers. Participants will also complete questionnaires to provide feedback on the delivery and quality of instruction.

The Program Manager and Program Coordinator will also monitor the clinic staff and CHW's implementation of the abnormal test protocol by observing the first two one-on-one counseling sessions with patients. Patients will complete questionnaires by mail to provide their

feedback on their counseling session and navigation experience. This will report patient satisfaction with the services provided and assess consistency in CHW implementation of the abnormal test protocol. Questionnaire data may inform strengths and weaknesses in CHW implementation and may lead to assessing each CHWs delivery for subtleties in communication and intervention delivery. Highly successful CHWs will be observed for assessment of best practices and will inform additional training for less successful CHWs.

The same evaluative methods will be used for the implementation evaluation of the community outreach activities. Performance measure data will be collected to quantify the number of: program advertisements; media campaign viewership assessed through rapid assessment survey; targeted mailings; informational centers set up throughout the community; home visits by CHWs; screenings scheduled from home visit encounters; church partners, church workshops held, church liaisons trained; community partners participating in the Women's Fest and attendants of the fest; and women screened for cervical cancer. Rapid assessment surveys conducted by CHWs outside public locations will determine the extent of media campaign viewership and will inform who is not being reached by the campaign and why. This information will inform needed adaptations to the media campaign's distribution or messaging to broaden its reach.

Pretest/posttest data will assess knowledge gained, attitudes changes, and changes in perception of barriers after one-on-one home counseling visits and the church program, which will also be initially and routinely observed by the Program Manager and Program Coordinator for implementation fidelity by the CHWs. Table 5 summarizes the performance measures and methods of evaluation for each programmatic activity.

Table 5. Process Evaluation Summary

Process Evaluation		
Activity	**Performance Measure**	**Method of Evaluation**
Training • Healthcare practitioners • Clinic staff • CHWs	Number of: • Individuals trained • Training classes held	• Observation of training sessions by program manager • Pretest/posttest assessments to measure knowledge gained • Questionnaires to provide feedback on training
Clinic in-reach • Posters, literature, visual prompts • Chart reminders • Educational classes • Personalized follow-up letters • Abnormal test protocol	Number of: • Posters, visual prompts, and literature displayed/distributed • Chart reminders issued • Educational classes taught and number of attendants • Personalized follow-up letters mailed • Patients navigated to follow-up care • Patients who received one-on-one counseling • Women screened for cervical cancer	• Pretest/posttest assessments to measure knowledge gained, attitudes changed • Questionnaires to provide feedback on educational classes, patient navigation experience, and on one-on-one counseling • Observation of educational classes and one-on-one counseling by program manager and program coordinator
Community outreach • Media campaign • Targeted mailings • Informational centers • One-on-one home visits • Church program • Women's Fest	Number of: • Advertisements • Media campaign viewership • Targeted mailings • Informational centers throughout community • Maintenance and update visits to informational centers • Home visits • Screenings scheduled from home visit encounters • Participating churches, church workshops, attendants, trained church liaisons • Partner informational booths • Women's Fest attendants • Women screened for cervical cancer	• Rapid assessment surveys • Pretest/posttest assessments to measure knowledge gained, attitudes changed • Questionnaires to provide feedback on one-on-one home visits, church-based program, media campaign, and informational centers • Observation of one-on-one home visits and church-based program by program manager

With rigorous implementation evaluation methods occurring throughout the duration of the program and monitoring for continuous quality improvement, the outcome goals for this program should be reached. The short term outcomes of the program will be realized first and will lead to the medium term outcomes which will lead to the singular, overall long term outcome of the program: reduced cervical cancer incidence, morbidity, and mortality in the KRADD region. These outcome goals are listed in Table 6 and in the logic model (Appendix A).

Table 6. Program Outcomes

Outcomes		
Short	**Medium**	**Long**
• Increased awareness of importance of cervical cancer screening and HPV vaccination • Increased healthcare provider knowledge about cervical cancer screening and surveillance guidelines • Reduced barriers (perceived and actual) and increased access to cervical cancer screening • Adoption of sustainable clinic in-reach activities • Improved coordination of services following abnormal test results	• Increased uptake and adherence to guideline-recommended cervical cancer screening among KRADD women • Increased HPV vaccination uptake among adolescents and young adults • Reduced disparities in cervical cancer screening rates in the KRADD • Improved clinical and community linkages • Improved coordination of resources and services to enable FoCaS Appalachia to become a sustainable program	• Reduced cervical cancer incidence, morbidity, and mortality in the KRADD region

Many of the short term and medium term outcomes will be evaluated during the periods of implementation/process evaluation. The most meaningful outcome that will lead to the attainment of the ultimate outcome goal is a change in the predisposing factors that affect cervical cancer screening. Surveys to measure attitudes, beliefs, and knowledge of cervical cancer will be completed by program participants at baseline and upon program completion. These constructs will continue to be measured on an annual basis among program participants to assess the enduring effect of the program. County- and district-level cervical cancer screening rates will continued to be monitored through the Kentucky BFRSS during the project and in the long-term. KRDHD will contract with the UK Survey Research Center to conduct a thorough assessment of programmatic impact in the target communities. The UK Survey Research Center will use a valid, statistically reliable questionnaire to measure knowledge gained and attitudes changed during the course of the intervention's implementation in the KRADD. The questionnaire will measure changes in norms and beliefs regarding cervical cancer screening and HPV vaccination. A quantitative measure of the number of women who have participated in screening and women who have received the HPV vaccine or who have influenced a loved one

to receive the vaccine will be derived from this questionnaire. Although beyond the scope of the current project, the long term outcome of the program, reduced cervical cancer incidence, morbidity, and mortality, will be evaluated through the districtwide collection of performance measure data (i.e., cancer surveillance data from the Kentucky Cancer Registry) that reflects incidence of cervical cancer and deaths related to cervical cancer over the long-term.

D. Capacity and Experience of the Applicant Organization

The Kentucky River District Health Department (KRDHD), with its mission to protect, maintain, and promote the health of the people of the community, serves the eight counties of the KRADD. Each county within the KRADD has its own local health center through which the KRDHD partners to promote its mission. Together with the local health centers and other vital community partners, the KRDHD has a successful history of implementing both evidence-based and community-based programs. The select sample of initiatives described below represents successful collaborations between the KRDHD, its community partners, local health systems, and academic research institutions.

Cooper Clayton Smoking Cessation Classes

The KRDHD, with its affiliate local health departments, provides the Cooper–Clayton Method to Stop Smoking Program. Since its initiation of the program in 2004, KRDHD has reached 890 individuals. This nationally renowned community and evidence-based program provides in-class, daily training for 12 weeks to promote smoking cessation and smoke-free maintenance. Nicotine Replacement Therapy is provided free of charge, and long term support is offered to all participants. Participants who complete the program are 85% more likely to quit and remain smoke-free.

Kentucky Health Access Nurturing Development Services (HANDS)

The Kentucky HANDS Program is a long-running state program established in 1999 that the KRDHD provides to expectant parents. This home visitation program provides direction in creating a safe, healthy home that fosters optimal development for newborns. The HANDS Program provides support throughout pregnancy and through the first two years of a baby's life. The KRDHD extension of the HANDS program has conducted over 36,000 home visits for over 3,000 families since the program's inception.

"1-2-3 Pap" Intervention

The Rural Cancer Prevention Center (RCPC), a Prevention Research Center at UK funded by the CDC, partnered with the KRDHD to design and implement a tailored cervical cancer prevention and screening program. The program was implemented all eight KRADD counties and targeted multiple levels of the socioecological model. An array of community partners were involved: eight local health departments, the KY Department of Public Health, 10 private providers, three Wal-Mart stores, one television station, and three radio stations. A tailored social marketing campaign promoting HPV vaccination and regular Pap testing was disseminated into the community. Eligible women (N = 344) were offered one dose of the HPV vaccination series free of charge and then asked to participate in a research study. Participants were randomly assigned to an intervention arm (N = 178) or a usual care arm (N = 166). Participants in the intervention group watched a short DVD called "1-2-3 Pap," which educated women on the importance of HPV vaccination and cervical cancer screening and addressed prominent barriers. Women in both arms received follow-up calls from local outreach nurses to remind them to complete the 3-dose vaccine series. Women in the intervention group were 2.44 times more likely than women in the usual care group to complete the full vaccine series.[43]

Uptake and Adherence to Annual Fecal-Immunochemical Testing (FIT)

To reduce the incidence of colorectal cancer in the KRADD, the KRDHD is partnering with the RCPC to promote annual FIT. Key community partners, including local health departments, faith-based agencies, healthcare providers, retail stores, employment services, and media outlets, assist in participant recruitment. Participants complete a questionnaire regarding knowledge and perceptions associated with colorectal cancer and are given a take-home FIT collection kit. RCPC staff processes the returned samples, delivers results and initiates patient navigation for follow-up care if needed. More than 320 participants have enrolled in the pilot study to date; 34 participants have sought a follow-up colonoscopy. Enrollment will continue until 400 participants have been enrolled.

Proactive Office Encounter Intervention

The KRDHD is partnering with the Appalachian Center for Cancer Education, Screening, and Support (ACCESS), a collaborating center of the Cancer Prevention and Control Research Network, to provide evidence-based, individually tailored cancer prevention protocols as patients are seeking routine care in local healthcare systems. Prior to an individual patient's appointment, clinic staff will be alerted by the electronic health record that a patient is overdue for specific routine screening procedures, for instance, a mammogram, Pap test, and/or fecal occult blood test. When the patient presents for her appointment, clinic staff will inform her that she is overdue for certain screening procedures and offer to perform those procedures at the present appointment. This novel approach of providing proactive clinical care rather than reactive care aims to increase screening rates by improving the convenience and accessibility of screening procedures.

KRDHD's long running, successful implementation of the Cooper Clayton Smoking Cessation program is just one example that demonstrates the organization's experience in

collecting performance measure data that led to improvements in program quality. This program is highly successful in meeting its outcome goal of smoking cessation when participants complete the entire program; those who complete the program are 85% more likely to quit smoking and remain smoke-free.[44] During KRDHD's first three years of implementing this program, this success rate was seen in participants who completed the program; however, program retention was low as more than half of the participants did not complete the 12 week course. Collection of the numbers of enrollers and completers of the program conveyed this information. The Program Coordinator conducted one-on-one interviews with participants who did not complete the program to determine what factors hindered their completion of the program. It was found that transportation to the daily classes was the key barrier to program completion. As a result, KRDHD expanded its partnership with several transportation services, including LKLP Transit and Middle KY Transportation, to provide free transportation to program participants.

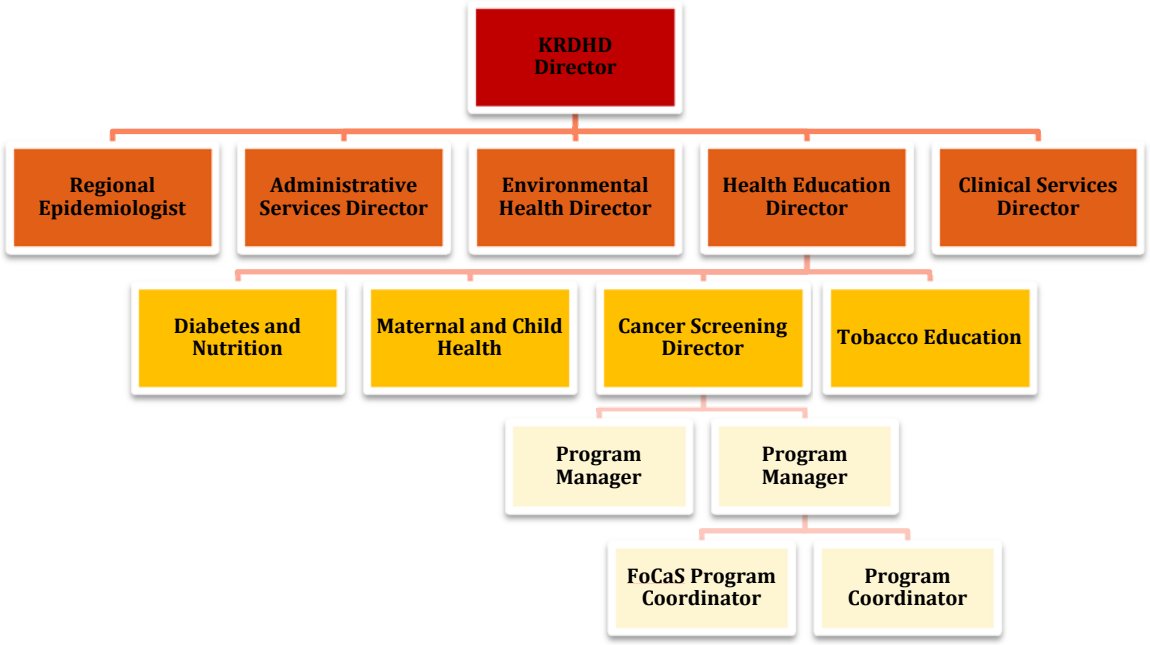
The successful and continued implementation of the Cooper Clayton Method to Become a Nonsmoker also exemplifies KRDHD's history of sustaining a grant-funded program after the initial grant period. After the initial grant period, KRDHD was able to sustain the program for three more years through a second grant awarded from the Kentucky Cancer Consortium (KCC). After this second successful grant period, the Kentucky Department for Public Health increased its annual allocation to KRDHD to allow the program to become a permanent budget line item. KRDHD also receives funding from the ACS, KCC, and the Appalachian Regional Commission to assist in financially supporting the implementation of its prevention programs and the maintenance of its facilities across the KRADD.

The objectives of FoCaS align with the mission and vision of KRDHD as this screening program seeks to protect, maintain, and promote the health of women, and cervical cancer is a disease of disproportionate and preventable burden in the KRADD. As a Kentucky health department, KRDHD is a provider of low-cost or free cervical cancer screening services as part of the Kentucky Women's Cancer Screening Program funded by the CDC's Breast and Cervical Cancer Early Detection Program. KRDHD is committed to reducing the cervical cancer disparity in this region and has implemented programs to target cervical cancer and promote its screening program, including the aforementioned "1-2-3 Pap Intervention" and its series of Ladies Health Days held across the region at multiple times throughout the year. KRDHD is capable of supporting and managing the implementation of FoCaS throughout the KRADD, not only through its experience in implementing and sustaining effective health programs, but also through its strong organizational infrastructure.

The District Director oversees the operations of all the services sectors of KRDHD. The organizational chart includes each service sector and specifically outlines the organizational structure within the Health Education division. KRDHD provides services and programs for maternal and child health, tobacco education, cancer screening and prevention, and nutrition and diabetes education.

The District Director and the other service sector directors oversee departmental operations and collect relevant performance measure data to inform continuous quality improvement throughout the organization. Performance measure data are numbers that reflect the reach of the health department through its offered services and programs. Low-reaching programs are assessed for areas of improvement through qualitative feedback provided by

program participants and through researching and applying evidence-based strategies and best practice methodology to programmatic approaches.



KRDHD is an instrumental partner and champion to fellow community organizations including the RCPC. RCPC is able to conveniently utilize KRDHD's infrastructure and patient population for its endeavors in community-based participatory research. The leadership and collaboration of KRDHD augment RCPC's community engagements in cancer prevention activities and research throughout the KRADD. KRDHD provides technical assistance and training to all its partners in evidence-based program delivery. KRDHD acquires community-level data through the UK Survey Research Center to ascertain insightful details into the health needs of the KRADD and to gauge community readiness to inform more tailored, relevant programmatic approaches.

KRDHD supports a work-life balance for all employees to ensure workplace satisfaction. KRDHD leadership conducts annual individual performance evaluations to celebrate

performance strengths and discuss performance weakness and to identify areas for growth and avenues for improvement. Performance measure data and observations (when relevant), as well as feedback provided by KRDHD clients, inform employee performance. KRDHD provides adequate training, support, and technical assistance to new employees and partners to promote self-efficacy and promote confidence and effectiveness in performing their respective job duties.

KRDHD maintains a strict nondiscrimination policy. The KRDHD does not discriminate against any individual on the basis of race, color, ethnic or national origin, ancestry, age, sex, gender, sexual orientation, gender identity and expression, religion, creed, political beliefs, or disability in employment, admission or access to, treatment or participation in, or receipt of the services and benefits under any of its programs, services and activities.[42]

E. Partnerships and Collaboration

Successful, multilevel interventions depend on strong partnerships and committed collaboration among stakeholders. KRDHD has a broad extent of partners at the national, state, and local community levels. Partners at the national level include the National Rural Health Association and the U.S. Office of Rural Health Policy. The KRDHD works with many state-level partners to ensure that its comprising counties receive equitable consideration and resources. These partners include the Kentucky Rural Health Association, the Kentucky Department of Public Health, the Kentucky Health Center Network, KCC, and UKCERH.

The KRDHD's strongest partnerships are those within the community, including UK's RCPC. RCPC, also located in Perry County, is federally-funded by the CDC and provides infrastructure and administrative services that support cancer prevention research activities and health promotion efforts in the KRADD. KRDHD and RCPC are united in their shared goal to prevent cancer morbidity and mortality among KRADD residents through collaboration of

residents, community organizations, public health professional, and academic health center researchers designed to reduce health disparities associated with cervical, breast, and colorectal cancer. The RCPC utilizes its CAB to bridge the gap between researchers and rural public health practitioners to develop and implement effective community-based strategies to promote primary and secondary prevention of cervical, breast and colorectal cancer in this region. Two recent KRDHD and RCPC collaborative projects implemented district wide are the "1-2-3 Pap" intervention and FIT Screening Program, both explained in greater detail in the preceding section.

KRDHD will further utilize its firmly established partnership with RCPC by adopting its CAB as the official CAB of FoCaS Appalachia. As discussed in Program Approach and highlighted in Table 4, this CAB is a multidisciplinary team of community stakeholders whose combined expertise will provide constructive and valuable insight into FoCaS adaptation and implementation for the KRADD. In summary, this CAB includes two registered nurses employed by KRDHD, a retired health educator, four representatives from local county health centers, one faith-based representative, two media representatives, one of whom is a city councilman, and representatives from WellCare of Kentucky, KCP, and ACS.

KRDHD will leverage its existing partnership with Kentucky Homeplace through recruitment and utilization of Kentucky Homeplace CHWs in a value added capacity. Kentucky Homeplace was established in 1994 by the UKCERH and is funded by the Kentucky General Assembly. Kentucky Homeplace trains CHWs to provide access to many health and social services predominately through home visits.[38] Examples of services include: providing health information and coaching; informing clients about available services in the community, state, and nation; providing referrals to agencies and providers; making appointments and contacting

agencies/providers on the client's behalf; assisting with transportation arrangements; assisting with completing applications for programs and services; and providing access to prescription assistance. To date, Kentucky Homeplace has served over 110,000 clients across 27 Appalachian counties.[38]

The skillset of Kentucky Homeplace CHWs is adept to the procedural needs of FoCaS Appalachia. CHWs will be the operating force of the intervention, the driving agents of change. CHWs will conduct home visits throughout the KRADD to educate women on cervical cancer, the disproportionate burden of the disease in their region, the importance of routine screening, and what a Pap test entails. CHWs will assist with making screening appointments for the participants with KRDHD/local health center and will assist with transportation as needed. CHWs will also provide one-on-one counseling for women with abnormal Pap test results and will serve as patient navigators throughout the treatment process. CHWs will also teach the monthly educational classes held in KRDHD and the local health centers, and along with the Program Coordinator, train church liaisons who elect to lead their congregation's workshop.

Another critical partner of KRDHD is Appalachian Regional Healthcare (ARH). ARH is a not-for-profit health system serving 350,000 residents across eastern Kentucky and southern West Virginia. ARH is another dedicated organization with the mission of improving health and promoting the well-being of all people in this impoverished region; to illustrate this dedication, in the past 12 months, ARH has provided nearly $138 million in uncompensated care for the uninsured and underinsured.[39] Within the KRADD, there are two ARH centers that provide cancer treatment: the Whitesburg ARH clinic located in Letcher County and the ARH Cancer Center located in Perry County, which is a UK Markey Cancer Center Affiliate and is one of the

most technologically advanced facilities in the region. If a participant of FoCaS Appalachia requires treatment following an abnormal Pap test, she will be referred to ARH for care.

The Program Manager will ensure the cooperation of all partners involved in the implementation of the program. She will maintain regular communication with designated organizational contacts via monthly email. Quarterly, she will meet in person with partner organizations to discuss program success and/or obstacles and challenges.

F. Project Management

For an adapted evidence-based program to yield its intended outcomes in another context, the program must be effectively managed, implemented, and monitored at all phases. This wide-scale, multilevel intervention will be complex in its implementation. A comprehensive program management plan, with a specific delegation of program responsibilities, will preemptively mitigate obstacles.

Cynthia Jones is the director of the division of Cancer Screening and Prevention and will serve as the Program Director of FoCaS Appalachia. Ms. Jones is a Kentucky native who earned her Master in Public Health (MPH) from the University of Kentucky in 1996. She began her 20-year career of promoting the health and wellness of KRADD residents as a KRDHD program coordinator. She has been a vital force in and contribute a 10% distribution of effort to the FoCaS program.

Kristen York, MPH, will serve as the Program Manager of FoCaS Appalachia. Ms. Jones is the Program Manager of all breast and cervical cancer screening initiatives for KRDHD. She has been a vital member in the implementation of several partnered projects including the "1-2-3 Pap" Intervention and the Proactive Office Encounter Intervention. She will be responsible for recruiting and supervising program staff, including the Program Coordinator and CHWs. In order

to retain skilled and trained program staff, the Program Manager will maintain a positive rapport with program staff and support a work-life balance. The Program Manager will create and maintain the program budget and conduct quality control and process evaluation throughout the entire program. Developing and maintaining relationships with community partners will be another duty of the Program Manager to promote the successful implementation of community outreach strategies and for patient navigation and referral services. Once the program is implemented in Breathitt and Owsley Counties, the Program Manager will develop and maintain closer relationships with clinic sites to conduct the in-reach activities.

The Program Coordinator, Sarah Nixon, is a recent MPH graduate with a concentration in Community Health Education from Eastern Kentucky University (EKU). The Program Coordinator will be at 100% distribution of effort for the FoCaS project. She will be responsible for the day-to-day management of all resources assigned to the project. She will work with the CAB and Program Manager to feasibly and culturally adapt the original program into FoCaS Appalachia and will conduct all focus groups and pilot-testing at the initial program planning stage. She and the Program Manager will recruit the most demographically appropriate CHWs and will train CHWs on the program's objectives and implementation procedures. She will work with CHWs to deliver the outreach education program, including the church program and the monthly clinic-based educational classes, and one-on-one home visits. Ms. Nixon will ensure the goals and objectives of the program's work plan are met including ensuring all data collection and program reports are completed in a timely manner and maintaining program integrity.

KRDHD will utilize the CHWs employed by Kentucky Homeplace as the direct implementers of the intervention's community-based and clinic-based educational activities as well as the navigators and counselors of program participants who receive abnormal results. The

Program Coordinator will ensure that CHWs are appropriately trained and prepared to fulfill their roles and responsibilities. Each CHW will receive a job description detailing their roles and responsibilities and an implementation checklist, which will be completed and given to the Program Coordinator monthly. They will receive curriculum training and KRDHD will provide professional development opportunities at multiple time points throughout year. CHWs will be integral in tailoring and consistently delivering the outreach education program as they are demographically similar to the women of the KRADD in terms of education and socioeconomic status.

Finally, Carrie Jones, APRN will be a fully grant-funded programmatic addition and will serve as an additional KRDHD healthcare provider. She will perform cervical cancer screening exams on the mobile Pap clinic, in the KRDHD clinic, and the Breathitt County and Owsley County local health centers. She is a native of Pippa Passes, Kentucky, a small KRADD community in Knott County. She is a graduate of EKU's College of Nursing and became a licensed APRN in the spring of 2016.

KRDHD prioritizes a positive workplace atmosphere by ensuring its employees work in a supportive environment with professional development and team building opportunities. KRDHD conducts an annual Employee Satisfaction Survey to measure employee satisfaction. The KRDHD director monitors the results of these surveys and addresses issues to minimize staff turnover. At the level of the FoCaS project, the Program Manager will conduct similar assessments to measure the Program Coordinator and CHWs' job satisfaction. In addition to the organizational Employee Satisfaction Surveys, the Program Manager will facilitate an open rapport between herself and project staff to allow for an honest assessment of the workload and job satisfaction.

Communication among the project team throughout the duration of the program will be prioritized as effective, regular communication will be vital in attaining program objectives. Numbers of conference calls and meetings will be tracked as performance measure data and reported to the funder semiannually to show engagement and interaction among key personnel and partners. Ms. Jones, Ms. York, and Ms. Nixon will meet quarterly with program partners to discuss and monitor implementation progress to ensure attainment of program outcomes. Program staff housed in KRDHD will meet on a biweekly basis to discuss key aspects of the program's implementation, including any needs for quality improvement, any challenges to program recruitment and to assess the program's progress toward obtaining program outcomes.

G. Budget Narrative

STUDY PERSONNEL

Cynthia Jones, MPH, Cancer Screening and Prevention Director (15% effort, 1.8 months, Years 1-3). As the Program Director of the Kentucky River District Health Department's (KRDHD) Cancer Screening and Prevention Program, Ms. Jones will devote 10% effort annually to executing the proposed grant. She received her cancer training as a health educator at the Cumberland Valley District Health Department in London, Kentucky. She has a successful record and 19-year history of directing multiple projects across the cancer care continuum. She will be fully responsible and accountable for all aspects of the program throughout the duration of the 3-year grant period. She will ensure that the funder receives timely reports of performance measure data and evaluation activities. She will be responsible for the communication with partner organizations including Kentucky Homeplace, ARH, RCPC, and the UK Survey Research Center. She will also be responsible for directing the assessment of program outcomes.

Kristen York, MPH, Breast and Cervical Cancer Screening and Prevention Program Manager (50% effort, 6 months, Years 1-3). As the Program Manager of KRDHD's Breast and Cervical Cancer Screening and Prevention Program, Ms. York will contribute 50% effort annually to executing the proposed grant. She has been a vital member in the implementation of several partnered projects including the "1-2-3 Pap" Intervention and the Proactive Office Encounter Intervention. She will be responsible for recruiting and supervising program staff, including the Program Coordinator and CHWs. She will create and maintain the program budget and conduct quality control and process evaluation throughout the entire program. Ms. York will develop and maintain relationships with community partners to promote the implementation of the program's community-based strategies and for patient navigation to follow-up care and referral services.

Sarah Nixon, MPH, FoCaS Appalachia Cervical Cancer Screening and Prevention Program Coordinator (100% effort, 12 months, Years 1-3). The Program Coordinator will be at 100% distribution of effort for the FoCaS project. She will be responsible for the day-to-day management of all resources assigned to the project. She will work with the CAB and Program Manager to feasibly and culturally adapt the original program into FoCaS Appalachia and will conduct all focus groups and pilot-testing at the initial program planning stage. She and the Program Manager will recruit and train CHWs on the program's objectives and implementation procedures. She will work with CHWs to deliver the outreach education program, including the church program and the monthly clinic-based educational classes, and one-on-one home visits. She will monitor CHW implementation of program activities for quality and fidelity assurance. Ms. Nixon will ensure the goals and objectives of the program's work plan are met by collecting appropriate performance measure data, conducting process

evaluations, and ensuring timely data collection. She will prepare semiannual reports to demonstrate program progress to funders and stakeholders.

TBN, Community Health Worker x 3 (50% effort, 6 months, Year 1; 100% effort, 12 months, Years 2-3). KRDHD will employ three Community Health Workers of Kentucky Homeplace. CHWs will be the direct implementers of the intervention's community-based and clinic-based educational activities as well as the navigators and counselors of program participants. They will receive curriculum training and KRDHD will provide professional development opportunities at multiple time points throughout year. They will collect performance measure data related to the program's outreach and forward the data to the Program Coordinator. CHWs will be integral in tailoring and delivering the outreach education program. They will be selected based on demographic similarity to the women of the KRADD.

Carrie Parker, APRN (50% effort, 6 months, Years 1-3). For the purpose of this grant and based on an increased clinical healthcare provider need (for needs outside the context of this program), KRDHD is seeking 50% support in grant funding for the salary of a new, prospective APRN. Ms. Parker is a graduate of Eastern Kentucky University's College of Nursing and became a licensed APRN in the spring of 2016. She will perform cervical cancer screening exams on the mobile Pap clinic, in the KRDHD clinic, and the Breathitt County and Owsley County local health centers.

Kate Geddens, PhD, Assistant Professor, University of Kentucky College of Public Health (10% effort, 1.2 months, Years 1-3). Dr. Geddens is an assistant professor at the UK College of Public Health who focuses her research on health communication to eliminate cancer health disparities and developing partnerships with community-based organizations for intervention

delivery. Her ongoing project "Connecting Appalachians to Lung Cancer Screening: Leveraging Social Networks to Reduce Lung Cancer" is highly relatable to the cervical cancer screening needs of this region and will be helpful in informing recruitment and retention strategies as program recruitment and retention are also known challenges in this region.

3% annual salary escalation

Year 1 Total: $196,500

Year 2 Total: $255,225

Year 3 Total: $262,882

FRINGE BENEFITS

Fringe benefits are requested as prorated based on the percentage of salary/wage support requested, as described above.

5% annual benefit escalation

Year 1 Total: $79,705

Year 2 Total: $111,064

Year 3 Total: $116,618

EQUIPMENT **Total: $152,000**

Mobile Pap clinic

The mobile Pap clinic will help reduce barriers to cervical cancer screening that many Appalachian, rural women experience due to a lack of transportation and geographic isolation. This total includes $12,000 in maintenance costs.

TRAVEL **Total: $20,263**

In-state travel

CHWs will travel throughout the KRADD to conduct at-home counseling visits and maintain informational centers. Mileage expenses are reimbursed at the federal rate of $0.54/mile. Mileage reimbursement is estimated at $0.54/mile x 8.5 miles/trip x 20 trips/month x 30 months x 3 Community Health Workers = **$8,263**

Out of state travel

We request travel funds for each team member to attend one regional or national conference per year. Proposed conferences include an NIH grantee meeting, the CDC Cancer Survivorship Conference, the American Association for Cancer Education, and the Annual Appalachian Studies Conference, among other conference options.

3 nights lodging x $200/night = $600
Airfare = $400
Registration = $250
4 days per diem x $75/day = $300
Ground transportation = $100
Baggage ($50 per trip for r/t flight) = $50
Parking at airport = $50 Total
Total: $2,000/person x 6 persons/year = $4,000 x 3 years = **$12,000**

MEDIA CAMPAIGN **Total: $80,000**

Year 1 = $40,000 to include graphic design fee; Years 2-3 = $20,000 x 2 years = $40,000

This grant proposal includes a robust media campaign to reach the residents of the KRADD. We are requesting $80,000 to create a custom television public service announcement, radio advertisements, billboard advertisements, and print advertisements. This amount includes the graphic design fee for the program's unique logo and the custom design of all print advertisements and program materials.

CONTRACTUAL COSTS **Total: $15,000**

$5,000 per year x 3 years

The UK Survey Research Center will assist in community-level assessment of the program's reach and effect. We will contract with the UK Survey Research Center at the end of each program year.

EVENTS **Total: $60,000**

Community-wide events are popular in the KRADD. The original program included an annual Woman's Fest at the conclusion of each program year. We are requesting funding for three Women's Fest events to be held at the end of years 1, 2, and 3.

SUPPLIES **Total: $9,000**

$3,000 per year x 3 years

Basic supplies are needed to support the implementation of the program. All program literature will be printed on high quality paper with color ink. Pens and notepads and other program materials given to participants will be branded with the FoCaS Appalachia logo. Supplies will include: copy paper, printer paper, printer cartridges, binders, tabs, envelopes, markers, post-its, pens and notepads. These supplies will also be used to stock the community-wide informational centers with program literature and advertisements.

PROPOSED BUDGET TOTAL **Year 1 Total: $497,858**

Year 2 Total: $435,594

Year 3 Total: $448,805

Total: $1,382,257

TOTAL AMOUNT REQUESTED **Total: $1,500,000**

We are requesting $500,000 per year over the course of a 3-year grant period beginning October 1, 2016 and ending on September 30, 2019.

	Year 1	**Year 2**	**Year 3**	***Total***
Salary	$196,500	$255,225	$262,882	$714,607
Fringe	$79,705	$111,064	$116,618	$307,387
Equipment	$140,000	$6,000	$6,000	$152,000
Travel (*in-state)*	$1,653	$3,305	$3,305	$8,263
Travel *(out of state)*	$12,000	$12,000	$12,000	$36,000
Media and Advertising	$40,000	$20,000	$20,000	$80,000
Contractual Costs	$5,000	$5,000	$5,000	$15,000
Events	$20,000	$20,000	$20,000	$60,000
Supplies	$3,000	$3,000	$3,000	$9,000
Total	**$497,858**	**$435,594**	**$448,805**	**$1,382,257**

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Appendix A
Cervical Cancer Prevention in KRADD Women

Situation: Women in Appalachian Kentucky are significantly burdened by disparities in cervical cancer incidence; findings indicate that cancer screening rates are low within the region.

INPUTS

STAFF
- KRDHD
- Local Health Centers
- Community Health Workers (CHWs)

FUNDING
- American Cancer Society

PARTNERS
- Rural Cancer Prevention Center
- KY Homeplace
- Appalachian Regional Healthcare
- KY Cancer Consortium

EXPERIENCE
- Community-Based Participatory Research
- Public health practice

INFRASTRUCTURE
- Facilities
- Administrative capacity
- Equipment, materials, technology, time

OUTPUTS

Activities

TRAINING
- CHWs
- Healthcare practitioners
- Clinic staff

CLINIC IN-REACH
- Chart reminders
- Literature, posters, and visual prompts in exam rooms
- Monthly educational classe
- Abnormal test result protocol including patient navigation and one-on-one counseling
- Personalized follow-up letters

COMMUNITY OUTREACH
- Media campaign
- Targeted mailings
- Women's Fest
- One-on-one educational sessions in women's homes
- Church program

Participation
- Community Advisory Board
- KRDHD and local health center staff
- Healthcare practitioners
- Residents of KRADD
- Community partners

Performance Measures
- Number of healthcare workers trained
- Number of home visits
- Number of educational classes taught
- Number of women screened for cervical cancer
- Number of personalized follow-up letters mailed

OUTCOMES

Short
- Increased awareness of importance of cervical cancer screening
- Increased healthcare provider knowledge about cervical cancer screening and surveillance guidelines
- Reduced barriers and increased access to cervical cancer screening
- Adoption of sustainable clinic in-reach activities
- Improved coordination of services following abnormal test results

Medium
- Increased uptake and adherence to guideline-recommended cervical cancer screening among KRADD women
- Reduced disparities in cervical cancer screening in the KRADD

Improved clinical and community linkages

- Improved coordination of resources and services to enable FoCaS to become a sustainable program

Long
- Reduced cervical cancer related disparities including incidence, morbidity, mortality in the KRADD region