

A. Specific Aims.

Over the past decade, approximately 13,000 new cases and approximately 4,600 deaths have occurred annually from invasive cervical cancer.¹ These numbers represent a 75% reduction from the previous five decades, largely attributable to the proliferation of screening with the Pap smear and improvements in treatment.^{2,3} Despite this encouraging reduction, certain groups of women have not experienced significant benefits and remain at disproportionate risk of death from cervical cancer. Among these women are those living in rural areas, particularly middle aged and older women who live in rural Appalachia.⁴ This population continues to have among the highest cervical cancer mortality rates, and efforts to address this problem have fallen short of their objectives. To reduce the unequal and unnecessary burden from cervical cancer experienced by rural Appalachian women, we propose to undertake a community-based Patient Navigator (PN) intervention in partnership with local public health departments. While extensive literature has established the dependence of rural populations on institutions such as Federally Funded Community Health Centers for health care, surprisingly few scientifically-based interventions are incorporated into health promotion and disease prevention activities within these public health programs. The central role of CDC-funded public health department programs in Appalachian communities and the availability of Medicaid to support screening, follow-up and treatment costs presents a unique opportunity to reduce breast and cervical cancer mortality by providing screening and case management. What appears to be more of a challenge is the willingness and ability of those at highest risk to actually use available health department services. In this proposed project, we intend to assess the utility of an innovative and theoretically based PN program working within the public health sector serving rural, Appalachian populations. The overall objective of the proposed project is to reduce the disproportionate cervical cancer burden experienced by rural Appalachian women by increasing adherence with recommendations for follow-up treatment after abnormal screening results. To achieve this objective, we intend to develop, administer, and evaluate a plan for effective utilization of lay health workers as PNs in local health department cervical cancer screening programs. Specifically, the following aims are proposed:

1. To develop a plan for effective utilization of lay health workers as PNs in local health department cervical cancer screening programs
2. To train PNs and establish working relationships between navigators and local health department personnel, including designated nurse case managers
3. To link patients with abnormal findings after cervical cancer screening in local health departments with a well-trained PN
4. To develop and implement an effective patient tracking and data collection system
5. To shorten the time intervals between the finding of abnormal screening results and establishment of a diagnosis, and between diagnosis and initiation of treatment

In addition to the aims listed above, the project will be designed to provide support during the post-screening period for women and their families, improve patient satisfaction with the services offered by the local health department screening program, and improve satisfaction of 'outside providers' with cancer screening programs of local health departments. The results from the proposed project have the potential to demonstrate that Federally-funded programs implemented by local public health departments, in partnership with health care providers and PNs from the community are able to address the real and perceived barriers that prevent rural women from receiving recommended follow-up care after receiving abnormal Pap smear results. The results will have the potential to demonstrate the efficacy of a community-based model that can be extrapolated to other rural, underserved communities for cancer prevention. The proposed project will also enhance the capacity of local public health departments to provide health promotion that is adherent to both community and scientific standards and thereby contribute to reduction of the unnecessary and disproportionate health burdens experienced by rural residents, particularly those in the older age groups. A final implication is the potential to increase the efficiency of management of abnormal Pap smear results by public health departments serving rural populations and thereby increase the capacity of public health departments to provide outreach to vulnerable populations.

B. Background and significance.

Invasive cervical cancer is the ninth most common cancer affecting women in the United States.⁵ While cervical cancer morbidity and mortality rates appear modest compared to other types of cancer, there are several reasons why cervical cancer remains a high priority. First, with greater use of the Pap smear, invasive cervical cancer is a disease that could be prevented in nearly all cases. Second, the Pap smear is a well-established, low cost, widely available screening test that *should* present minimal barriers to its use. Finally, despite our ability to prevent and treat cervical cancer, the burden of cervical cancer morbidity and mortality continues to fall most heavily on particular segments of the female population, a reality that demands priority attention. Enhancing existing knowledge of the complex factors that shape the use of cervical cancer screening and subsequent treatment procedures will generate data-driven interventions. Such interventions, particularly those that are theoretically-based, culturally-situated, and developed in conjunction with communities, have the potential to reduce the disproportionate burden of cervical cancer experienced by rural women.

B1. Pap smear screening and follow-up

Pap Smear: The NIH Consensus Conference on Cervical Cancer screening strongly advocated the use of Pap smears for early detection of invasive cervical cancer.^{6,7} With a long preinvasive stage, early detection and treatment of abnormalities has proved successful in preventing the development of invasive cancer. Indeed, the International Agency for Research on Cancer (IARC) has estimated that screening reduces the likelihood of invasive cervical cancer onset by 90% for up to 3 years.⁸ Moreover, 50-70% of new cases of cervical cancer occur in women who have never been screened or where more than five years has elapsed since the last Pap smear.⁹ This level of efficacy has led the guiding public health document Healthy People 2010 to set a goal of 97% 3-year screening rate for women age 18+.¹⁰ While this goal remains elusive, rates of screening have increased over the past several decades. In 1970, 68% of women indicated that they had a recent Pap smear. By 1997, this percentage had increased to nearly 80%.¹¹

Follow-up: A second and closely related explanation for the declining incidence and mortality from cervical cancer involves improvements in the efficacy of procedures following an abnormal Pap smear.^{3,4} Without timely follow-up upon detection of an abnormal result, the benefits of both screening of and treatment for cervical disease go unrealized. For example, in retrospective chart reviews of women who were diagnosed with invasive cervical cancer, Mandleblatt and colleagues found that between 11% and 30% had not completed recommended follow-up procedures from an abnormal Pap smear.^{12,13}

B2. Appalachia: A Region of Persistent and Pernicious Health Disparities. The US Department of Health and Human Services considers rural residents a “special population.”¹⁴ Rural Americans tend to be older, poorer, less educated, suffer higher rates of disease and disability, and are more likely to be uninsured than their urban counterparts.^{15,16} Systemic factors such as lack of public transportation, fewer community services, and a shortage of health care providers contribute to sub-optimal health among rural Americans.³ While these features are common in much of rural America, Appalachia, a largely rural and predominantly white population, represents an extreme version of these characteristics.³

Table 1. Selected Socioeconomic Data

	2000 Population ⁴	1999 Per Capita Income ⁴	1999 % Below Poverty ¹⁷	2000 % Unemployed ⁴	2000 % High School Graduate or Higher (Age 25+) ⁶
United States	281,421,906	\$28,546	12.4	4.0	81.6
Appalachian Kentucky	1,141,511	\$17,403	24.4	5.6	62.6
West Virginia	1,808,344	\$20,921	17.9	5.5	75.2

Appalachia is a geographically and culturally diverse region of 410 counties in 13 states that contains nearly 22 million people, or 8.3% of the total U.S. population.^{18,19} Appalachia has long been characterized as a

region of the country with high rates of extreme poverty, isolation, and poor health.¹ This view of Appalachia has existed for decades; indeed, Appalachia was the setting where the ‘War on Poverty’ of the 1960s was launched.²⁰ Although poverty rates have been cut in half since 1960, significant economic and educational disparities persist.⁴ For example, the Appalachian areas of Kentucky (51 of 120 counties) and West Virginia (all 55 counties in the state) have socioeconomic status (SES) and educational indicators that are among the lowest in the United States (Table 1). We include data on West Virginia, a state where our proposed research could be replicated to address similarly burdensome health disparities.

B2a. Unequal burden of cervical cancer for rural Appalachian and older women. Although cervical cancer mortality has decreased over recent decades,²¹ mortality data from the Surveillance, Epidemiology, and End Results (SEER) program reveals that mortality rates in Appalachia are substantially higher than the national average (Table 2).

Table 2. Age-Adjusted Cancer Incidence Rates, Selected Cancers (invasive only), 1995-1999*

	All Cancers			Lung and Bronchus			Colorectal			Cervical
	Total	Male	Female	Total	Male	Female	Total	Male	Female	
SEER ²²	468.9	549.2	415.9	62.8	81.5	49.3	53.6	63.4	46.2	9.8
Appalachian Kentucky ²³	476.9	564.4	418.7	104.8	151.4	69.2	56.8	65.6	50.3	14.4
West Virginia ^{24,25}	N/A	569.2	424.0	90.8	126.0	65.8	58.8	69.3	51.7	13.7

*All rates are per 100,000 population and are age-adjusted to the 2000 U.S. Standard Million.

Within the female population in general and Appalachian women in particular, middle aged and older women are at heightened risk of cervical cancer. A linear relationship exists between age and cervical cancer mortality.²⁶ Due to a general trend in population aging and outmigration of younger people, Appalachia has an older population than national figures. For nearly all age groups from 45-49+, the Appalachian population percentage is greater than for the U.S.²⁷

B3: Addressing cervical cancer disparities:

There is little doubt that Pap smear use and appropriate medical follow-up after an abnormal Pap results have the potential of practically eradicating cervical cancer mortality. What remains troubling and unclear is why certain populations continue to experience a disproportionate burden from cervical cancer.²⁸ Since the vast majority of existing research on cervical cancer has focused on urban populations and rural-focused literature has mostly been gathered through telephone surveys-- a noted limitation in a region where as much as 18% of household lack telephone service- we lack necessary information to confront disproportionate cervical cancer burdens.²⁹

One recent document sponsored by the NCI and the NIA has provided plausible suggestions for elevated rates of cervical cancer and cervical cancer mortality in rural regions.³⁰ Researchers offered four hypotheses to account for these disproportionate cervical cancer rates, including: a) high prevalence of risk factors; b) low rates of screening c) insufficient access to treatment after diagnosis; and d) incomplete or poor follow-up post diagnosis. In this proposal, we intend to address the latter three hypotheses, focusing on screening and follow-up.

Screening: Table 3 demonstrates that inadequate Pap screening, including lack of and lapses in screening, may account for the elevated cervical cancer rates among Appalachian and older women. Kentucky’s BRFSS found that nearly 1/3 of women age 50+ have not had a Pap test within the past three years, despite their similar rates of hysterectomy to national figures.³¹ Given that BRFSS data are collected by telephone and a substantial portion of the most underserved Appalachian population lack telephones, these low screening rates may be overestimations. Indeed, studies on rural Appalachian women by Elnicki³² and Rosenfeld³³ found that only 68% and 60%, respectively, had received a Pap smear in the past 3 years.

Table 3: Kentucky and within state comparisons of Pap Smear Screening, 1999-2000.^{34, 35}

	Ever had Pap			Never + >3yrs.
	Ever had Pap	Pap in last 3 yr.	Pap >3 yr.	
US	94.8%	87.4%	11.4%	16.6%
Kentucky	92.1%	86.5%	12.6%	20.5%
Appalachia	90.8%	84.5%	14.8%	24.0%
Non-Appalachia	92.6%	87.3%	11.8%	19.2%
< 50 yrs.	94.2%	92.5%	7.2%	13.0%
>= 50 yrs.	89.2%	77.5%	20.7%	31.5%

Older age is associated with inadequate cervical cancer screening, and this disadvantage is amplified if a woman lacks health insurance.³⁶ Older women report significantly lower rates of Pap smears than their younger counterparts.^{8, 10} Two-thirds of uninsured women aged 40-64 received a Pap smear, and the screening estimates for older women, irrespective of the type of health insurance coverage, are lower still. As a result, older women are more likely to have regional and distant cervical cancer diagnoses than younger women (54% versus 26%, respectively) while younger women are more likely to have localized diagnoses than their senior counterparts (69% versus 30%, respectively).³⁷

B4. Follow-up:

It is estimated that between one-quarter and three-quarters of women who receive an abnormal Pap result do not obtain appropriate follow-up diagnosis and treatment.³⁸ While we currently lack specific data on follow-up rates among Appalachian women, given the low rate of Pap smear screening among Appalachian older women, it is probable that they mirror national trends indicating a lack of follow-up³⁹ and/ or a delayed return visits.^{24,40} These behaviors may, in part, contribute to the greater likelihood for older women to be diagnosed with late stage, invasive cervical cancer.⁴¹ It has been suggested that such behaviors may result from patients' and providers' perceptions of minimal need for cervical cancer prevention or follow-up visits.¹⁴

B5. Determinants of screening and follow-up procedures:

The well-documented disease burden from cervical cancer, in conjunction with more limited use of Pap smear screening and follow-up procedures underscores the importance of examining determinants of screening and treatment experienced by middle aged and older rural women. While many studies have identified breast cancer screening and treatment determinants, fewer studies have examined these same issues for cervical cancer and, relative to disease burden, very few have focused on rural Appalachian women. According to a recent Institute of Medicine report,⁴² the burden of cancer in the US is born disproportionately by the medically underserved, including individuals residing in a disadvantaged locality which offers distinctly differing opportunities for screening and treatment.^{43,44,45,46,47} Comprehensive frameworks that examine the determinants of cancer control highlight characteristics of the individual, the environmental or community context, the health care provider (HCP) and the medical system.^{14,48}

Evaluations of existing cervical cancer interventions justify focusing on all of these factors; however, we have elected to examine the individual in her cultural and community context rather than health care providers and the medical system for several reasons. First, as extensive health research has documented, the mere availability of health services, including physicians' recommendations of procedures, does not insure patient uptake of those services.⁴⁹ Indeed, it is likely that many of the rural women who do not receive Pap smears or appropriate follow-up treatment are insured by either Medicare or Medicaid or may have access to free or reduced cost screening programs. For example, despite services available through the Kentucky Women's Cancer Screening Program and the CDC's National Breast Cervical Cancer Early Detection Program (NBCCEDP), disparities continue to exist. Thus, it is likely that the uptake of services is influenced by more than mere availability issues and also involves norms, beliefs, and current health practices.

Existing literature that has attempted to provide a "cultural explanation" for inadequate screening and follow-up often has implicated culturally-informed attitudes and beliefs such as embarrassment or modesty

during gynecological examinations, reluctance to interact with male health care providers (HCPs), originating either from the woman herself or her male partner, and the equation between cervical cancer risk/testing, sexual activity and perceived immoral behavior. Other researchers have suggested that the strong traditions of religion and fatalism have adversely affected women's screening and follow up orientations, such that "God's will" rather than proactive behavior direct cervical cancer outcomes. Finally, researchers have suggested that older rural women's perceptions of their diminished sexuality leads them to forgo cancer control activities.^{50,51}
52,53,54,55,56

We have elected to focus on the individual in the local public health department and community contexts because many of the HCP and medical system characteristics implicated in inadequate cervical prevention and treatment are not particularly amenable to extensive modification (e.g., inadequate practice time, particularly in rural health care shortage areas, difficulty scheduling appointments, and a lengthy waiting time at the provider's office^{57,58}). Given this assumption, greater emphasis on providing direct support to patients confronting the need to obtain follow-up care is indicated. While many of the patient characteristics associated with greater barriers to cervical cancer prevention and treatment activities, including lower education and income and inadequate health insurance^{59,60,61} are similarly unmodifiable, locating the intervention within the woman and her community holds considerable promise.

B6. Interventions to increase Pap screening and appropriate follow-up procedures

In a meta-analysis of 61 interventions, Yabroff and colleagues²⁹ came to several conclusions. First, cognitive interventions, involving patient education through the mail and telephone, showed either no beneficial outcome or only a modest increase in the Pap smear use. Second, behavioral interventions, including reminder letters and phone calls to patients appeared highly successful, with increases in Pap smears use ranging from 10-24%. Third, sociological interventions, which often were employed in conjunction with cognitive and behavioral approaches, generally increased Pap smear use from 3-36%.^{28, 29, 50} For follow-up, cognitive intervention ranged in success (5-31% improvement in compliance), with the personalized interventions yielding greater success rates.^{29, 50} Behavioral interventions yield improvements ranging from 6-18%.^{15,28,50}

B7. Lay Health Advisor and Navigator Interventions:

To reduce health disparities in underserved populations requires collaborative engagement among community members, health care providers, and researchers, with the former providing insights about local institutions and practices that can be instrumental in health promotion.^{62,63} Drawing on evidence from existing intervention literature and on our pilot research in rural communities, we propose to develop a cervical cancer control intervention that is primarily oriented around the use of lay health advisers functioning as PNs.

B7a. Lay Health Advisor Interventions. LHA interventions, categorized as mixed sociologic/ cognitive/ behavioral approaches, have demonstrated successes in educating women on the need for and access to obtaining Pap smears and appropriate follow-up, decreasing distrust about the health care environment, and even providing suggestions on overcoming barriers experienced.⁶⁴ Analysis of the efficacy of these LHA interventions demonstrates that the majority of LHA programs have increased Pap smears from 3-36%.²⁹ LHA programs have been shown to be especially useful for the rarely and never screened because these populations are often excluded from key predictors of cancer screening services, including physician referrals, educational enrichment, and positive patient-physician communication. Additionally, traditionally underserved women have been shown to draw heavily on the input from their peers, thereby laying the groundwork for the utility of LHA programs.⁶⁵ For rural women, PNs have been particularly helpful to tailor area resources and information to specific community barriers. For example, Dignan and colleagues demonstrated significant increases in Pap smears among Native American populations in the rural Appalachian North Carolina^{66,67, 68} The North Carolina Breast Cancer Screening Program (NC-BCSP) trained LHAs and community outreach specialists not only to convince women about the importance of mammogram, but also to provide informational and instrumental support on obtaining free or low cost screenings.⁶⁹ The intervention was associated with a 6% increase in communitywide mammogram use, with lower income women demonstrating the highest increase, 11%. In another LHA program administered in North Carolina (the "Save Our Sisters" program), rural PNs initiated

discussions that promoted mammogram or Pap test use. PNs have proven to be versatile and have played a vital role in community health providing care for a wide variety of health care issues. Lewin⁷⁰ and colleagues prepared a review of 43 random control trials evaluating the effectiveness of LHA in primary healthcare and community settings. Earp and colleagues⁷⁴ trained LHAs to implement an intervention to promote mammography in rural North Carolina and increased the intervention group screening rate from 41% to 58%, while Taylor et al. found that women who were under users of Pap tests who had high-intensity outreach workers working with them significantly increased their pap test rates compared to the control group.⁷¹ The success of LHA interventions is associated with many factors, but primarily because LHAs have the ability to penetrate barriers between health care providers and the people who need healthcare. The LHAs are people from the community that are trusted and respected by the people in the community. Training LHA to become PNs is the next logical step. The PNs will essentially walk these women through every step of the healthcare process, helping with childcare, transportation, language or literacy barriers, and personal fears. This program will allow these women every opportunity to receive follow-up care that is available, which for a lot of them might not have been possible before this program.

B7b. PN Interventions: The NIH has had a long-standing interest in PN programs. Health policymakers have determined that a major gap exists between cancer research discovery and the delivery of those research findings in the form of improved patient care. Unrecognized barriers prevent many Americans from receiving the best quality care and health disparities arise when the delivery system does not provide access to timely, standard care to everyone in the nation. The National Cancer Institute (NCI) has established the goal of eliminating suffering and death due to cancer by 2015. To meet this goal requires immediate action to address the gap between development and delivery, particularly among underserved populations. PN interventions have the potential to make a substantial contribution toward reaching this goal. "Patient navigation" in cancer care refers to the assistance offered to healthcare consumers (patients, survivors, families, and caregivers) to help them access and then chart a course through the healthcare system and overcome any barriers to quality care. Navigators help their patients move through the complexities of the healthcare system getting them more timely treatment, more information about treatment options and preventive behaviors. Navigators serve as a reliable ally to lean on for advice, support and direction. A navigator is someone who understands the patient's fears and hopes, and who removes barriers to effective care by coordinating services, increasing a cancer patient's chances for survival and quality of life.

PNs assist patients and their families through the cancer care continuum. Examples of navigation services may include: arranging various forms of financial support; arranging for transportation to and childcare during scheduled diagnosis and treatment appointments; identifying and scheduling appointments with culturally sensitive caregivers; coordinating care among providers (such as screening clinics, diagnosis centers, and treatment facilities); arranging for translation/interpretation services; ensuring coordination of services among medical personnel; ensuring that medical records are available at each scheduled appointment; and coordinating other services to overcome access barriers encountered during the cancer care process. A key role proposed for this project involves the linking of patient navigators with patients and families to encourage the appropriate use of follow-up services

Navigation spans the period from an abnormal finding via a cancer detection procedure, through necessary cancer diagnostic tests, to completion of cancer treatment. Evidence shows that in addition to unequal access to health care, racial/ethnic minorities and underserved populations do not always receive timely, appropriate advice and care when confronted with a cancer diagnosis. PNs can make the difference between someone from an underserved population becoming a cancer survivor or a cancer death. If navigators get involved early enough after a person has received a cancer diagnosis, they can help steer patients and their families to appropriate care and treatment that could dramatically improve patients' chances of getting the best care and have an opportunity to live with cancer as a manageable disease. By navigating patients around barriers to quality care, PNs actually help ensure that cancer patients are not shortchanged in their options and their care. Cancer patients from underserved populations are likely to face a variety of barriers to quality care and treatment. For example, there are financial challenges (especially for the uninsured and underinsured); communication and information problems including language barriers; problems with an inferior healthcare

system within their communities; travel and distance challenges that can lead to missed doctor appointments; and emotional barriers where irrational fears lead to cancellation or delay of medical services. The PN offers disadvantaged cancer patients someone with whom they can feel comfortable; someone who has the knowledge base and confidence the patient might not possess.⁷²

B8. Significance: While important advances have been made in reducing the rates of cervical cancer over the past several decades, significant morbidity and mortality from this preventable cancer continues to be experienced by rural women, particularly those from older age groups. Since successful cervical cancer reduction has been associated with increased use of Pap smear screening and appropriate follow-up procedures, it is logical to focus health disparity reduction on bolstering the proper use of these procedures within vulnerable populations. Previous interventions to increase Pap smear screening and appropriate follow-up have demonstrated that well-designed interventions can overcome numerous barriers faced by women. However, identification of population-specific barriers and assets is a necessary precursor to such interventions so that appropriate, theory-driven activities can address the challenge. The proposed project heavily draws on the involvement of community participants and lay insights to insure that the activities are culturally-situated. Combining a PN approach with a public health department-based program represents a novel approach to stemming cervical cancer mortality in the Appalachian population.

C. Preliminary Studies: The principal investigator, Dr. Mark B. Dignan, will provide the scientific leadership for the proposed project. Dr. Nancy E. Schoenberg, Associate Professor of Behavioral Science, will also provide leadership as Co-Principal Investigator. Dr. Gilbert Friedell, Director Emeritus of the Markey Cancer Center at UK will also be a Co-Principal Investigator on this project. Dr. Brent Shelton, Associate Professor of Biostatistics and proposed Co-Investigator, has extensive expertise in cancer control biostatistics. In addition, we will develop a community advisory board to participate in all phases of the project. Fran Feltner, BSN, Program Director for SKYCAP at the Center of Excellence in Rural Health at the University of Kentucky (located in Hazard, KY), will be a Co-Investigator on this project. Ms. Feltner has extensive experience with development, implementation and evaluation of programs designed to improve health in rural Kentucky.

Dr. Mark Dignan has been PI, Co-PI, or a Co-Investigator on cancer control research projects since the early 1980s. These projects have addressed several issues that are directly related to health disparities and cervical cancer, including self report of Pap smear history,⁷³ development and evaluation of cervical cancer educational materials,⁷⁴ outreach methods,⁷⁵ and evaluation.^{76,77} Two particular NCI-funded projects demonstrate Dr. Dignan's experience that is directly relevant to this proposed project.

Dr. Dignan was Co-PI on The Forsyth County Cervical Cancer Prevention Project. Dr. Dignan was responsible for leading the development and implementation of the intervention. In this role, he oversaw development of all intervention components, including efforts to reach women through the public health department's clinics. This aspect of the project was delivered in the family planning and adult medicine clinics of the health department. The team led by Dr. Dignan was successful in introducing the idea of intensive attention to cervical cancer education to the clinics and finding ways to integrate outreach and education into the busy environment. The results from the Forsyth County Project showed an intervention effect among women attending the public health department clinics.⁸²

Building on the results from the Forsyth County Project, the North Carolina Native American Cervical Cancer Prevention Project employed lay health advisors (LHA) to provide direct, personal education to Native American women. The Native American Project focused specifically on cervical cancer among high-risk, medically underserved Native American populations in North Carolina. Two populations were included in the study, the Cherokee and Lumbee tribes. The Cherokee tribal lands are in a five-county area of western North Carolina. The population is considered Appalachian and includes many characteristics that are attributed to Appalachia, including isolation, self-reliance, and distrust of outsiders. The project was designed to prevent cervical cancer by increasing the proportion of women who receive regular Pap smears and return for follow-up care when necessary. The intervention was presented to women individually by trained local PNs, and included two home visits. During the initial visit, information about cervical cancer, the importance of Pap smears and

follow-up care was presented. In addition, specific information on risk factors was collected. Between the first and second visits, the research team produced intervention materials tailored to the situations of individual women. During the second visit, the tailored educational materials were discussed with the women. Outcome measures included changes in knowledge, attitudes, and behavior with regard to cervical cancer and early detection. The results of this project demonstrated statistically significant increases in self-reported Pap smears within the past year among the Cherokee and Lumbee study populations.^{78,79,80} This study is directly relevant to the proposed project in that it demonstrates experience with implementing a complex intervention in rural populations and experience conducting evaluation of a randomized, community-based cancer control project.

An important sub-study of the NCP was a carefully planned investigation of study group contamination. The study revealed that randomization at the individual level was associated with a low rate of contamination. Less than three percent of the women in the control group recognized the educational materials used in the intervention. These results suggest that contamination among the study groups was minimal, even though the study population was rural, relatively isolated, and very familiar with one another. This investigation of study group contamination is directly relevant to the proposed project in suggesting that carefully managed cancer control interventions can be implemented with minimal contamination in rural areas.⁸¹

Dr. Nancy Schoenberg's research has focused on the cultural and contextual circumstances that underlie health status and health behavior. For example, during a two year long ethnographic examination of the correlates of adherence to an anti-hypertensive dietary regimen (NSF, Dissertation Grant and National Institute on Aging, RO1-AG11183), Schoenberg found that contextual factors, including transportation, community resources (e.g., supermarkets and social service programs like food stamps), and food sharing practices and traditions,⁸² play a significant role in dietary decisions. In addition, Schoenberg described both the positive and negative aspects of social support.⁸³ While the study population often indicated that friends and family supported their attempts to reduce salt, fat, and caloric intake, oftentimes transporting them to the supermarket for fresh produce or preparing healthy foods, loved ones also frequently discouraged healthy dietary regimens. This was especially the case for multigenerational households, where the grandmother's dietary requirements were often at odds with the demands of young grandchildren.^{84,85,86} Particularly useful in explicating nutritional risk patterns were the combinations of methodological approaches, including ethnographic and large data sets, employed by Schoenberg and colleagues. Recent findings from a Scientist Development Grant awarded to Dr. Schoenberg (AHA #30022N) indicate that such an ethnographic, in-depth exploration of these contextual factors that shape health behavior is necessary prior to developing interventions.⁸⁷ For example, health promotion activities located at church and attended by friends and family members may reach people who would not otherwise attend such a program.^{88, 89}

Results from a recently completed project (National Institute on Aging: R03 AG17671) that aims to improve our understanding of the community barriers and assets confronting rural adults in negotiating medical services will help guide the proposed project. Specifically, Dr. Schoenberg and colleagues undertook a community inventory of health-related resources to better understand this context of obtaining health services, an approach we propose to employ in this application. Among other features, community assets listed by elders include church and social groups from the church setting.

Finally, Dr. Schoenberg has provided scientific leadership for The Appalachian Community-Based Cervical Cancer Outreach Demonstration Project (ACCODP), funded by the Appalachian Regional Commission and the Centers for Disease Control and Prevention. The ACCODP is a three year project that seeks to develop a community-based outreach model to increase the use of cervical cancer screening services. The findings of the ACCODP provide relevant and timely pilot work to support the development of a recently funded cervical cancer screening project (R01 CA108696). During twelve structured and semi-structured interviews, each of which lasted between 70 and 90 minutes and were conducted by personnel from local communities, several key findings emerged. First, in forced choice checklists, participants (all rural women aged 40 and older who are rarely or never screened for cervical cancer) indicated that they consider two sources of assistance very trustworthy, their religious congregation and their local health department. Local health departments were frequently mentioned as providing the most accurate information to clients at a low cost. However, one of the challenges mentioned by participants lay in accessing

the health department, which is often seen as difficult to secure appointment, receive timely and efficient services, and obtain personal feedback.

Dr. Gil Friedell, proposed Co-Principal Investigator, has had a career that has included attention to cervical cancer for over 50 years. He is author of one of the first publications on adenocarcinoma of the cervix (1953).^{90,91,92} He is also one of the pioneer investigators who contributed substantially to understanding of treatment and screening. Dr. Friedell came to the University of Kentucky in 1983 and during his time at the University he has focused extensive attention on the problem of excess cervical cancer mortality in Appalachia. Dr. Friedell has led several community based research efforts including the Appalachian Leadership Initiative on Cancer (ALIC),⁹³ and has been instrumental in the development of several navigator programs.

With his interest in the pathology of pre cancerous cervical lesions, as well as in situ and invasive cancer, Dr. Friedell found on his arrival in Kentucky in 1983, as the first director of the Markey Cancer Center, that the cervical cancer problem in Kentucky was not one of pathologic or cytologic diagnosis. The problem - - and a very real one - - was that the incidence and mortality of the disease in the predominantly White population of eastern Kentucky were higher than those in White women in almost every other state. A population-based investigation in Appalachian Kentucky revealed incidence figures that were comparable to the African American population in SEER and twice as high as that for the White population reported in SEER. It became clear that both the cytopathologic and histopathologic diagnoses in the area were comparable to those seen elsewhere, but that there was a higher proportion of late stage cases seen in this population. Pap smears had been provided in eastern Kentucky beginning in the 1950's by local health departments, but in the mid-1980's it was clear that although screening services were available and accessible, they were not being utilized. Moreover, once cases of pre-invasive or invasive cervical cancer were diagnosed, there was no mechanism to facilitate the further investigations which would be necessary leading to possible treatment. Utilizing the resources of the Markey Cancer Center Community Outreach Program and the Kentucky Cancer Registry, both of which were developed during Dr. Friedell's tenure as Director of the Markey Center, community health advisor program's to increase screening rates among high risk women were established. The first of these was the Mountain Surveillance, Counseling and Outreach or Mountain SC-Out Program followed by the Kentucky Homeplace Program. Both programs encouraged women to get screened and facilitated their access through the program. General efforts were made in local health departments to assure adequate follow-up for women with abnormal Pap smears, but this effort was limited by the small number of personnel who could be assigned to this task. Within the Homeplace Program, largely concerned with improving access to a broad range of health services in the community, it became obvious that some level of patient navigation once people gained access to the system was necessary. This led to the development of the SKYCAP Program, one for which Dr. Friedell has served as an advisor and consultant since its inception. Most recently, in his role as an outside reviewer of the overall Kentucky Department for Public Health Breast and Cervical Cancer Screening Program, it has become even more evident that in the health department program of cervical cancer screening a missing ingredient is an effective program of patient navigation for those women with abnormal Pap smears both to increase compliance and to facilitate compliance within a much shorter time than is now evident. This latest effort follows Dr. Friedell's review of cervical cancer in Kentucky.⁹⁴

Fran Feltner, BSN. The Southeast Kentucky Community Access Program (SKYCAP) was a rural demonstration and evaluation program funded by the federal Health Resources and Services Administration. Led by Fran Feltner, BSN, proposed Co-Investigator, SKYCAP was launched on Sept. 1, 2000, one of 23 initial grantees in a national program aimed at improving access to health care for the poor, with an emphasis on working as partners with safety net providers, social services and housing agencies in low-income areas. SKYCAP employed 12 indigenous lay health workers, called family health navigators. Working with licensed nurses, these lay workers were trained to help clients not only access but also navigate physical and mental health services, housing and environmental assistance options, and other quality of life services. SKYCAP's administrative home was the University of Kentucky Center for Rural Health in Hazard, KY. In its four years of activity, SKYCAP provided case management services to a total of 8,668 residents of four southeastern Kentucky counties as well as 4,815 referrals, for a total of 13,483 clients served. About one in ten (9.3 percent) of SKYCAP case management clients received the more intense level of service, indicating an appropriate

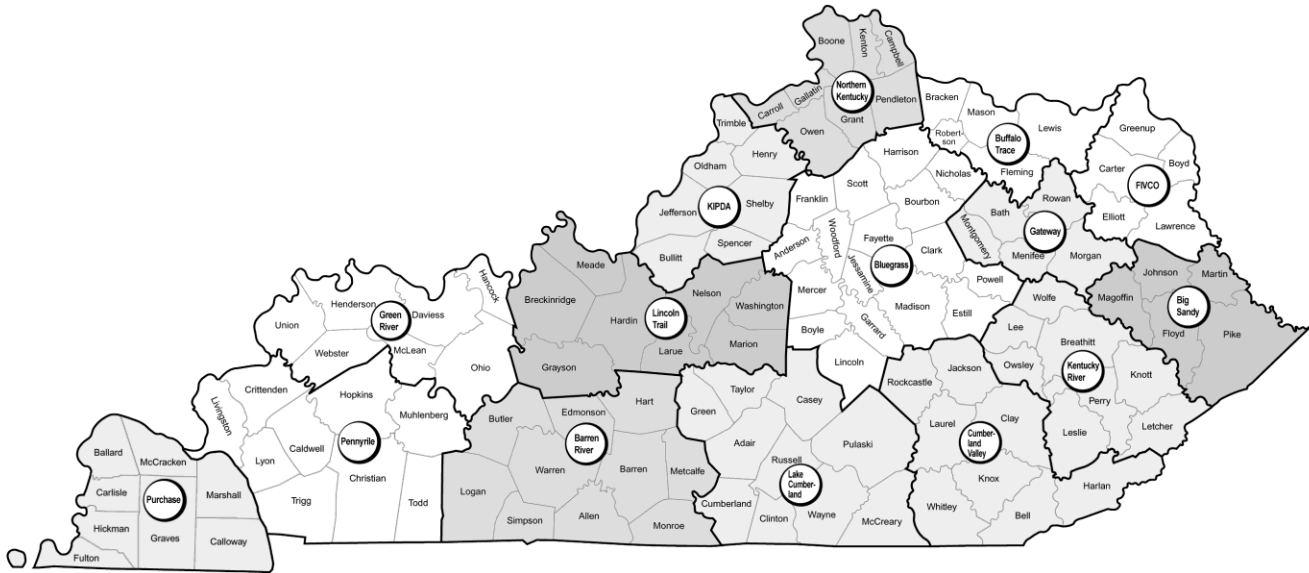
degree of selectivity in allocating case management resources where they were most needed. The annual growth in service volume over the four years of SKYCAP's existence suggests the ongoing existence of both unmet need and capacity for service. SKYCAP clearly exceeded its goals of implementing information systems and serving substantial numbers of clients in targeted diagnostic categories. SKYCAP exceeded all its quantifiable objectives in its brief existence. Its impact on the quality of life of its clients has been amply documented in narratives and videotapes that have reached national audiences. However, it is clear that a program serving such under-resourced communities cannot be sustained with local resources alone. A longer period of exogenous funding (whether from federal or other sources) may be a better test of the ability of such a program to raise the economic level of the community as a whole by reducing the burden of chronic illness that affects so many of its residents. The experience from SKYCAP will form the basis for the proposed navigator intervention. Ms. Feltner led development of the SKYCAP program, including recruitment, training and management of navigators. In an article published in the *Journal of Rural Health*, Schoenberg and colleagues provide a case study approach to the successful administration of the Kentucky Homeplace Project, the antecedent for SKYCAP.⁹⁵ Additional information describing the SKYCAP and Kentucky Homeplace Programs are included in Appendix A.

D. RESEARCH DESIGN AND METHODS.

We propose to contribute to reduction of mortality from cervical cancer by developing and implementing a PN intervention to increase adherence to recommendations for follow-up for women who have had abnormal Pap smears. The project will be implemented in public health departments in Southeastern Kentucky, an area with pronounced cancer health disparities. The proposed project will be carried out in three distinct phases. During the first phase we will identify barriers/assets that affect women's receipt of diagnostic and treatment services for cervical cancer. This will include focus groups with public health department patients to identify barriers to and facilitators of cervical cancer services and key informant interview sessions with public health and health and social service agency employees will inform the development of the navigator protocol. The second phase involves development and implementation of the intervention. The health departments will be randomized to intervention or delayed intervention groups, with all participants from a health department treated in the same group. Women who do not keep appointments for follow-up services, based on Pap smear results, will be assigned to PNs in the public health departments. The PNs, who will be trained using well-established protocols of the SKYCAP (See Appendix A), will administer a baseline questionnaire and provide individualized outreach, education and support with the goal of increasing adherence to follow-up. The third phase of the project will focus on evaluation. Three months after the baseline survey is completed, project interviewers will administer a posttest interview. Additional data on outcomes will be obtained from public health department records (as shown in Table 4). Process evaluation will include monitoring of recruitment, training and deployment of PNs, the amount of work provided to them and production; outcome evaluation will focus on the percent of women with abnormal Pap smears who are not lost to follow up time from screening to diagnosis to treatment, and their satisfaction with the navigator intervention.

D1. Study Population

This project will be carried out in conjunction with public health departments in rural southeastern Kentucky. The health departments serve 26 counties in three Area Development Districts (ADDs), Cumberland Valley, Lake Cumberland and Kentucky River. Figure 1 shows the location of the ADDs in the state of Kentucky. Additional information on each ADD is included in Appendix B.



Lake Cumberland Cumberland Valley Kentucky River

Figure 1. Study Population and ADDs in Kentucky

Table 4 shows the distribution of results from Pap smears in fiscal year (FY) 2002 in the health departments included in this project. As Table 4 indicates there were 244 patients with HGSIL results from Pap smears during FY2002; 94 in the Cumberland Valley ADD, 80 from the Lake Cumberland ADD, and 70 from the Kentucky River ADD. Patients with HGSIL are referred for follow-up by the public health departments. Those patients who do not return for follow-up will be referred to the PNs.

Table 4. Health Department Pap Smear Results – FY 2002					
	Negative	Negative, Benign Changes	ASCUS	LGSIL	HGSIL
Cumberland Valley ADD					
Bell	1691	343	130	134	7
Clay	7580	148	30	34	8
Harlan	1197	235	70	59	4
Jackson	368	35	18	20	3
Knox	942	110	91	42	20
Laurel	769	88	59	30	14
Rockcastle	362	68	29	17	5
Whitley	1163	288	119	54	33
Total	7250	1375	546	390	94
Lake Cumberland ADD					
Adair	820		145	29	14
Casey	523	74	32	28	5
Clinton	229	55	34	3	4
Cumberland	268	42	32	16	4
Green	297	198	43	22	3
McCreary	508	230	51	27	7
Pulaski	1357	248	135	62	23
Russell	509	162	39	24	7
Taylor	411	208	51	17	5
Wayne	587	147	43	42	8
Total	5509	1364	605	270	80
Kentucky River ADD					

Breathitt	308	298	56	45	10
Knott	1021	162	84	31	8
Lee	408	155	59	19	3
Leslie	587	391	80	27	10
Letcher	541	222	45	27	6
Owsley	260	152	43	11	10
Perry	1037	600	135	54	17
Wolfe	374	257	52	22	6
Total	4536	2237	554	236	70

D2. Phase I: Developmental activities

During this developmental phase, we will conduct focus groups and key informant interviews. These activities will be carried out to provide information that is critical to development and implementation of the PN intervention and include: 1) documentation of contextual factors that are related to obtaining Pap smears and follow-up care among the study population; 2) identification of barriers and facilitators for PNs to function effectively; and 3) identification of health care delivery system characteristics that help or hinder patients needing diagnostic services after abnormal Pap smears and/or treatment for cervical cancer or its precursors.

D2a. Focus groups: Focus groups, which rely on “the dynamic of the group interaction to stimulate the thinking and thus the verbal contributions of the participants to provide the researcher with the rich, detailed perspectives that could not be obtained through other methodological strategies,”^{96: 415} are an appropriate data gathering technique for both the population and the intended research activity. Focus groups are particularly promising data collection venues for groups that have been disenfranchised and yet maintain a strong tradition of oral expression and dialogue exchanges,⁹⁷ characteristics of Appalachian communities.

Potential participants from the participating public health departments will be recruited to participate in one of four focus groups (each with 6-10 women). We will conduct four focus groups with women who have recently (within 3 years) received an abnormal Pap test result to assess the processes and factors influential in receiving follow-up treatment. While not every participating health department will have a focus group conducted at their site, the study population is homogenous and we anticipate that findings will be widely generalizable. Recruitment of participants will take place in the local health department. Potential participants will be invited to attend by the health department staff, who will inform them that this discussion group is designed to better understand the subsequent treatment decisions made by women who receive an abnormal test result.

Each of the focus groups will be convened in a community venue (like the Cooperative Extension meeting room or a similarly suitable location) to gather information on lay perceptions of factors that influence cervical cancer follow-up treatment and intervention strategies. Dr. Schoenberg, who has extensive experience conducting focus groups, will serve as the moderator. The co-moderator, the project director, will also receive extensive training and will record non-verbal interactions, take field notes, assist with analysis of the data, and assist the moderator.⁹⁸ The research assistant will also attend the session. The following activities will take place during each focus group session. After introductions are made, the moderator will briefly describe the purpose of the session, administer informed consent procedures, and request that the session be tape-recorded. Next, the moderator will request that the participants complete a brief questionnaire of their knowledge about cervical cancer and its treatment. The questionnaire, created for a 4th grade literacy level, will be administered verbally if the participants indicate any trouble with its completion. Finally, the focus group will begin and the moderator will ask participants to discuss how a patient navigator might be instrumental in encouraging adherence to follow up recommendations by asking semi-structured questions such as: a) What are the most important reasons for getting regular follow up treatment if your Pap test results come back abnormal?; b) What are women likely to think if the result from their Pap smear is abnormal (indicates something may be wrong)?; c) Some women don’t get the follow-up care if their Pap smear comes back abnormal. Why do you think this is?; d) Do you think women would be more likely to get follow-up care if they had someone to help them? What types of help are needed?; e) Who might be a good person to help a woman get the follow-up care she needs?; and f) What kind of help would this person provide?

If acceptable to the participants, all sessions will be tape recorded and transcribed for subsequent analysis. (If recording is not acceptable, extensive written notes, journalistic style, will be taken.) The transcribed sessions will be analyzed through line-by-line or axial coding, wherein a label or code is affixed to chunks of text.⁹⁹ To insure rigorous, systematic, and comparable analysis, the qualitative data analysis program, NVivo, 70 (QSR, Melbourne, Australia, 2005) will be employed. The program allows the investigator to insert a code or a theme that emerges in the transcripts and assists in the development of a codebook, which is a compilation of the codes and themes. For example, when asked, “Why do you think other health promotion programs haven’t worked in the past?” two qualitatively-trained researchers familiar with the NVivo program will insert codes according to the narratives obtained. These codes may include statements like “other programs came and left the community too quickly” or “few members of the community participated in designing the program” or “no one understood what the program was supposed to do.”

Verification will be enhanced by having these two researchers code the text, develop a codebook, and meet to discuss interpretation and placements of codes. An inter-coder reliability rating of .90 or greater (the reliability rating = the number of times both coders agreed on a label divided by the number of times labeling was possible) will be established.¹⁰⁰ When this inter-coder reliability rating has been achieved, a grid will be established that systematically summarizes the findings of each group and allows for data to be easily accessed to present to key informants during the interview sessions and to allow investigators to formulate the intervention protocols.

D2b. Key Informant interviews: We will conduct in-depth interviews or mini-focus groups with key public health professionals, health care providers, and health care system representatives in the study area to provide information needed to help develop the navigator protocol. We anticipate interviews with approximately 22 informants from each ADD. The interviews will be conducted in a group format for efficiency. To gauge public health assets and barriers, we will hold 3 sessions with representatives from district and local health departments. Similarly, we will hold 3 sessions with health care providers who offer follow-up care for women with abnormal Pap smears and 3 sessions with representatives from hospitals who provide in- and outpatient services such as radiation therapy. It is anticipated that 2-3 informants will attend each group sessions, for a total of 9 sessions with approximately 22 informants.

For both the focus groups and key informant interview sessions, we will employ a relatively small sample size for several reasons. First, as a relatively under explored topic within this disproportionately affected population, we will necessarily identify factors that influence the use of cervical cancer prevention and treatment in addition to and beyond the established literature. Undertaking such a thorough and valid description and examination of a range of factors that may influence cervical cancer screening and follow-up is a time-consuming activity that necessarily limits the number of participants.¹⁰¹ Involving fewer participants, but allowing the “informants to speak for themselves”^{102:17} increases our capacity to elicit profoundly rich data due to more in-depth conversations and greater time expenditure. Maintaining a modest sample size should also allow the investigators to approach or reach the point of theoretical saturation, the term used to describe “data adequacy” or collecting data until no new information is elicited. Indeed, as Luborsky and Rubenstein note, such qualitative, exploratory approaches, as analogous to statistical power, are capable of generating *qualitative clarity*, or theoretical grounding and sensitivity to context.¹⁰³ In addition, the key contribution of this developmental phase lies not in its ability to accurately predict the correlates of cervical cancer prevention or treatment use, but rather in its potential to elicit appropriate and rich data unavailable in large-scale survey research and certainly not focused on this notable health disparity population.

D2c. Implementation of Phase I findings & summary: This developmental phase of the program is a necessary precursor to the administration of the intervention as it will establish the foundation for the PN intervention in the context of the study population, and identify specific barriers and assets influential in cervical cancer diagnosis and treatment. By undertaking a community inventory, we will be very familiar with the county level challenges or assets to women. For example, we may learn that there are community resources available to provide transportation to needy women, a finding that can be disseminated to PNs. On the other hand, learning that the nearest gynecological oncologist has an office 60 miles away over a mixture of gravel and paved roads will require creative strategies. The key informants and focus group findings will affect the

patient intervention in the following ways: (1) Identified barriers and assets to follow-up care will be used to develop a barriers/assets checklist that will be administered during baseline, posttest 1 and 2 interviews. This checklist will identify factors that influence decisions to try to obtain follow-up care and the ability to act on such decisions. Ultimately, the research team will tailor PN activities to assist in removing barriers by drawing on assets; (2) Findings that suggest misunderstanding of the benefit from treatment will be addressed directly by the PN intervention. For example, if analyses reveal common perceptions that treatment is ineffective, we will provide counterexamples.

D3. Phase II

D3a. Theoretical Basis for the Navigator Intervention. After careful review, the investigators determined that Social Cognitive Theory (SCT)^{104,105} is the most appropriate theoretical foundation for this proposed project. Table 5 presents the basic concepts included in SCT, implications for community based cancer control research, and how SCT is used in the proposed project. As Table 1 shows, SCT provides a conceptual foundation for all aspects of the intervention. Such concepts follow through the intervention and also provide structure to the evaluation. For example, as shown in the second row of Table 1, the Navigators will offer to accompany women to follow up appointments. Such support will help to reduce fears associated with the changes in environment that occur as patients have appointments for diagnosis and treatment from providers practicing in different locations.

Table 5. Social Cognitive Theory (SCT) and the Navigator Intervention

Concept and Definition	Implications	Navigator Intervention
Environment – External factors influencing the individual’s behavior	Provide opportunities and social support	Navigators interact with women describing nature of follow up testing after abnormal Pap smears
Situation -- Individual’s perception of the environment	Correct misperceptions and promote healthful norms	Navigators offer to accompany women to follow up appointments, thereby making the experience more comfortable and acceptable
Behavioral capability -- Ability (knowledge and skill) to carry out new behavior	Promote mastery learning through skills training	The targeted behavior is obtaining recommended follow-up after an abnormal Pap smear. Appalachian cultural perceptions of diagnostic testing, diagnosis and treatment planning are addressed by the Navigators
Expectations -- outcomes anticipated	Model positive outcomes of healthful behavior	Participants anticipate logistical difficulties and discomfort and yet with the support of the Navigators, we plan to target those expectations so that the women return for follow-up care
Value Expectancies -- internal value placed on behavioral performance	Present outcomes of change that have functional meaning	Adherence to recommendations for follow-up results in positive identifying cancers at earlier stages that are more responsive to treatment and cure (and therefore have value), which is likely to result in improved survival (value for the women is being alive and well to see their grandchildren grow).
Self-control -- personal regulation of goal-directed behavior	Provide opportunities for self-monitoring, goal setting, problem solving, and self-reward	Woman has control for scheduling and keeping her appointment (i.e., Navigators assist and reinforce both behaviors, but the actual implementation is in the control of the woman herself).
Observational learning -- watching the actions and outcomes of others’ behavior	Include credible role models of the targeted behavior	Observe appropriate behavior through interactions with the Navigators and through educational materials

Reinforcements -- Responses to a person's behavior that increase or decrease the likelihood of recurrence	Promotes self-initiated rewards and incentives	Through interactions with the Navigators, the women observe positive behaviors (obtaining follow-up care) and are rewarded with messages such as, "You're being a good model for your daughters and nieces." Receiving results from follow-up care that indicates that invasive cervical cancer was prevented or detected at a treatable stage is another positive, reward of emotional relief, therefore the screening event is of value.
Self-efficacy -- The person's confidence in performing a particular behavior	Approach behavioral change in small steps to ensure success; seek specificity about the change sought	The patient has the opportunity to schedule routine follow-up examinations and annual re-screening examinations on her own.
Emotional coping responses -- Strategies or tactics that are used by a person to deal with emotional stimuli	Provide training in problem solving and stress management; include opportunities to practice skills in emotionally arousing situations	Most women feel heightened anxiety when obtaining follow-up care for a suspected diagnosis of cancer. Navigators will assist the women in addressing cultural barriers, of which most have strong emotional basis -- the women learn methods from the Navigators that help to reduce the emotional arousal. The Navigators help patients deal with family members or cultural beliefs that may challenge obtaining recommended follow-up care.
Reciprocal determinism -- The dynamic interaction of the person, the behavior, and the environment in which the behavior is performed.	Consider multiple avenues to behavioral change including environmental, skills, and personal change	Interactions with the Navigators will provide the means to document factors that affect adherence with recommendations to obtain follow-up care (e.g., negative interactions with health care systems/providers, changes in health insurance status, etc)

As Table 5 indicates, SCT provides a rich source of guidance for development and implementation of the navigator intervention. The concept of modeling and the use of Navigators are both supported by SCT. The Navigators carry the rural Appalachian culture with them, are able to describe, interpret and function in the often unfamiliar environment of follow-up care after abnormal Pap smears, and provide encouragement and support for women.

D3b. Phase II Recruitment and training of PNs. PNs will be recruited with the assistance of Fran Feltner, BSN, proposed Co-Investigator and Director of SKYCAP. As described previously, Ms. Feltner has extensive experience with recruitment, training and management of lay health workers and PNs. Two PNs will be recruited for each ADD. Each will be assigned to patients from within their ADD and will be trained to collect data during the baseline and posttests. Dr. Dignan's previous research revealed the necessity of having female PNs and interviewers provide cervical cancer education and collect data, respectively. Engaging PNs and interviewers from a similar background who generally share health experiences, values, and living circumstances, increases comfort level and credibility. Moreover, embedding the program and the process within a key community institution (the public health department) increases the likelihood that it will be sustained.¹⁰⁶ The characteristics of good candidates for PNs include excellent communication skills and demonstrated ability to interact effectively with the study population. In addition, since PNs will serve as role models it will be necessary that they have experience with local health care delivery services. For this reason, we will seek individuals who are either survivors of cervical cancer, have undergone treatment for cervical cancer, have received an abnormal Pap smear result, or at minimum have had regular Pap tests.

D3b1. Recruitment: Recruitment of PNs will be led by Ms. Feltner. Potential PNs will be recruited through participants in the focus groups and key informant interviews. Those women who are interested in becoming PNs will need to meet the eligibility criteria described above and undergo two training sessions. Other strategies for identifying potential PNs will include advertisements in the community newspapers, recommendations from the local Health Departments and cancer coalitions. In consultation with Dr. Dignan, the project director will place advertisements, contact and hire the interviewers. Our extensive involvement with the

Cancer control community in rural Eastern Kentucky increases the likelihood that we will have a strong pool of potential health navigators to choose from.

D3b2. Training: At least two PN training sessions will take place. These sessions will last 3-4 hours each and will precede the relevant data collection or intervention activities. Since previous experience indicates that training small groups is more likely to result in successful, personalized training, the PNs will be trained in groups of 2. The sessions will take place in a central location and attendees will be compensated for their time. Training sessions will be led by Dr. Dignan who carried out this task in the North Carolina Native American Cervical Cancer Prevention Project, with input from Ms. Feltner.

Training sessions will consist of the following components: (1) an overview of the project; (2) information about cervical cancer risks factors, screening recommendations, procedures used to detect and diagnose cervical cancer, and treatment methods; and (3) their roles and responsibilities as a PN. A training manual, similar in content and scope to that developed by Dr. Dignan for the Native American Cervical Cancer project, will be developed for each of these roles and will be used to guide the session. Sessions for each role will vary according to responsibility. All PNs will receive information about the project and whom to contact. Dr. Dignan, the project director, and the research assistant will telephone each of the PNs and interviewers a week after each training session to answer questions. We will convene another training session before each of the major tasks to provide reinforcement of earlier training and to answer questions.

D3c. Phase II Study participants. Women who have not returned for follow-up after the detection of an abnormal Pap test result will be eligible to participate in the study. Specifically, patients who have been identified by public health department case managers will be referred. Our preliminary work with the public health departments demonstrates that it will not be difficult to recruit women meeting these criteria into our study. Our previous research experiences suggest that, in the Appalachian context, rarely or never screened women can be found in all walks of life, not simply in low socioeconomic status groups. In our recently completed pilot work, 90% of the women (age range 47-59) indicated that it had been at least 4 years since their last Pap test. Thus, it is likely that recruiting from public health departments will be very productive. A recent study on cancer screening among rural women obtained a 83% recruitment and 90% retention rate, which the authors attribute to integrating community members' insights, insuring interpersonal contact between respondents and project staff, skill and training of local staff, and "the endorsement of the study by the community,"¹⁰⁷ key elements of the proposed project's recruitment and retention strategies.

As with all components of this project, we will call upon our community-based co-investigators to advise us on how to sensitively and effectively recruit study participants. We will obtain a list of women needing follow-up from public health department case managers. The approach we anticipate using is to follow the standard protocol used by public health departments. In addition, we will mail each patient a letter with a self-addressed stamped envelope that contains a questionnaire on overall health behavior information (i.e., recency of last mammogram, Pap test, and blood pressure screening) and willingness to participate in our project. Alternatively, eligibility could be determined by brief face to face interviews by our PNs or in a telephone conversation or another private venue. If eligible and willing to participate, the PN will arrange a baseline interview at the respondent's home or wherever is most convenient.

D3d1. Phase II Theoretical Foundations: The proposed project draws on the strengths of several conceptual frameworks, including the PRECEDE/PROCEED, the Transtheoretical model (TTM), and Social Cognitive Theory (SCT). The PRECEDE/PROCEED model is well known among planners of health education and health promotion programs.^{108,109} The model facilitates the identification of many different classes of factors that influence health and health behaviors, focusing on social, epidemiologic, behavioral and environmental, and educational and organizational views of a health problem within a community context. The PRECEDE/ PROCEED model makes explicit the identification of predisposing, enabling and reinforcing factors that need to be considered when developing an intervention.⁷¹ The main thrust of the proposed intervention will be to manipulate key predisposing factors that will help promote cervical cancer screening and appropriate follow-up after an abnormal Pap result. However, attention will also be directed to specific enabling factors that can be mobilized to promote adherence with recommendations to obtain follow-up, especially fear (apprehension about what may be found at follow-up), cost, transportation, and child/elder care responsibilities.

Our key informant interviews with health and social service providers will provide insights that PNs will pass along to participants on how to overcome these tangible barriers to cervical prevention and treatment. The PRECEDE/PROCEED model recently has been used successfully in a LHA intervention to promote Pap tests among underserved Vietnamese women.⁶⁸

The key predisposing factors that will be manipulated by the intervention are knowledge, self-efficacy and attitudes. The principal theoretical framework guiding the intervention will be Social Cognitive Theory (SCT).¹¹⁰ This well-known theory presumes that modeling is an essential component of learning. This concept guided the decision to utilize lay health advisors for the North Carolina Native American Cervical Cancer Prevention Project.¹¹¹ SCT also guided the intervention itself.¹¹² In sum, while PRECEDE/PROCEED provides a general framework for intervention development and implementation, SCT provides direction for the specific elements of intervention. However, multiple theoretical models will be used to develop the intervention. As concluded by Curry and Emmons,¹¹³ no single theoretical model is sufficient to predict and improve participation in cancer prevention activities.

D4. Phase II Research Design. We will implement a group-randomized trial consisting of intervention and delayed intervention groups for patients in public health departments in the three ADDs included in the study. Both the intervention and delayed intervention groups will be developed in conjunction with key informants and delivered by the trained PNs. The PNs will assist women in obtaining diagnostic and, if necessary, treatment for cervical cancer. The tailored intervention will consist of PNs who will make home visits to participants to strategize on how to overcome barriers to obtaining follow-up care. The intervention components will be oriented to converge with the women's real life circumstances and educational background and are designed to be interactive and enhance existing skills.

Figure 2 illustrates the research design, timing of intervention and evaluation of the proposed project. Patients identified by LHD case managers will be eligible for referral to the DHD Nurse Administrator for assignment to a PN. Public health departments will be assigned at random to receive the intervention immediately or to a delayed intervention status. To reduce the chance for study group contamination all patients referred from a public health department will be treated within the 'intervention' or 'delayed intervention' group. Outcome data will be collected by interview at baseline and again on two occasions at three months and 12 months. The design is shown in Figure 2, where R indicates that women will be

Figure 2. Research Design

	N	Baseline	Intervention	Post-Test 1	Intervention	Post-Test 2
Local Health Departments randomized to two groups	Patients	Referral from LHD & Baseline interview	PN outreach, education, support	Interview	PN outreach, education, support	Interview
Intervention	156	O	X	O		O
Delayed Intervention	156	O		O	X	O

LHD = Local Health Department, PN = Patient Navigator

randomized to group 1 or 2, O designates data collection and 2 identifies points where the intervention will be provided. As Figure 2 illustrates, a randomized, controlled design is proposed in which all patients will receive the intervention during the study period. The design shown in Figure 2 was selected for two main reasons. First, it will allow estimation of effects of the intervention for one group of patients at two points in time; one proximal to the intervention and the second at a later point in time. This approach will allow assessment of short-term intervention effects and detection of longer term effects. The second reason for selecting this design is that the lagged approach allows the investigators to address the ethical concern of denying patients access to a potentially helpful service, and extend the intervention to all participants.

D4a. Baseline Interviews: Baseline interviews will be conducted in either the participant's home or another convenient location and will involve three activities. First, the interviewer will insure that the eligibility

criteria have been met and, if so, administer informed consent. Next, she will assess literacy level and either verbally administer the baseline interview or provide a written questionnaire, either of which is anticipated to take 30 minutes to complete. The questionnaire will gather baseline data on: knowledge of recommendations to obtain follow-up after abnormal Pap smear results, perceived efficacy of follow-up testing and treatment for cervical cancer. The interview will also collect specific information on cervical cancer screening and follow-up including the date of the last visit to a health care provider (HCP), date of the last pelvic exam, date and result of last Pap smear, and recommendation from the HCP regarding follow-up. Responses from these questions will be used to determine the expected outcome for each participant. In addition, to identify each woman's particular barriers and assets that shape follow-up treatment after the detection of abnormalities, we will administer a barriers and assets checklist. This checklist will have been developed during the Phase I focus groups and will include a wide range of barriers to and facilitators of obtaining follow-up. The checklist will be pre-tested by the PNs during their training to insure completeness and semantic appropriateness.

Finally, the PNs will describe the next stage of the program, assistance with obtaining follow-up, and will encourage the participant to accept assistance. To defray expenses associated with travel, day care or elder care arrangements, etc., participants will receive a \$25 honorarium for completing the baseline assessment and any subsequent interviews.

D4b. Tailored Intervention: One month after the baseline interview, individuals in the early intervention group will be sent a letter thanking them for participating in the interview and informing them that the PN will contact them about setting up another home visit in the next two months. This home visit will consist of an intervention tailored to the targeted outcome (i.e., obtain follow-up), her knowledge and literacy level, and to her perceived barriers/assets in obtaining needed cervical cancer services. While this aspect of the intervention is a departure from previous projects, existing literature documents the efficacy of tailored, home-delivered programs.¹¹⁴ The PNs will contact women by telephone or through a home visit (if a telephone is not available) to schedule a visit. Six attempts to contact women will be made, varying time of day and day of week. PNs will return the names and telephone numbers for women who cannot be contacted or scheduled, to the project director who, in turn, will notify the investigators that the woman cannot be contacted. This will be an intent to treat analysis and all women enrolled will be analyzed irrespective of the delivery of the program. Secondary analyses will examine only those women in whom at least 1 visit was conducted.

After the PN and participant agree upon an acceptable date for the home visit, the visit will proceed as follows: the PN will briefly review the recommendation that the woman received following her abnormal Pap smear. Following this opening segment, the PN will then present the participant with her personalized newsletter.¹¹⁵ The tailored, educationally-appropriate newsletter will be designed according to information obtained during the baseline interview (i.e., accounting for targeted cancer prevention activity barriers, literacy level). Given the modest level of educational background in this population, information contained in the newsletter will be pictorially displayed, or will be written at a basic grade level appropriate for the participant. Tailoring will be carried out using the "Mail Merge" feature of Microsoft Word. The Mail Merge procedure is simple and efficient. The template newsletter is merged with information on the individual. Dr. Dignan led the development and management of tailored message production as part of the North Carolina Native American Cervical Cancer Prevention Project. In that project, individualized educational materials were produced for each woman at the project office at Bowman Gray School of Medicine and sent to the PNs working with the Cherokee and Lumbee study populations (N=1000). More recently, Dr. Dignan has led development of software and procedures for producing tailored print messages advocating mammograms for low income, minority women.

The newsletter will be approximately four pages in length. The intervention protocol and newsletter will be tailored according to three domains: (1) the participant's specific type of follow-up treatment recommended; (2) the barriers and assets indicated by the participant during the baseline interview; and (3) the participant's literacy level. The proposed newsletter will contain the following content: Page 1: Brief introduction to the tailored newsletter with the PN listed as the information source (with insert photograph of the PN). The introduction will briefly review the cervical cancer program and the contents of the newsletter. In addition, a column will be written by Dr. Friedell, proposed co-investigator, with a testimonial about the importance of

follow-up. In addition, we will print the contact information for the PNs so that the participant can personally query them, if desired. Page 2: A question and answer column from Dr. Gil Friedell will convey information about the need for prompt follow-up after abnormal Pap smears, the types of follow-up that may be recommended, and the advantages of obtaining follow-up. Page 3: A half-page layout highlighting the most important barriers reported by the participant in the baseline interview will be provided in bullet format, followed by a half page providing strategies for overcoming barriers and/or counter arguments. For example, if fear, cost, transportation, and/or child/elder care are significant barriers for the woman, the programs identified in the community inventory and during the key informant interviews with the health and social service providers will be described and contact information will be provided. For women who list no barriers, the newsletter will discuss the most common barriers to follow-up. Page 4: A half-page column written from the point of view of the public health department (with photograph insert) that is responsible for making appointments for follow-up. This column will provide a description of the process of making an appointment, identify phone numbers, and explain how the appointment can be made. The objective is to promote self-efficacy by describing how to overcome barriers to making an appointment. The remaining half-page will be reserved for a final message by the PN (with a signature byline).

The PN will spend about 30 minutes reviewing the newsletter with the woman during the home visit. Then, in conjunction with the PN, each woman will create her own specific action plan to be recorded on the form adjacent to each barrier listed. The PN will provide assistance in calling the woman's health care provider or low cost/free health clinics and making the appointment before exiting the home. The standardized form will include space to record the time, date and location of the visit. The PN will then thank the participant, review the essential components of the action plan, and give her a copy. Following this home visit, the PN will mail a tailored thank you letter to the participant, reinforcing the need to visit her health care provider. This tailored thank you letter will bullet key highlights from the visit, including acknowledgment that a specific action plan was developed.

In summary, the intervention will include personalized attention from the PN in making appointments for follow-up care, a newsletter tailored to each woman's particular cervical cancer follow-up need, the barriers and assets she indicated during the baseline interview, and her literacy level. The cultural acceptability of this newsletter will be enhanced by messages from the PNs.

D5. Pilot testing. Pilot tests of all components of all intervention procedures will be carried out with the PNs. Pilot testing will focus on the following issues: (1) appropriateness of language, illustrations and presentation of the educational materials, (2) appropriateness of reading level (3) estimates of time required for implementation, (4) eliciting unanticipated barriers, and (5) overall satisfaction with the process and materials. Pilot testing the materials on the PNs is a significant benefit since these individuals are from the same background as the participants, but will not contaminate the results by providing data themselves. Pilot testing will include quantitative and qualitative components and will be undertaken during the training sessions. Quantitative information to be collected during pilot testing directly prior to providing the PNs with training about cervical cancer and will include recall of factual information provided by the PNs. Qualitative information will be collected by interview and will include perceptions about the extent to which the intervention materials appear to be relevant to women, culturally consonant, appropriate in terms of reading level, and appearance. Following analyses of these data, intervention protocol and materials will be revised, and additional pilot testing will be done if necessary. The results from pilot testing will be reviewed and discussed with key informants before a final version of the intervention protocol is produced.

D6. Implementation. Lists of women needing follow-up will be provided to the PNs by the district public health department case manager on a weekly basis. The PNs and project director will negotiate weekly goals to help structure time expenditures. This system was successfully used in the North Carolina Native American Cervical Cancer Prevention Project. Reports on intervention activity will be collected in weekly face-to-face meetings with the project director, interviewers, and PNs. These reports will be based on the schedule decided

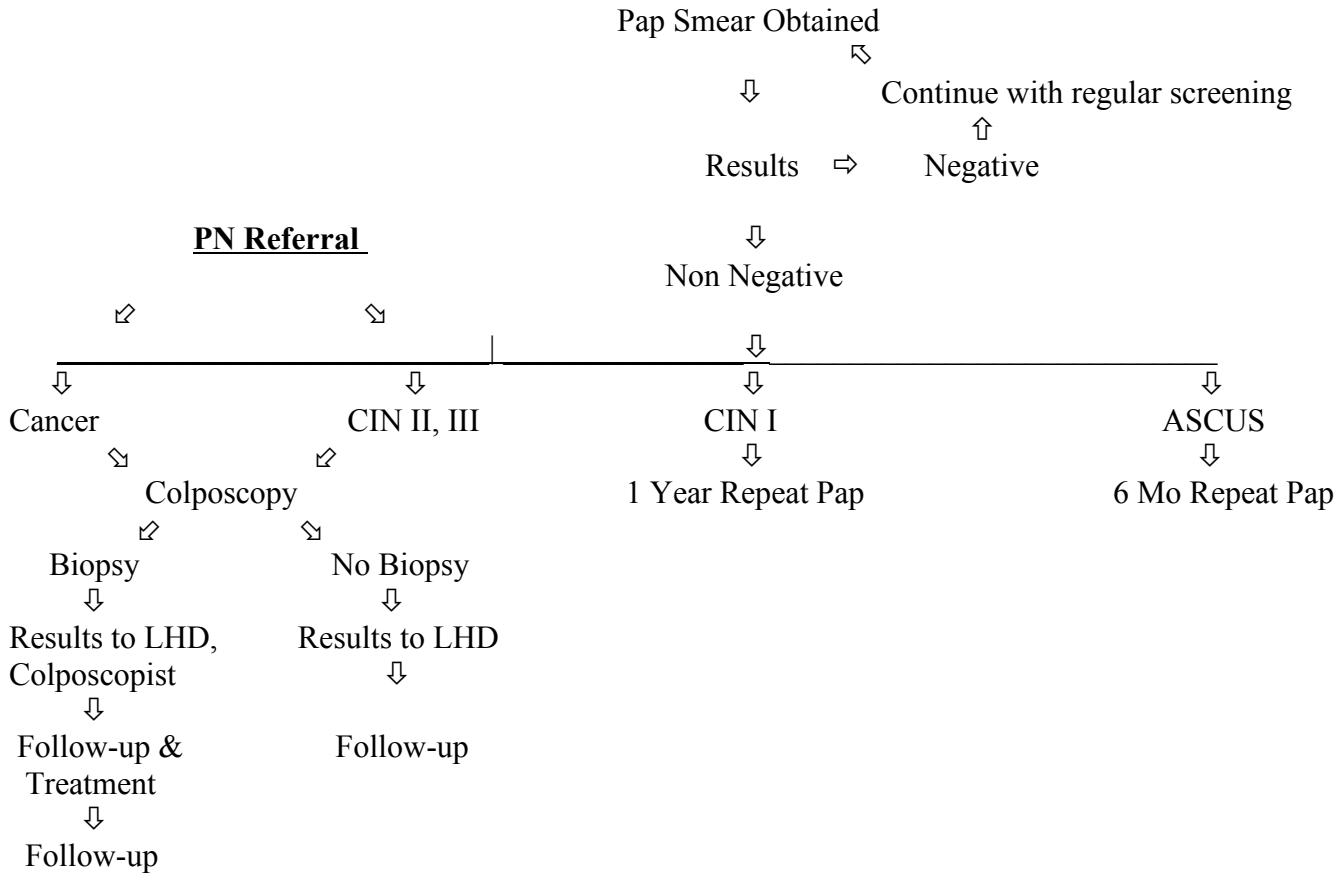
earlier, and will convey the number of women contacted, the number for whom the intervention has been scheduled, refusals, and the number that were not contacted.

D6a. Quality Control. To insure optimal quality check of the intervention, each PN will be observed in one home visit during the earliest portion of the intervention or interview activities. In addition, each PN will be provided with a log book, where she will record every contact (time, date, place, and nature of each contact) that she has with participants. These logs will not only assist with recruitment and retention records and efforts, but also will provide an audit trail to monitor successful and problematic interactions for modeling and intervening. As a further check on the intervention, Dr. Dignan will lead monthly meetings with the PNs as a group to review the protocol, provide solutions to common problems, to encourage and reinforce efforts, and to explore untoward effects of the intervention on the PNs and participants. Dr. Gil Friedell will be available to discuss clinical aspects of follow-up and to suggest how PNs could respond to possible negative reactions to interactions with health care providers and others. PNs who have difficulty performing at expected levels will be given additional training by Drs. Dignan and Schoenberg. PNs will also be made aware of the high rate of false positives that frequently occur in Pap test results, and special training will be provided on how to manage a positive Pap test result, a situation that might prove problematic to the completion of the intervention. If such a result is detected, the PN will provide additional visits to the woman's home, if desired, to convey the frequency of false positives, but to encourage the participant to obtain appropriate follow-up treatment.

D6b. Administration of the Intervention. The proposed PN intervention will be carried out under the direction of case managers in the local health departments (LHDs). The PNs will be based at one of the three district health departments (DHDs), and will serve women at more than one LHD. The DHDs will be the administrative headquarters for the PNs. This structure is needed because it is critical that the PNs be part of the public health structure, rather than be perceived as being "imposed on" from an outside source. PNs will function as part of a team consisting of the DHD nurse administrator, the nursing supervisor at each LHD and the LHD case manager. Day to day supervision of the PNs will come from the DHD nurse administrator. Evaluation of PN performance will be based on not only a specific job description, but on an overall protocol for the functions of PNs, the protocol to be drawn up by DHD nurse administrators with input from LHD nursing supervisors and case managers. The evaluation protocol will be constructed so that as a check list it could be used in day to day activities by PNs. Figure 3 shown below outlines the basic steps involved in Pap smears and follow-up care and indicates that PNs will become involved when the results indicate CIN II, III, or Cancer.

D7. Phase III: Evaluation

The health departments will be assigned at random to intervention and delayed intervention groups. A randomization schedule will be developed for this project to organize treatment assignment. The schedule will be formed in blocks of 6 so that there will be approximately equal numbers of control and intervention health departments at any point in time. All patients receiving care in LHD who are referred for follow-up based on abnormal Pap smear results will be treated in the same study group. Patients failing to return for follow-up will be referred by LHD case managers to the DHD nurse administrators for assignment to the PNs. We carefully considered assigning individual patients to study groups versus assignment of health departments to study groups. The randomization of individuals to study groups within health department would carry a substantial risk of study group contamination and would threaten to undermine one of the major benefits of using the proposed approach, so instead we decided to randomize health departments. We recognize that this introduces a cluster effect because patients in the same health department may be similar in key ways that affect their response to the intervention. However, locating the intervention in health departments is likely to yield compelling enough benefits (high participation rates, a trustworthy venue, etc.) to compensate for concerns about cluster effects. In addition, several issues mitigate against a contamination effect. First, the intracluster correlation is lower in this design compared to others because, the actual behavior of obtaining a Pap test or follow-up care, is more individualized. Further, since the primary outcome variable is the proportion of women who report obtaining Pap smears, little is known about the magnitude of the intraclass correlation to move

Figure 3. Flow Diagram for Abnormal Pap Smears

groups as units, thus, one might expect the intraclass correlation to be variable across public health departments. Finally, we have included process evaluation procedures to detect and assess contamination.

To determine the level of success of the intervention, two main evaluative approaches, one quantitative and the other qualitative, will be used. First, posttest data will be conducted to examine outcome measures. Second, a qualitative process evaluation will be administered to determine whether activities are consistent with project objectives, the level of participant satisfaction with the intervention, perceptions of PNs about the effectiveness of the interventions, and the costs of the project. Evaluation will be implemented to address each aim of the project. Process evaluation will be used to assess achievement of aims 1-5: 1) development of a plan for effective utilization of lay health workers as PNs in local health department cervical cancer screening programs; 2) training of PNs and establishment of working relationships between navigators and local health department personnel; 3) linkage of patients with abnormal findings after cervical cancer screening in local health departments with a well-trained PN; and 4) development and implementation of patient tracking and data collection systems. Quantitative methods will be used for evaluation of the remaining aim: 5) reduction of the time intervals between the finding of abnormal screening results and establishment of a diagnosis, and between diagnosis and treatment.

D7a. Qualitative Evaluation. While the quantitative evaluation will determine associations between the interventions and outcomes, it is less capable of answering other essential issues. For such issues, including the acceptability and experience of the intervention and the sensitivity in which cultural issues were handled during the intervention, qualitative evaluations will be used.¹¹⁶ For this evaluation component, a process evaluation will be used to examine key indicators of program implementation, including contamination detection and costs

and the experiential evaluation will focus on the meaning-centered experience of the intervention, including participants' perception of the program and consistency with programmatic goals.^{117,118}

Both the process and the experiential evaluations will use the same data collection protocol. Debriefing exit interviews will be conducted with a random sample of participants (n= 20, including 10 from the delayed and 10 from the early intervention group), and a subsample of key informants (n=10) to determine institutional satisfaction with the intervention and promote community-based partnerships. In order to insure the involvement of a wide range of participants, we will employ maximum variation sampling, whereby lists of participants are arranged according to these key characteristics, and participants are randomly selected from these lists (i.e., every fifth person will be invited to have an additional interview). Similarly, for the key informants we will create a list of all of those who participated in the earlier interview and randomly select persons from that list. The interviews will occur throughout the intervention. Dr. Schoenberg will lead administration of the interviews.

The interview will consist of two parts, each of which pertains to either the process evaluation or the experiential evaluation and uses semi-structured questions. For the process evaluation, questions will focus on determining the presence and extent of contamination and assessing the programmatic costs. Specific questions will also be asked during the posttests to detect contamination between the intervention and delayed intervention groups. For example, women in the delayed intervention group will be asked if they have heard about the intervention or if they have seen any of the tailored intervention materials and those in the experiment group will be asked if they shared information that they received with other women in the community. The PNs will also be asked routinely if they have been asked any questions about the program that they are providing from other individuals. In cases where the PNs report being asked about the program, assessment will include collection of the type of information provided and to whom. Process evaluation measures, which are modeled after those used in the NCI-funded North Carolina Native American Cervical Cancer Prevention Project, will continue throughout the intervention and evaluation periods.

Since the exportability of the intervention will depend in part on cost, we propose to monitor costs as part of process evaluation. Costs to be tracked include the following: PN recruitment and training; educational material printing and duplication; PN time required to (1) schedule appointments, (2) travel to women's homes for visits, (3) correspondence costs (thank you and reminder letters), (4) educational materials printing and duplication; and, (5) supervision costs. Furthermore, during all debriefing interviews, respondents will be asked to estimate any expenditures related to cervical cancer activities (e.g., medical appointments, etc.). Since every item in the project will be carefully budgeted, this monitoring should be quite feasible.

The protocol for the qualitative evaluation is identical in approach to the development phase focus group and key informant interviews. That is, all evaluation interviews will be tape-recorded and transcribed and subjected to the same procedures discussed in Phase I. To identify possible differences in the extent and nature of satisfaction with services, we will create a comparative matrix that contains a thematic and evaluative summary from each subgroup (those women who did or did not take recommended action, women from both study groups, PNs, etc.).¹¹⁹

D7b. Quantitative Evaluation. The quantitative evaluation, like the project activities themselves, will be tailored to the participant's specific cervical cancer diagnostic or treatment circumstances. For example, for women who receive a recommendation to have colposcopy to follow-up after an abnormal Pap smear, the expected outcome will be obtaining the colposcopic examination.

The main outcome measure examined will be adherence with recommended follow-up after an abnormal Pap smear. In addition, several mediating variables will also be assessed that represent constructs or variables that the intervention is hypothesized to manipulate or impact, including: (1) knowledge of the importance of follow-up, perceived efficacy of the screening tests; (2) decisional balance; and (3) self-efficacy. These psychosocial constructs have been documented to be predictive of health behaviors.^{33,66} Existing instruments with demonstrated validity and reliability, including a cervical cancer specific instrument,¹²⁰ a cervical cancer-specific knowledge questionnaire,¹²¹ a measure of decisional balance,¹²² and self efficacy for cervical cancer-related activities,¹²³ will be used. However, the items and instruments that we intend to administer will undergo

a final revision based on input from the study population to insure cultural consonance, the use of appropriate language, and overall relevance. Dr. Shelton will assist with the assessment of validity and reliability.

Analyses for this project will be carried out, in collaboration with Dr. Shelton, employing the “intent to treat” principle. Drop-outs and refusals following randomization will be retained in the analyses, but considered as failures if they dropout prior to posttest1 and will be assessed in two ways (last observation carried forward and as a failure at time point 2). The first steps in the analysis will focus on process. Delivery will be assessed by examination of participation in the delayed intervention and intervention groups, calculating the intensity of intervention (How many visits were completed, attempted, etc.) The principal question to be answered by data analyses will focus on the main outcome: was receipt of the intervention associated with statistically significant increases in the proportion of women who took recommendation action? The simplest test for the main outcomes will be a Pearson Chi-square test comparing the proportions in the upper triangular portion of the stage of change at baseline by stage of change at posttest1 matrix (Transition probability matrix). Additional analyses using logistic regression via Generalized Estimating Equations to account for the clustering within health department will be carried out with obtaining screening (Yes/No) as the dependent variable and intervention group adjusted for various covariates such as age, ethnicity, self efficacy, knowledge, and socioeconomic status.

We will also determine the presence of any interactions on an exploratory basis. Because this study uses random assignment, the sample size calculations provided above will be conservative with respect to the performance of these analyses.¹²⁴ Secondary questions to be answered will focus on the moderating effects of demographics, knowledge, self-efficacy and other variables on the effectiveness of the intervention. An important related question will be if there are differences in the proportion of women who take recommended action during the period between posttest1 and posttest2. The simplest approach to answering this question will be a McNemar’s Chi-Square test for correlated proportions, comparing the proportions screened at posttest1 and posttest2. Crane’s work found that among those women compliant at baseline, 15% did not remain in this categorization over time. We will examine the characteristics predictive of remaining compliant and test them within each intervention group. For this exploratory analysis we will use logistic regression or GEE models to estimate the transition probabilities from baseline to posttest1 and from posttest1 to posttest 2 and the covariates associated with these transitions. We will be able to compare the results of baseline to posttest 1 in the experiment group to the posttest1 to posttest 2 results in the delayed intervention group to assess the reproducibility of the covariates associated with successful intervention. In the experiment group we can then examine whether the covariates associated with maintenance are the same as those associated with successful intervention.

Additional analyses will examine the effect of the intervention on intermediate outcomes, such as knowledge and attitudes toward cervical cancer screening. As noted previously, this study will utilize survey instruments adapted from previous studies conducted by Dr. Dignan, and will primarily use knowledge and attitude scales, including measurement of decisional balance, used in those studies. Dr. Shelton will assist with the formulation of any new scales which may include pilot testing and depending on the type of scale invoked, factor analysis and/or determination of internal reliability (Cronbach’s alpha), as appropriate.

We will assess the possible impact of contamination between the intervention and delayed intervention groups. In general, it is believed that contamination acts to attenuate differences between the intervention and delayed intervention groups by making them similar to one another and adds a conservative bias to results. Thus, if significant differences are found using intention to treat and contamination is present, the results will be more convincing than if there were no contamination. Contamination will be difficult to establish, although we will include in the posttest questions that specifically try to isolate sources of information. The public health department based unit of randomization actually works in the opposite direction. That is, by inducing a correlation within the responses within a health department, the variation in the response is underestimated and thus, results that are significant may need to be adjusted for this intraclass correlation and we will do this using models appropriate to the question (GEE for the proportions and Proc Mixed for mean scores on questionnaires). Although this is of concern theoretically and can be estimated from the data once collected, it

is likely to be lesser of a problem than might be expected. Individual behaviors tend to be more variable than the traditional clustered analyses.

D8. Sample size and power calculations. Power analysis guided the selection of the number of public health departments to be randomized to each arm of this intervention study. Emphasis is placed on the comparison of the intervention and delayed intervention groups at posttest 2. This reduces to a comparison of the proportion of successes between the two groups which, in the absence of baseline covariate adjustment, reduces to a comparison of proportions based on a nested cohort design. Power can be computed from Equation (5.5) of Donner and Klar¹²⁵ which is reproduced in a more convenient form below (see, also, Liu and Liang¹²⁶):

$$\text{Power} = 1 - \Phi(x)$$

Here Φ denotes the standard normal cumulative distribution function; its argument x can be expressed as follows:

$$x = -z + \frac{p_1 - p_2}{\sqrt{km}} \sqrt{\frac{1 - p_1 + p_2}{1 - p_2}} \sqrt{[1 + m - 1 \rho]}$$

Here z is the standard normal percentile corresponding to the level of significance for the comparison, p_1 and p_2 are the two success rates to be compared, k is the number of clusters (number of health departments assigned to each arm), m is the cluster size (number of women per cluster) and ρ is the intra-class correlation coefficient (ICC) (correlation between responses from two women in the same health department). Power calculations presented here assume a significance level of 0.05 for a two-tailed test, $k = 25$ health departments per group, $m = 12$ (after accounting for up to 20% of respondents lost to follow-up), and ρ is in the range 0.00 to 0.01.

Previous research by Dr. Dignan using an intervention strategy to increase cervical cancer screening produced intervention effects of about 15 percentage points in the Lumbee population and about 10 percentage points in the Cherokee population.⁹¹ Information from the Behavioral Risk Factor Surveillance Survey, a statewide survey of health behaviors, suggests that for women age 50 and older nearly half (48%) had not had a Pap smear in more than 3 years, if at all. In a two-year follow-up study of mammography behavior, Crane found that among the delayed intervention group of women that included a substantial portion of low income and minorities, who had no mammogram in the past 2 years at baseline, 44.8% became compliant over the study period. Given these sources of information, we calculated samples sizes needed per group to detect estimated differences in effects. The data suggest we can improve positive health activities in this group approximately 10% to 15%, we thus assume 12.5% absolute percentage increase. Using the data from Crane, we estimate that the delayed intervention group of women who do not receive follow-up treatment will achieve 45% adherence after 1 year. (Although the rate of adherence is expected to be lower than 45%, for estimation purposes the rate

Table 6: power estimates for proposed intervention project

	P_1 (Intervention)	P_2 (Delayed Intervention)	$P_1 - P_2$	Power
.000	.575	.450	.125	87%
.005	.575	.450	.125	85%
.010	.575	.450	.125	83%

has been set conservatively high for sample size calculations since the power to detect a difference between proportions declines as the proportions approach 50%; therefore, our power estimates are expected to be conservative as well). Thus, we expect to achieve 57.5% adherence in the experimental compared to 45% in the delayed intervention group. With an effective sample size of 12 women from each of 26 health departments in each of the two treatment groups, an alpha level of 0.05, the power to detect a difference between the intervention and delayed intervention group response rates is displayed in the Table 3 below for values of ρ ranging from 0 to .01:

D9. Data Processing. All data files will be transferred from the PNs to the project office via mail service on a weekly basis. Under direction of Drs. Dignan and Shelton, data will be entered and stored in SAS on the networked PC computer system at UK. To insure complete confidentiality, each study participant will be assigned a code number that will be entered in place of the name on the interview schedule and in the data set.

D10. Summary. This proposed project has numerous strengths that should be noted: **1. The proposed study will target an underserved, disproportionately burdened rural population.** As noted in numerous NCI reports, more research is needed to promote cervical cancer screening in underserved populations using tailored interventions. **2. The proposed study builds on a substantial foundation of experience:** This intervention project builds on the experience of Ms. Feltner with SKYCAP, Dr. Dignan's track record of cancer prevention interventions, Dr. Schoenberg's background in health behavior from a contextually based and anthropological perspective, and rural outreach. **3. This study employs a tested, yet innovative combination of approaches to reduce well-documented health disparities:** While our research team has experienced great accomplishment in lay health advisor cancer control models, few studies have applied a PN intervention to rural White populations. **4. The proposed study incorporates extensive needs assessment and community analysis into the design of the intervention.** The research team has been active in discussing this proposal with public health department leaders and outreach workers who will participate in the intervention. Furthermore, the intervention will employ interviewers and PNs from the same background as the study population, enhancing acceptability of the intervention. We also intend to report our results to the public health departments. **6. The scientific integrity of the proposed research will be maximized through the use of a randomized, controlled design.** Randomization will help ensure the initial equivalency of the intervention and control groups at baseline. The plan for recruitment and sample size estimates will also ensure ample statistical power for data analysis.

D10. Implications of this project for reducing health disparities

Implementation of the proposed project has numerous implications for reducing health disparities. First, identifying factors that shape adherence with recommendation for follow-up among rural women with abnormal Pap smear results brings us a step closer to being able to overcoming barriers and drawing on assets to facilitate positive behaviors. Second, modeling our navigator intervention on an extensive foundation of experience with cancer control research, drawing on local input to inform the intervention, and grounding the project in several predictive health behavior models enhances the likelihood that the program will be successful. With such evidence of success, this project can serve as the prototype for other cultural groups that suffer health disparities similar to rural Appalachian populations. Indeed, since those groups that are most adversely affected by cervical cancer share some similar challenges (having low incomes and less education, compromised access to medical services, etc) and assets (having strong community and social ties), it is reasonable that, with local modification, the proposed intervention can be applied to reduce cervical cancer in the most affected populations nationwide.

D11. Time Table. The major activities anticipated for the proposed project are listed below along with the approximate time that they will be carried out.

	Year 1	Year 2	Year 3	Year 4	Year 5
Formative evaluation	X-----X				
Intervention development, pretest	X-----X				
Instrument development, pretest	X-----X				
PNs to Intervention Group		X-----X			
PNs to Delayed Group			X-----X		
Qualitative evaluation		X-----X			
Quantitative evaluation			X-----X		
Data Analysis, Report Writing				X-----X	

E. Human Subjects**E1. Risks to the subjects**

Human subjects involvement and characteristics: It is anticipated that the proposed study will involve women who live in rural Appalachian Kentucky and both genders for the public health and health care provider participants. Our sample will include women of any race and ethnic background. Informed consent will be obtained during the initial baseline assessment and is described below.

We have proposed a randomized, controlled design in which all women will receive assistance from PNs during the study period primarily for ethical reasons. While it may be scientifically optimal to avoid contamination by denying intervention services, ethical considerations preclude us from involving communities that experience huge health burdens only to deny them any direct advantages from their participation in this research. One of our current projects (R01 CA108696) demonstrates the greater acceptability of an intervention that has a delayed approach.

Sources of materials: Data will be obtained in the form of interviews and all participants will be asked to provide informed consent during initial recruitment. Data collection will consist of a baseline interview that will take approximately 30 minutes and two follow up interviews (posttests) that will take approximately 45 minutes each. Key informant interviews will be conducted among health care professionals and representative from local health departments. In addition, qualitative interviews lasting approximately one hour will be conducted with a random subsample of the participants, key informants and PNs to assess their perspectives on the interventions.

Potential risks: The potential risks from participating in the study are very small. Some risk of psychological upset could result from responding to interview questions or the emotional distress over abnormal Pap test results upon receipt of screening. However, previous experience with the conduct of similar interviews suggests that psychological upset is rare, and the interviewers and PNs will be sensitive to and have contingency plans in the case of this possibility. The final concern or risk of this project lies in insuring confidentiality. All of the steps that will be undertaken to prevent or address these potential risks are discussed in E2 below.

E2. Adequacy of protection against risks

Recruitment of subjects and informed consent: We will recruit women who have received recommendations to obtain follow-up care after an abnormal Pap test result. Women will be referred from public health department collaborators and will be contacted and screened for eligibility, and the project will be explained. This explanation will consist of the overall goal of the research (to increase women's participation in follow-up); a brief description of the research; the baseline, posttests and intervention activities, including the number of interviews involved, the intervention and randomization process, and time required for participation; the type of questions that will be asked during the interviews; the minimal risks to participants and the potential benefits; procedures to assure confidentiality; and the voluntary nature of participation. Potential participants will be encouraged to ask questions about the project and participation. We will also recruit representatives from local health care agencies, including the local health department. We will similarly administer informed consent and employ procedures to insure confidentiality (see below).

Protection against risks: In the rare event that a participant experiences psychological distress resulting from the interview questions or from an adverse outcome from a Pap test result, we will arrange to have a counselor available at the Center for Rural Health or another local health center available to debrief and discuss the participants concerns. In addition, all interviewers and PNs will receive training on how to respond to a participant who receives an abnormal test result, including information and referral on follow-up procedures and referral to psychological counseling as mentioned above.

The final concern of this project lies in insuring confidentiality. Confidentiality of all data will be maintained by never linking paper or computer copy of data with the participants' names. A sheet with the participant's name, address, telephone number, and identification number will be kept by the principal

investigator separately in a locked file. Only staff members who are authorized to review files will be permitted access to the data. As part of our training, all personnel will be asked to sign a confidentiality pledge promising never to reveal, alter, or falsify survey data. This pledge is especially important in small, tight knit rural communities.

We will convey these procedures to the participants including informing them that they may refuse to participate in the study, or if they decide to participate, they may decline to answer any specific question, or drop out of the study at any time with no effect on their medical care. Finally, participants will be told that in the unlikely chance that they should incur illness or injury as a result of participation, a name and number to call to obtain information will be provided. In addition, there will be a name to call for additional information on the rights of participants in this study and a person to contact for answers to questions about the study (principal investigator or project coordinator). Since the project does not access, recruit from, or in anyway involve itself in medical records, HIPPA requirements are not relevant.

E3. Potential benefits of the proposed research to the subjects and others: Participation in the study involves little risk for subjects in comparison to the potential benefits of participating in screening and follow-up programs. During the informed consent procedures, participants will be informed that they can expect to receive several benefits from participating in the research program. First, they will be told that they will incur no additional costs for participation in the study. In addition, they will be told that they will be provided with information on risks and screening tests for cervical cancer or information on another important health issue, and that their participation could improve their chances of prevention or early detection of these illnesses. Finally, they will be told that they will receive a \$25 honorarium for participating in the various activities of the project, including the baseline and posttest interviews and receive a lunch during the intervention activities.

E4. Importance of the knowledge to be gained: An additional benefit of participating in this research project lies in the potential to enhance our understanding of the barriers and assets that influence obtaining appropriate follow-up procedures among rural women and to participate in a community-participatory, theoretically informed, and culturally consistent intervention designed to increase adherence with recommended follow-up. As other projects have revealed, projects aimed at reducing disproportionate disease burdens have the potential to be extremely effective if they are grounded in local institutions and developed in partnership with local communities. While there is little doubt that appropriate medical follow-up after an abnormal Pap results have the potential of practically eradicating cervical cancer mortality, the toll that cervical cancer continues to take on the lives of rural women and their families warrants an innovative, empirically-based and theoretically driven intervention that can be sustained within the community.

E5. Data Safety and Monitoring Plan

E.5a. Study Safety Monitor

The Safety Monitor for this study will be:

Mark Dignan, Ph.D. phone: (859) 219-0771, ext 271, e-mail: mdignan@prc.uky.edu

Dr. Dignan will be responsible for evaluating all Serious Adverse Events, and preparing and sending the pertinent expedited reports to the appropriate persons, as detailed below. In addition, the Medical Safety Monitor for this project will be Nancy Schoenberg, PhD, phone: (859) 323-8175; email: nesch@uky.edu. Dr. Schoenberg will assist Dr. Dignan in preparing the educational and tailored health materials as well as insuring that the health information provided is timely and appropriate.

E.5b. Safety Monitoring

Study participants (N=approximately 418 total). This includes: 30-40 in focus groups, 66 key informants of any gender, race and ethnicity, and 312 patients with abnormal Pap smear results. The primary main investigators on this project, Drs. Dignan and Schoenberg, have had experience administering community-based interventions and have had negligible safety concerns.

It is possible that some psychological trauma will result from the interviewing. While this is extremely rare, we have established, through our colleagues at the University of Kentucky Center for Rural Health and the University of Kentucky Department of Family Practice, names and contact information for counseling services. If a participant is in need of counseling, all she need do is to inform the interviewer, who will contact Dr. Dignan to arrange a counseling session. If the participant experiences psychological discomfort with the interview, she will be reminded that she need not complete the protocol.

Staff will be instructed to be alert and careful in the protection of volunteers from the risk of any psychological trauma and will be trained by Drs. Schoenberg, Dignan and Cohen. This protection will be especially emphasized regarding protecting the confidentiality of study participants. No identifying patient information will be revealed without the study participants' written authorization.

E.5c. Reporting of Adverse Events

Although the proposed study is a behavioral, educational intervention, according to the requirements of the University of Kentucky, any adverse event (AE) will be classified by a principal investigator as serious or non-serious, and appropriate reporting procedures followed. Dr. Dignan will report any AE to the appropriate program officer at the NIH and to the UK Human Subjects Office in writing within three working days. Dr. Dignan will prepare the summary of all Adverse Events for each of the two years of the project's duration. The written SAE report will also be sent to the University of Kentucky Institutional Review Board chair:

Dr. Thomas Foster
College of Pharmacy
201a College of Pharmacy Building
University of Kentucky
Lexington, KY 40536-0082
Phone: [859] 323-5329
e-mail: foster@pop.uky.edu

E.5d. Reporting of Other Study-Safety Events

As the study is being conducted, the principal investigator will also inform the NIH promptly of any changes in recruitment or in the protocol that are relevant to safety, as well as any actions taken by the IRB as a result of its continuing (annual or more frequent) review of the study. In the event of any major changes in the status of an ongoing protocol, the PI will inform the NCI/NIA's program officer immediately. Such changes would include:

- Amendments to the protocol
- Temporary suspension of participant accrual, or of the protocol
- Any change in informed consent or IRB approval status
- Termination of participant accrual, or of the protocol
- Other problems or issues that could affect the human subjects in the study

E.5e. Data Confidentiality, Protection, and Monitoring

All activities concerning data and human subjects protection will be approved by the University of Kentucky IRB with the following requirements:

- (1) All participants must understand, agree to, and sign a consent form before participating;
- (2) Strict adherence to a participant's right to withdraw or refuse to answer questions is maintained;
- (3) The interview is completely confidential and no names will be associated with the interviews or intervention activities. In all instances, the data files do not contain the name of the participant. Instead, each participant is assigned a unique four-digit identifying number
- (4) Data will be secured. A computer file linking the unique number with the participant's name will be kept in the PI's office and stored in a locked file cabinet. All computer data will be stored in a file that is password protected to ensure confidentiality;
- (5) At no time will a person who is not study staff be permitted to review identifying data;

- (6) Consent forms and identifying information will be kept separate from the actual participant data;
- (7) All identifying information (consents, locator data, W-9s) will be kept locked at all times;
- (8) All documentation of IRB approval, original consents, human participants certification for staff, and other related study information will be filed and easily accessible to the PI; and
- (9) All key personnel and students must successfully complete the Protecting Study Volunteers in Research Certification.

Targeted/Planned Enrollment Table

Total Planned Enrollment: 418, 40 focus group, 66 key informants, 312 Patients

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino	17	3	20
Not Hispanic or Latino	338	60	398
Ethnic Category Total of All Subjects*	355	63	418
Racial Categories			
American Indian/Alaska Native	2	0	2
Asian	0	3	3
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African-American	10	3	13
White	343	57	400
Racial Categories: Total of All Subjects *	355	63	418

*The "Ethnic Category Total of All Subjects" must be equal to the "Racial Categories Total of All Subjects."

Gender/Minority/Children Composition

As a project focusing on cervical cancer, this study necessarily involves mostly women as participants. However, participants from both genders will be involved, as we intend to conduct interviews with health care providers. Appalachian Kentucky is a predominantly White population. In 1996, 96.8% of central Appalachian residents considered themselves White, 2.2% African American, and .5% Hispanic. Despite this rather ethnically homogenous population, every attempt will be made to insure the representation of minorities in this research.

Children under the age of 18 will be excluded from the project, as most guiding organizations (including the American Cancer Society, National Cancer Institute, American College of Obstetricians and Gynecologists, American Medical Association, American Academy of Family Physicians) suggest Pap testing begin around the onset of sexual activity or at approximately 18 years of age, but no later than 21 years of age.

F. VERTEBRATE ANIMALS (NA)

H. CONSORTIUM/CONTRACTUAL ARRANGEMENTS

Consortium arrangements will be developed with the Kentucky River, Lake Cumberland, and Cumberland Valley district public health departments. These consortium arrangements will be necessary for all phases of the project and will provide support for the PNs. Letters from each district health department indicating their agreement to enter into a consortium agreement with the University of Kentucky are attached.

I. CONSULTANTS/COLLABORATORS

Dr. Gil Friedell will be paid as a consultant on this project. He is the emeritus director of the Markey Cancer Center at the University of Kentucky. Although he is retired, he remains actively involved in efforts to address cancer concerns in Appalachia. He will bring an outstanding background in working with communities, public health departments, and over 50 years of experience in cancer pathology.

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