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CONTRACTING ORGANIZATION: Duke University Medical Center
Durham, NC 27710

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14. ABSTRACT The overall objective of this study is to determine factors associated with sustaining regular participation in free prostate cancer screening clinics among African American men. The expected outcome will be to define a set of intervention strategies that can be conducted at the community level by nurses in free screening clinics or programs. This study will provide understanding of the factors that influence African American men's choice to sustain participation in mass prostate cancer screening. Strategies used in this study show that African American participation can be increased. However, a challenge remains to sustain their participation in the free prostate cancer screening from one year to the next, and over several years. Tailored messages have been developed which respond to reasons men give for not returning, and also for reasons given that they seek the screening. Targeted mailed reminders can promote use of free screening clinics. Work in year 3 included continued collection of demographic data on the screening participants. In addition, conduct of prostate cancer screening information sessions was continued at area African American churches. Tailored messages were developed and used by free screening planners to facilitate enrollment of new and past year screening. Data cleaning and analysis were continued to determine the unduplicated count of study participants for each study year. In 2004 there were 508 participants. Of those 58% were African American which is an 18.5% increase over the three study years.					
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Introduction

The report starts with an overview of the study, followed by a report of Statement of Work.

This study is being conducted to determine factors associated with sustaining regular participation in free prostate cancer screening clinics among African American men. From those factors, a risk profile will be developed to determine which men are less likely to return to annual prostate cancer screening clinics. The study objectives are to (1) to identify facilitators and barriers to regular adherence to prostate cancer screening among African American men in Durham, N.C. (2) to determine barriers and facilitators that sustain screening, and (3) define strategies that will encourage consistency in participation of lower-income African American men in prostate cancer screening clinics.

Hypothesis/Rationale/Purpose: The hypothesis for this study is that profiles can be determined that will predict which men are likely to be consistent in annual prostate cancer screening, and men who are at risk not to engage in follow-up when their screening results are abnormal. Those profiles can lead to appropriate culturally sensitive strategies to encourage lower-income African American men to participate in free screening clinics. Men included in this study volunteered for free screening during years 1998–2004.

This three-year study uses quantitative and qualitative methods. The focus is on understanding how to sustain prostate cancer screening participation from one year to the next, especially among African American men. Participants in the study come from a screening database of men who volunteer for free prostate cancer screening. A participant database is maintained. From the database, sustainers and non-sustainers have been identified for years 1998–2004 (non-sustainers are men who previously participated in either of the two free prostate cancer screening, but who did not return in the subsequent year). A focus of the study is to increase study participation of low-income minority men. This group of participants is being targeted through recruitment of subjects from health centers that tend to serve more low-income patients.

In study year 1, focus was on study initiation, assessment of attitudes towards screening among community leaders, accruing of screening participants, and data management.

In study year 2, nonsustainers were mailed questionnaires to determine facilitators and barriers to free screening participation, and management and analysis of the data. In addition, information sessions on prostate cancer were conducted at area African American churches.

This year, study year 3, areas of concentration included:

- Evaluating free screening participation;
- Developing tailored message based on facilitators and barriers to return participation;

- Continuing to identify church groups to present information sessions on prostate cancer screening and detection;
- Data management; and
- PI mentoring and professional development

Body

Year 3 Statement of Work

Task 3 - Months 4-6

Information sessions were offered to church groups on prostate cancer screening and early detection. Pastors who participated in a focus group in Year 1 continue to be contacted, and we continue to follow-up on leads to other community church pastors, and faith based organizations on a continual basis during Year 3. The desired task was to meet with men in two African American churches to offer information sessions about prostate cancer screening and early detection. Three sessions were scheduled and conducted. One church session and two community sessions occurred out of church contacts that had been made. There were a total of 30 male participants. Information about the disease was presented, along with screening and detection guidelines. Discussion was frank and open among participants to reach personal clarity about the disease, and address barriers to regular screening. Participants were invited to the next free prostate cancer screening clinics.

Task 4

A total of 236 nonsustainers were identified. Approximately 56% were African American, and 38% were White. The study Nonsustainers Surveys are in preparation for mailing. The mailer will include an announcement about upcoming screening dates and times. Follow up postcards to screening sustainers will be mailed 4 weeks in advance of the scheduled free clinics. Future analyses will determine if significant differences exists between ethnic groups and study years 2003 and 2004.

Task 5

A longitudinal database of the total population of men ever screened was updated and data cleaning is being continued.

Task 6

Interim statistical analyses were continued and annual reports for the Department of Defense and University Institutional Review Board were compiled. Data analysis will continue.

Task 7

The research team continues to identify strategies to address barriers and facilitators to sustain clinic participation. Currently four strategies have been identified:

- Consistent marketing of the screening clinics in community newspapers, 500 Durham churches, and area ethnic radio stations. The free screening clinic has been scheduled on a consistent weekend and consistent time over the three years of the study (third weekend of September).

- Notification to screening participants from two previous consecutive years to announce the screening dates and invite their continued participation.
- To increase participation by men who are uninsured or low-income in each of the study years, the nurse supervisor at Lincoln Community Health Center mailed letters to 1,000 non-white men 40 years and older. These were clinic patients who had not been formally informed or invited to the screening in previous years. Lincoln is a comprehensive health center located in a Durham low-income inner city neighborhood. Tailored messages were developed by staff to be used in marketing the free screening clinics.
- These positive messages were provided to nurses and others who organize the free screening clinics to include in announcements about the screening opportunity. These messages were based upon reasons most frequently cited as facilitators and barriers to clinic participation. This data was obtained from surveys that were administered to nonsustainers and sustainers in study year 2. The tailored messages were:
 - It (*screening*) gives me peace of mind, to protect my health
 - The doctors are urology specialists
 - It's convenient and on a weekend
 - I'm doing the right thing
 - It's free
 - If I had signs – I'd like to know early
 - I am in control of what happens to my health
 - I know I need to get it done every year
 - I want to have both the blood test and prostate exam
 - At my age I should get screening

Task 8

An amendment/modification to the contract was requested and granted for one year to further data analysis, along with report and manuscript writing.

Conclusions

In 2004 there were 508 participants. Of those 58% were African American, and 32% White. Ten percent comprised other ethnic groups. The number of African American men who present for free screening continues to increase. In 2002, 246 men participated. In 2004, 292 men participated. This is an 18.5% increase over the three study years. In 2004, 66% of new participants were African American while 15% were White. The most important finding from this past study year is that sustained participation for African American men was surprisingly low with 56% not returning (men who came in 2003 and failed to return in 2004). While overall participation increased among African Americans, many of the 2004 participants were new. We found that there were nonsustainers who returned for screening in 2004 after one or more years absence. We moved them to the sustainer category.

The ages of the participants who attended study year 3 free screening included 96% over age 40. Seventy eight percent of men were over age 50. Among participants 50 and over; 57% were African American and 38% were White. This indicates that overall we are reaching the age group that has been stressed to target among health care organizations.

Unexpected Difficulties Encountered:

Continued difficulties have been encountered with church recruitment to conduct education sessions. Pastors continue to state an interest but consistently state that they have to check the church activity calendars. Upon call backs, they continue to fail to follow through. Continual effort is being made to reach other area church and faith based organizations, and advertising is being conducted on the availability of the sessions to parishioners in study year 3.

Determining an accurate unduplicated screening participant list from one year to the next has been a challenge. There are no official medical record entries maintained for participants in the free screening clinics. Therefore, a medical record number can not be assigned. It has been discovered by study personnel that participants sometimes use different names in multiple years. For example:

1. Participants may have used their first name on one visit and their middle name on another.
2. Participants sometimes using a first initial and middle name.
3. Participants using "Jr" or "Sr" sometimes but not every time.
4. Sometimes participants reversed their first and last name when completing the registration materials.
5. Sometimes a middle initial was used and sometimes it wasn't.
6. Mistakes occurred in participants' recording their birth year. We do not know if this was intentional in some instances.
7. There are participants who have the same names.
8. Returning participants may have a change of address coupled with variations in how they list their name on registration materials.

Continual effort is being made to achieve accuracy. We do not have a method to identify participants who die during the study period. In some cases, spouses notified us of the death of a husband when the questionnaire was received. When a death is known, it is indicated in the database and no further information will be mailed to that address. Managers of the free screening clinics conduct the clinics in a unique manner. Appointments are not made; participants show up in mass with approximately half arriving in the first hour of the clinic opening. This creates a long waiting time which could discourage some participants.

Training Activities:

The PI continues to meet with mentors (Cary Robertson, MD, and Paul Godley, MD) on a regular basis to discuss study progress and review newly published articles about prostate cancer. For professional development, the PI continues to seek out prostate cancer and related seminar activities at the University of North Carolina and Duke University Medical Center, in addition to searching for opportunities at the National Institutes of Health.

Research Administrative Activities:

PI holds regular meetings with the biostatistician and student research assistant to discuss study progress, data entry, data analyses, and project issues.

Key Research Accomplishments:

- Preliminary analyses show that community-based recruitment efforts to promote participation in mass prostate cancer screening programs tends to increase overall clinic attendance by African American men from one year to the next. However, sustained participation by the same men from one year to the next is a continual challenge.
- Tailored messages used in marketing free prostate clinics are instrumental in maintaining approximately half of the previous year's attendees. We are able to determine that a majority of participants who fail to return in a subsequent year are similar to those who return in that their chief reason for ever attending was cited as "I believe that at my age I should get the digital rectal examination and PSA blood test done every year"; and "Getting screened gives me peace of mind".
- Maintaining a longitudinal database provides systematic evaluation of attendance in a community-based free screening program.
- Screening clinic promotion is consistent with the age-related criteria for prostate cancer screening set by national health care agencies in that the majority of participants are over 50 years of age.

Reportable Outcomes:

Abstracts/Presentations

Price, M.M., Jackson, S.A., & Robertson, C.N. (2004, November). "Utility of Longitudinal Prostate Specific Antigen Measures in a Screening Population", 132nd Annual Convention of the American Public Health Association, Washington, D.C. p. 37.

Abstract is included in Appendix A.

Price, M.M. (2004, June). "Prostate Health", Presentation in Honor of Our Men, Alpha Kappa Alpha Sorority, Durham, NC. No abstract.

Price, M.M. (2004, October). "Prostate Health", Presentation for Mt. Zoar Baptist Church, Durham, NC. *No abstract.*

Price, M.M. (2005, March). "Prostate Health", Presentation for Men's Health Group, Lincoln Community Health Center, Durham, NC. *No abstract.*

Conclusions:

Strategies used in this study show that African American participation can be increased. However, a challenge remains to sustain their participation in the free prostate cancer screening from one year to the next, and over several years. Recruitment efforts in this study continue to be in the age-related screening range that is supported by national health care organizations, with the majority of participants falling primarily in their 50's and the next larger group in their 40's. Tailored messages have been developed which respond to reasons men give for not returning, and also for reasons given that they seek the screening. Targeted mailed reminders can promote use of free screening clinics. Preliminary results indicated that direct mail marketing to male patients by free clinic organizers at an inner city low income clinic, and by the university free prostate clinic organizers appears to be effective. Over half of participants indicated that they heard about the screening by a postcard or letter that they received in the mail.

So What

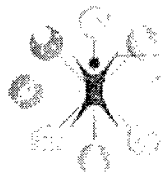
Sustaining participation is a major challenge. We can get men to screening, but maintaining consistent screening practices from one year to the next is not easy. However, this work is very important as there is no previous literature that has examined how to sustain screening participation in mass community screening drives. We will work with local free screening organizers to compare screening participation in September 2005, particularly among African American men, to determine how well clinic marketing strategies, including tailored messages, sustains continued clinic participation over several years.

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Appendices

- A. Meeting Abstract (American Public Health Association)
- B. PI Curriculum Vitae
- C. Prostate Health Surveys
- D. Study Personnel
- E. PI Contact Information
- F. Duke University Medical Center IRB Report, May 2005
- G. Consent Form



PUBLIC HEALTH
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Longitudinal variation in prostate-specific antigen levels in a screening population

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Research has identified elevated prostate-specific antigen (PSA) levels and rates of change in PSA levels between consecutive visits as early clinical markers for prostate cancer development. Data for this study comes from a nurse-run free annual community-based prostate cancer screening program. This is the first known study evaluating rate of change in PSA measures in a community-based screening population. Participant PSA levels were observed from 1998-2003. Descriptive analyses were performed in SAS v8. Longitudinal data was collected on 1,565 predominately African-American and White volunteer screening participants. Forty-seven percent was black; forty-six percent was white. Thirty-nine percent attended at least two annual screening visits. Eleven percent had PSA levels above the cutoff for a normal PSA. Of those with abnormal PSA's 38% of African-Americans were in their 60's, while 44% of whites were in their 70's at baseline. There were 57 men with a rate of change in PSA levels between two consecutive visits greater than the suggested cutpoint of one. Eighteen participants had a running average of rate of change over three consecutive annual visits beyond the cutpoint of 0.75. Forty percent of these were between 60 and 69 at their initial visit. Sixty-one percent was white and 39% was African-American. This analysis provides methods to examine the significance of PSA findings in an assumed well population. Further, this study provides evidence for careful monitoring at normal range and sequential PSA levels. Findings from this study could lead to guidance in best practices for community-based annual prostate cancer screening programs.

Learning Objectives:

- Assess serial prostate-specific antigen (PSA) levels in an assumed well community-based population.
- Evaluate various methods of PSA testing in this volunteer population.
- Identify similarities and differences between African-American and White participants of an annual cancer screening program.

Keywords: Cancer Screening

APPENDIX. B.

DUKE UNIVERSITY MEDICAL CENTER
CURRICULUM VITAE
for
Permanent Record
and the
Appointments and Promotions Committee

Name (complete with degrees): Marva L. Mizell Price, DrPH, MPH, FNP, FAAN
 Primary academic appointment: School of Nursing
 Social Security number: xxx-xx-2343
 Present academic rank and title (if any): Assistant Professor

Nursing Licensure: North Carolina Registered Nurse
 Date of License (Month/Day/Year): August 1972 - November 30, 2005

Specialty certification(s) and dates (Month/Day/Year):
 American Nurses Credentialing Center (ANCC): Family Nurse Practitioner, Issued 1982; recertified March 2002 – April 2007.

North Carolina Medical Board of Nursing: Family Nurse Practitioner, Initial Approval 11/ 1974; Reapproved 11/25/03 – 11/25/2005.

Date of birth: 11-25 Place: Columbia, N.C. USA Citizen: USA

Visa status (if applicable): N/A

<u>Education</u>	<u>Institution</u>	<u>Date (Year)</u>	<u>Degree</u>
College	School of Nursing N.C. Agricultural & Technical State University Greensboro, NC	1972	B.S.N.
Graduate or Professional School	School of Public Health, Department of Maternal and Child Health, University of North Carolina, Chapel Hill, NC	1974	Master of Public Health (M.P.H.) in Maternal Child Health
	School of Nursing University of North Carolina, Chapel Hill, NC	1974	Family Nurse Practitioner
	School of Nursing University of Washington, Seattle, Child Development and Mental Retardation Center	1979	Post-Masters in Developmental Pediatrics
	School of Public Health, Department of Maternal and Child Health and Program in Public Health Leadership, University of North Carolina, Chapel Hill, NC	1997	Doctor of Public Health (Dr.P.H.) in Maternal and Child Health and Public Health Leadership

Scholarly societies:

1973-present	Invited, Delta Omega Honor Society in Public Health
1974- present	Invited and Inducted, Sigma Theta Tau, Alpha Alpha Chapter, International Honor Society in Nursing; Junior and Senior Counselor, 1978-1980
1996- present	Inducted, Charter Member, Sigma Theta Tau, Mu Tau Chapter, International Honor Society in Nursing
2002- present	Invited and Inducted, Fellow, American Academy of Nursing

Professional training and academic career:

<u>Institution</u>	<u>Position/Title</u>	<u>Date</u>
Post-Baccalaureate:		
Annie Penn Memorial Hospital Reidsville, NC :	Registered Nurse Rotated on all services in a 120 bed community hospital (Medical/surgical, ER, Delivery Room, Pediatrics, Recovery Room)	1972-1974
Post-Master's		
University of North Carolina, School of Public Health, Department of Public Health Nursing for Orange Chatham Comprehensive Health Services, Chapel Hill, NC	Family Nurse Practitioner	1974
University of North Carolina Employees Health Services, Chapel Hill, NC	Family Nurse Practitioner	1974-1976
University of North Carolina, Chapel Hill, NC Division for Disorders of Development and Learning (currently Center for Development and Learning)	Family Nurse Practitioner	1976-1982
State of North Carolina Department of Health and Human Services, Winston Salem & Raleigh, NC	Family Nurse Practitioner and Nursing Consultant, Family Planning and Women's Health, Division of Maternal Child Health	1982-1991
Duke University Medical Center, Durham, NC Department of Obstetrics and Gynecology, Division of GYN Oncology	Family Nurse Practitioner and Program Coordinator, Women's Cancer Screening Program & Cervical Dysplasia Private Clinic	1991-1994
Chatham County Health Department Pittsboro, NC	Interim Health Director Chief Executive Officer	1992
Kaiser Permanente Durham-Chapel Hill Office, NC	Family Nurse Practitioner	1994
Randolph County Health Department, Family Planning Clinic, Asheboro, NC	Family Nurse Practitioner	1996
Post-Doctorate:	Clinical Assistant Professor	1996-2001
Duke University School of Nursing, Durham Family Nurse Practitioner Program Program Director, Family Nurse Practitioner Program	Assistant Professor	May 2002-present

Publications:

1. Refereed journals:

1. **Price, M.M.** (1980). Critique of the Milani-Comparetti Motor Development Screening Test. Physical And Occupational Therapy In Pediatrics, 1 (1), 59-68.
2. **Smith, E.M., Phillips, J.M., & Price, M.M.** (2001). Screening and early detection among ethnic minority women. Seminars in Oncology Nursing, 17 (3), 159-170.
3. **Van Buren, K.G. & Price, M.M.** (2002). Recognizing Obstructive Sleep Apnea in Children. The American Journal for Nurse Practitioners, 6(7), 9-17.
4. **Brown, S.M. & Price, M.M.** (2003). Man with swollen lips and tongue. Clinician Reviews, 13 (4): 81-86. (*article on Ace-Inhibitors for Hypertension*)
5. National Organization of Nurse Practitioner Faculty (NONPF) Practice Doctorate Task Force: Marion, L., Viens, D., O'Sullivan, A.L., Crabtree, K., Fontana, S. **Price, M.** (2003). The Practice Doctorate in Nursing: Future or Fringe? NONPF Practice Doctorate Task Force. Topics in Advanced Practice Nursing eJournal 3 (2), 2003. © 2003 Medscape.
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3. **Price, M.M.** (1985, April 7; 1980, October 5). Thumb, finger sucking common behavior in caring for kids, Chapel Hill Newspaper.
4. **Price, M.M.** (1986). Nurse practitioners are also caught in national malpractice insurance crunch, Contraceptive Technology Update, American Health Consultants: Atlanta, 7 (11), 138-139.
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6. **Price, M.M.** (1987). Nurse practitioner has complex role in managing high-cholesterol patients, Contraceptive Technology Update, American Health Consultants: Atlanta, 8 (4), 49-50.
7. **Price, M.M.** (1987). Help long-term OC users manage healthy, gradual return to fertility, Contraceptive Technology Update, American Health Consultants: Atlanta, 8 (6), 82-83.
8. **Price, M.M.** (1987). Try varied approaches to encourage our OC patients to stop smoking, Contraceptive Technology Update, American Health Consultants: Atlanta, 8 (8), 101-103.
9. **Price, M.M.** (1987). North Carolina's NFP initiative is effective and well received, Contraceptive Technology Update, American Health Consultants: Atlanta, 8 (10), 133-134.
10. **Price, M.M.** (1987). Physically, mentally disabled teens require special contraceptive care, Contraceptive Technology Update, American Health Consultants: Atlanta, 8 (12), 154-156.
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11. **Price, M.M. & Price, L.N.** (2002). Concerns of white and merica merican consumers about colon cancer screening. In M. Kowalski (Ed.). Transcultural Nursing Special Interest Newsletter – Oncology Nursing Society, 12 (1), 1-3.
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3. Chapters in books:

1. **Price, M.M.** (1980). Special Populations Sexual Abuse of the Developmentally Disabled. In D. Kay, Leadership Training Workshops. Bethesda: National Institute of Mental Health, National Center for Prevention and Control of Rape. Training Grant No. T31MH15664.
2. **Price, M.M.** (1985). Nursing Care of the Child With A Mental Deficiency. In S.R. Mott, N.S. Fazekas, & S.R. James, (Eds.), Nursing Care of Children and Families, pp. 755-783, Menlo Park, CA: Addison-Wesley Publishing Co.
3. **Phillips, J. Price, M.M.** (2002). "Breast Cancer Prevention and Detection: Past Progress and Future Directions". In K. Jennings-Dozier & S. Mahon, S. (Eds.), Cancer Prevention, Detection and Control: A Nursing Perspective. Pittsburgh, PA. Oncology Nursing Press.

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4. **Books:** N/A
5. **Non-authored publications (contributions noted in author's acknowledgements):**
 - Public Sector NFP Program, (1988). The NFP Reader, 5 (1), Bethesda: KM Associates.
 - 1.
 - 2. Nurses, physicians prefer different postpartum prescriptions practices, Contraceptive Technology Update, (1986). American Health Consultants: Atlanta. 7 (9)
 - 3. Self-Exams Key to Detecting Cancer In Men, Duke Center for Integrative Medicine, The Herald Sun, August 7, 2003, Cancer Seminars to Open Today, The Herald Sun, January 30, 2004.
6. **Other Materials:**
 - a. **Published scientific reviews (for mass distribution):**
 - Book Reviews:**
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 1. **Price, M.M.** (1986, May). "Nurse Practitioner Prescribing Practices", Paper presented at the Annual Conference on Women's Health for Nurse Practitioners, Emory University, Atlanta
 2. **Price, M.M.** (1988, May). "Helping Family Planning Patients Stop Smoking", Paper presented at the Annual Conference on Women's Health for Nurse Practitioners, Emory University, Atlanta
 3. **Price, M.M.** (1989, May). "Is There an Ideal Contraceptive for the Breastfeeding Woman?" Paper presented at the Annual Perinatal Nursing Conference, Duke University Medical Center, Durham, NC
 4. **Price, M.M.** (1993, February). "Cancer Prevention and Early Detection – Changing Lifestyles in Vulnerable Populations", Paper presented at the Health Promotion Disease Prevention Nursing Conference, Friday Conference Center, University of North Carolina School of Nursing, Chapel Hill
 5. **Price, M.M.** (1994, April). "Cancers That Worry Women the Most and Screening Dilemmas", Paper presented at the Annual Spring Symposium for Primary Care Nurse Practitioners, Charlotte.
 6. **Price, M.M.** (1994, October). "Developing and Using Computer Generated Slides for Oral

Presentations", Paper presented at the Dissemination Workshop during the Oncology Nurses Symposium on Cancer in African Americans, Atlanta.

7. **Price, M.M.** (1994, October 28-30). "Living with Genital Herpes: Counseling the Patient", Paper presented and Seminar Moderator for the Burroughs Wellcome Pharmaceutical Corporation Nursing Conference on Genital Herpes, Research Triangle Park, NC.
8. **Price, M.M.** (1995, April, Miami; 1995, March, Washington, DC; & 1995, February, Philadelphia). "Breast Health", Papers presented at the National Black Nurses Association Regional Conferences.
9. **Price, M.M.** (1995, August). "Gynecologic Cancers-Cervical Cancer", Paper presented at the National Black Nurses Association National Conference, Washington, DC.
10. **Price, M.M.** (1996, August). "Cervical Cancer", Paper presented at the Oncology Nursing Society Post-Conference Seminar at the Annual Meeting of the National Black Nurses Association, Chicago.
11. **Price, M.M.** (1997, May). "What Your Mother Needs to Know about Breast Health, Paper presented at the 9th Annual National Black Graduate Student Conference, Research Triangle Park, NC.
12. **Price, M.M.** (1997, August). "Cervical Cancer", Paper presented at the North Carolina Baptist Ushers Conference on Cancer Prevention, UNC Lineberger Comprehensive Cancer Center and the UNC School of Public Health Summer Public Health Conference, Raleigh, NC.
13. **Price, M.M.** (1997, August). "Intergenerational Influences on Cervical Cancer Screening", Poster Session presented at the Women's Health Issues - A Global Nursing Perspective, University of Cincinnati, St. Thomas, Virgin Islands.
14. **Price, M.M.** (1997). Generational Influences on Cervical Cancer screening and the capacity of the public health system to assure responsive Services. Dissertation Abstracts International, University of North Carolina, Chapel Hill. Microfiche No. W4.P9462. 1997.
15. **Price, M.M.** (1998, August). "Intergenerational Influences on Cervical Cancer Screening", Paper presented at the 11th Union of International Cancer Congress, Rio de Janeiro, Brazil.
16. **Price, M.M.** (1999, April). Enhancing nurse educators' knowledge base to teach their students cancer prevention and early detection in America; and Using the Albert Schweitzer fellowship program to foster cross-cultural experiences for nurse practitioner students. Symposium conducted at the annual meeting of the National Organization of Nurse Practitioner Faculties (NONPF), San Francisco.
17. **Price, M.M.** (1999, November). "African American Women's Concerns about Cervical Cancer Screening", Paper presented at the American Public Health Association Annual Convention, Chicago.
18. **Price, M.M.** (2000, February). "African American Women's Concerns about Cervical Cancer Screening", Paper presented at the 7th Biennial Symposium on Minorities, The Medically Underserved & Cancer, Washington, DC.
19. **Price, M.M.** (2000, March). "African American Women's Concerns About Cervical Cancer Screening", Paper presented at the Howard University School of Nursing Research Day, Washington, DC.
20. **Price, M.M.** (2000, April). "Creating a Faculty Research Opportunity with a Community Prostate Cancer Screening Program", Paper presented at the National Organization of Nurse

Practitioner Faculties (NONPF) 26th Annual Conference, Washington, DC.

21. **Price, M.M.** (2000, August 3; July 30). "Follow-up of Men Who Participate in a Free Community Day Prostate Cancer Screening Clinic", Poster Session presented at the 11th International Conference on Cancer Nursing-Building The Future, Oslo, Norway.
22. **Price, M.M.** (2000, August). "Follow-up of Men who Participate in a Free Community Day Prostate Cancer Screening Clinic" and Generational Influences on Cervical Cancer Screening", Papers presented at the National Black Nurses Convention, Washington, DC
23. **Price, M.M.** (2000, September). "Gynecologic Cancers", Paper presented at the National Astra Zeneca Challenge Conference for Oncology Nurses, Atlanta.
24. **Price, M.M.** (2000, November). "Free Community Prostate Cancer Screening: Who Attends and Why?", Paper presented at the American Public Health Association Annual Convention, Boston.
25. **Price, M.M.** (2001, February 16). "Free Community Prostate Cancer Screening: Who Attends and Why?" Poster Session presented at the Annual School of Public Health Minority Health Conference, University of North Carolina, Chapel Hill.
26. **Price, M.M.** (2001, September). "Free Community Prostate Cancer Screening: Who Attends and Why", Paper presented at the Biennial Conference of the Center for Disease Control and Prevention (CDC), Using Science to Build Comprehensive Cancer Programs: A 2001 Odyssey, Atlanta.
27. **Price, M.M.** (2001, October). "Lessons Learned From 58 African American Men About Prostate Cancer Screening", Paper presented at the American Public Health Association Annual Convention, Atlanta.
28. **Price, M.M.** (2002, June). "Free Community Prostate Cancer Screening in A Small Urban Community". Poster presented at the 18th Union of International Cancer Congress, Oslo, Norway.
29. **Price, M.M.** (2002, August). "Prostate Cancer Screening – Who Attends and Why". Podium presentation at the 12th International Conference on Cancer Nursing 2002: Making A Difference, London.
30. **Price, M.M. & Robertson, C.N.** (2002, September). "Increasing Sustained Participation in Free Mass Prostate Cancer Screening Clinics". Poster presentation at the Ninth Annual CapCure Scientific Retreat Program, Washington, D.C.
31. **Price, M.M., Powe, B.D., & Underwood, S.M.** (2003, March). Symposium 22 "From Research to Practice to Policy: Designing Research-Based Interventions Focused on Cancer Prevention and Control Among African-Americans". 24th Annual Meeting and Scientific Sessions for the Society of Behavioral Medicine, Salt Lake City, Utah.
32. **Price, M.M.** (2003, October). "Increasing Sustained Participation in Free Mass Prostate Cancer Screening Clinics in Durham, North Carolina" Sixth Annual Sigma Theta Tau Research Day Conference: Health Disparities in Underserved Minority Populations from a Global Perspective. North Carolina A&T State University School of Nursing, Greensboro, N.C. p.13.
33. **Price, M.M.** (2003, October). "International Cancer Care Nurses Attitudes about Cervical Cancer Screening" Sixth Annual Sigma Theta Tau Research Day Conference: Health Disparities in Underserved Minority Populations from a Global Perspective. North Carolina

A&T State University School of Nursing, Greensboro, N.C. p.24.

34. **Price, M.M., & Combs, I.** (2003, November 7-9). "How to Use Innovative Health Education and Screening Programs to Promote Health in the African American Community: Durham, North Carolina and Omaha, Nebraska". Symposium conducted at the 4th Annual Institutes of Learning Conference. Oncology Nursing Society, Philadelphia, P.A. p. 27-31.
35. **Price, M.M., Jackson, S.A., & Robertson, C.N.** (2004, March). "Utility of Longitudinal Prostate Specific Antigen Measures in a Screening Population", Intercultural Cancer Council and Baylor College of Medicine: 9th Biennial Symposium on Minorities, The Medically Underserved & Cancer, Washington, D.C. p. 37. Abstracted accepted November 2003.
36. **Price, M.M.** (August 2004). "International Cancer Care Nurses Attitudes About Cervical Cancer Screening". Podium presentation at the 13th International Conference on Cancer Nursing 2004: Celebrating Diversity, Sidney, Australia.
37. **Price, M.M., Jackson, S.A., & Robertson, C.N.** (2004, November). "Utility of Longitudinal Prostate Specific Antigen Measures in a Screening Population", 132nd Annual Convention of the American Public Health Association, Washington, D.C. p. 37.
38. **Price, M.M.** (2004, June). "Prostate Health", Presentation in Honor of Our Men, Alpha Kappa Alpha Sorority, Durham, NC
39. **Price, M.M.** (2004, October). "Prostate Health", Presentation for Mt. Zoar Baptist Church, Durham, NC
40. **Price, M.M.** (2005, March). "Prostate Health", Presentation for Men's Health Group, Lincoln Community Health Center, Durham, NC

Organizations and participation (regional and local):

Dates	Office held and/or Committee Assignment	Organization
2002	<u>International:</u> Member	Union of International Cancer Congress Nursing Committee, Geneva, Switzerland. Congress, Oslo, Norway
2002-2004	Member	International Society of Nurses in Cancer Care (ISNCC)
1974-present	<u>National:</u> Member	American Public Health Association
1974-present	Member	American Nurses Association
1978-2004	Member	National Black Nurses Association (local chapter: Central Carolina Black Nurses Association)
1998-2004 Invited	Member	American Social Health Association, RTP, NC, National Cervical Cancer and Human Papilloma Virus Project
1995-present	Scientific Advisory Board Member Member	Oncology Nursing Society
January-August 2000; Invited	10 member committee from across the U.S. charged with planning a community outreach course on cancer screening and detection for 300 oncology nurses	ONS National Challenge Conference, Conference held in Atlanta, September 14-17, 2000
January – April 2002	Committee Member for participant follow up and to plan a reunion luncheon and poster session	Invitational for Best 100 Oncology Nurse Community Outreach Cancer Prevention and Early Detection Programs, held in Washington,

Dates	Office held and/or Committee Assignment	Organization
1997-2004 2003-2005	Member; Member, Clinical Doctorate Task Force, National Organization of Nurse Practitioner Faculties (NONPF)	D.C., April 20, 2002 National Association of Nurse Practitioner Faculties (NONPF).
March 2005 Invited 1994; serving 4 th term; Gubernatorial appointment	Member, National African American Advisory Council <u>State:</u> Member, the Public Health Commission writes the rules for all legislation passed by the North Carolina General Assembly including environmental and personal health legislation, immunization laws, restaurant and lodging grading standards, childcare facility, food establishment grading standards, HIV, smallpox, other communicable disease control.	The Susan G. Komen Breast Cancer Foundation Governor's 12 member Commission for Health Service (Public Health Commission), Raleigh. Quarterly meetings.
1995-1997; Invited	Chair, Evaluation and improvement of cancer screening services (clinical, laboratory, and radiological) for women in private and public sector clinics	North Carolina Health and Human Services, Department of Health, Breast and Cervical Cancer Assurance Committee
2000-present; Invited	Member, Board of Advisors and Fellowship selection subcommittee. The Foundation provides paid fellowships for community service learning projects conducted by medical, dental, nursing, veterinarian, and law graduate and professional students across North Carolina universities with major medical centers.	The Albert Schweitzer Foundation; fellow interview and selection annually in March; fellowship mentorship, and guidance in seminar development
2001-2002; Invited 1975-present 1985-1987 2001-2003	Member Member; Secretary for Triangle Region; Commission on Standards and Practice	Old North State Medical Society, Raleigh- Durham Chapter North Carolina Nurses Association (formerly District Eleven)
January 2000	Participant, North Carolina Nurses Association Leadership Day	North Carolina Nurses Association
January 2000- 2001 2001-2003 February 2003; Invited	Participant, Awards Selection Committee for Outstanding Nursing Leadership and Service Commission on Standards and Practice Member, Advisory Board	North Carolina Nurses Association North Carolina Nurses Association University of North Carolina School of Public Health, Department of Maternal and Child Health, participated in review of candidates for department chair; annual board meetings Piedmont Health Care, Inc. Federally funded primary care centers in three rural North Carolina counties Chatham County Board of Health
1986-1987	<u>Local:</u> Member, Board of Directors	
1993-1994 1989-2000 2001-2004, term expired	Chair; Board Member Member	Copernicus Group Independent (International) Review Board, Inc. Cary, NC
2001-2004, County Commissioners	Member, official certifier for Board proceedings	Orange-Chatham-Person Developmental Disabilities and Mental Health Authority (Mental Health Board), monthly meetings

Dates
Appointment
2nd term expired
2004
Invited 2004

Office held and/or Committee Assignment

Board Member and
Health Committee

Organization

Carolina Meadows Retirement Community, a
700 resident continuing care retirement
community, meetings four times a year

External Support Grant funding:
PI

**%
Effort**

Purpose

Amount

Duration

PRESENT

Principal Investigator, U.S. Army Department of
Defense

25%

Partnering Research Involving
Mentoring and Education (PRIME)
in Prostate Cancer
Training Grant with North
Carolina Central University to
provide beginning prostate cancer
education to 12 sophomore nursing
students over three years.

\$199,000

Awarded
January
2005
Funding
cycle
2005-2008

Principal Investigator, U.S. Army Department of
Defense (Co-PI Mentor: Cary Robertson,
M.D., DUMC)

47%

Prostate Cancer Screening, Health
Disparity Research-Prostate
Scholar Award: Increasing
Sustained Participation in Free
Mass Prostate Cancer Screening
Clinics
Mentor:
Cary Robertson, M.D.

\$406,421.00

Funding
cycle June
2002- 2006

Scientific Mentor: Paul Godley,
M.D., Ph.D., Surgical Oncologist,

Attend monthly seminars in
Methods in Health Disparity
Research, cosponsored by the
Cecil Sheps Center, UNC School
of Public Health; and Lineberger
Comp. Cancer Center.

PI, Cervical Cancer Screening, International
Nurses Survey

Attitudes and Practices for
Cervical Cancer Screening Among
International Nurses in Cancer
Care.
Surveys conducted at the UICC
Congress, Oslo, Norway, June-July
2002 & the International Nurses in
Cancer Care, London, August-
September 2002

\$500
District
Eleven, North
Carolina
Nurses
Association

June 2002-
June 2003

PI, Department of Defense

30%

Using a Tracking System to
Improve Prostate Cancer Screening
Follow-up in a Small Urban

\$74,984

2000-2001

PI, Avon-NABCO, Inc

25%

Breast Cancer Access Grant for
Nurse Practitioners in Nine-County
Area in Southeastern North

\$75,000
(\$5,000 match
by Carson

October
1997-98

		Carolina	Products, Savannah)	
PI, (Pre-doctoral Fellow), NCI sponsored Cancer Control Education Research Program (CCEP) University of North Carolina Lineberger Comprehensive Cancer Center, Training Grant -CA64060	45%	Intergenerational Influences on Cervical Cancer Screening Dissertation Research	\$20,000 \$20,000	1995-1996 Renewed 1996-97
PI, Association of School of Public Health and The Association of Teachers of Preventive Medicine, National Center for Infectious Disease, Division of HIV/AIDS, Surveillance Branch CDC, Atlanta		Protocol Development for Resource Assessment of HIV+ pregnant women's access and use of AZT and other social and medical resources	\$23,000	1994-1995

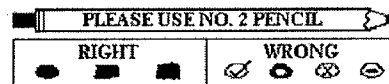
**Prostate Health Survey 2004
Duke University School of Nursing**

You have been selected to receive this survey because you attended at least one free prostate cancer screening clinic at Duke University Medical Center or Lincoln Health Center in 2003. Please return the survey by (date) in the stamped addressed envelope. Thank you,

Marva Price, RN, DrPH, Assistant Professor
Duke University School of Nursing
Box 3322
Durham, N.C. 27710

Phone: 919-684-3786 ext. 245

Please darken in the best response in each section with a No. 2 pencil. You do NOT need to write your name on the survey.



1 Year of Birth

19

- ☐ 1990
- ☐ 1991
- ☐ 1992
- ☐ 1993
- ☐ 1994
- ☐ 1995
- ☐ 1996
- ☐ 1997
- ☐ 1998
- ☐ 1999
- ☐ 2000
- ☐ 2001
- ☐ 2002
- ☐ 2003
- ☐ 2004

2 What is your race?

- ☐ Black (African American)
- ☐ White (Caucasian)
- ☐ Hispanic (Latino)
- ☐ Asian
- ☐ American Indian
- ☐ Other (please specify) _____

3 What is your highest level of education?

- ☐ Grade school
- ☐ Some high school
- ☐ High School graduate
- ☐ Some technical school
- ☐ Technical school graduate
- ☐ Some 4 year college
- ☐ 4 year college graduate
- ☐ Some graduate school
- ☐ Graduate School or Professional School

4 Are you currently...?

- ☐ Retired
- ☐ Disabled
- ☐ Unemployed
- ☐ Still working

5 Do you have a family doctor?

- ☐ Yes
- ☐ No

6 When was the last time you went to see a doctor for anything about your health?

- ☐ This year (2004)
- ☐ Last year (2003)
- ☐ Longer than a year ago
- ☐ Probably more than 2 years ago

7 Have you ever had somebody kin to you with prostate cancer?

- ☐ Yes
- ☐ No

8 I had my prostate screened last year by my doctor or healthcare provider

- ☐ Yes
- ☐ No

Select the MOST IMPORTANT REASONS that STOPPED OR PREVENTED you from returning for free prostate cancer screening

- ☐ I usually see my regular doctor each year for my prostate cancer screening digital rectal examination and PSA blood test
- ☐ I did NOT know that I was at the age for prostate cancer screening every year
- ☐ I thought the digital rectal examination was too embarrassing to have done
- ☐ The time of the free prostate cancer screening clinic was not convenient
- ☐ I was afraid or scared of what a prostate check up might find
- ☐ I was afraid of impotence (inability to have sex) if a problem were discovered and treatment needed
- ☐ I thought that if the doctor found prostate cancer that treatment WOULD NOT help
- ☐ I did not know that I needed to get the digital rectal exam and PSA blood test done every year
- ☐ Thinking about getting the digital rectal exam and PSA blood test caused me to be nervous or worried
- ☐ I believe its God's Will if I get prostate cancer
- ☐ I DO NOT think that the PSA blood test or the rectal exam are accurate or dependable
- ☐ I thought the digital rectal examination hurt too much to have it done
- ☐ I was found to have prostate cancer

Please Turn Page Over

pro2004b.fsf

Prostate Health Survey 2003

PLEASE USE NO. 2 PENCIL

RIGHT

WRONG

MOST IMPORTANT REASONS that have STOPPED OR PREVENTED (continued)

- ☐ I was worried or scared that a prostate cancer exam and blood test might NOT be normal
- ☐ I thought that if the doctor found prostate cancer that treatment could cause more problem than NOT treating

Other significant reason that stopped you from getting free prostate cancer screening (write in)

Now, write in the #1 reason that kept you away from free prostate cancer screening

Select the MOST IMPORTANT REASONS that CAUSED YOU TO GO for free prostate cancer screening

- ☐ I believe that at my age I should get the digital rectal examination and PSA blood test done each year
- ☐ The time of the free prostate cancer screening clinic is convenient (weekend)
- ☐ I believe in protecting my health
- ☐ My doctor encouraged me to be screened for prostate cancer
- ☐ If I had signs of prostate cancer I wanted to find out so that treatment decisions can be made early
- ☐ My wife, family member, or someone close to me encouraged me to get screened
- ☐ I believe that I am in control of what happens to my health
- ☐ Getting prostate cancer screening gives me peace of mind

Other important reason that helped you decide to get free screening for prostate cancer (write in)

Now, write in the #1 reason that caused you to get free prostate cancer screening

THANK YOU FOR YOUR TIME

Prostate Health Survey 2004

PLEASE USE NO. 2 PENCIL

RIGHT

WRONG

First Name	Last Name	
Address	City	Zip
Date of Birth ____/____/____ Month Day Year	Home Phone# () _____ Work Phone # () _____	

pro921c4.fsf

Med Center

☐ Duke

☐ Lincoln

1. What is your race?

- ☐ Black (African American)
- ☐ White (Caucasian)
- ☐ Hispanic (Latino)
- ☐ Asian
- ☐ American Indian
- ☐ Other (please specify) _____

2. How did you hear about today's Prostate Screening Clinic?

- ☐ Newspaper
- ☐ Postcard or Flyer in the mail
- ☐ Radio or TV
- ☐ My doctor told me
- ☐ Wife or somebody in my family
- ☐ Church
- ☐ At the clinic
- ☐ Duke Med. Center sent me
- ☐ Heard from a friend

3. What is your highest level of education?

- ☐ Grade school
- ☐ Some high school
- ☐ High School graduate
- ☐ Some technical school
- ☐ Technical school graduate
- ☐ Some 4 year college
- ☐ 4 year college graduate
- ☐ Some graduate school
- ☐ Graduate School or Professional School

4. Are you currently...?

- ☐ Retired
- ☐ Disabled
- ☐ Unemployed
- ☐ Still working

5. Do you have a family doctor?

- ☐ Yes
- ☐ No

6. When was the last time you went to see a doctor for anything about your health?

- ☐ This year (2004)
- ☐ Last year (2003)
- ☐ More than a year ago
- ☐ Probably more than 2 years ago

7. Have you ever had somebodykin to you

- ☐ No
- ☐ Yes

Select the MOST IMPORTANT REASON that CAUSED YOU TO COME for free prostate cancer screening (check one)

- ☐ I believe that at my age I should get the digital rectal examination and PSA blood test done each year
- ☐ The time of the free prostate cancer screening clinic is convenient (weekend)
- ☐ If I had signs of prostate cancer I wanted to find out so that treatment decisions can be made early
- ☐ I believe that I am in control of what happens to my health
- ☐ Getting prostate cancer screening gives me peace of mind
- ☐ Other _____

Clinics like the one today are checking for signs of prostate cancer.

In a few medical centers in the U.S. medical science is trying to find ways to prevent prostate cancer in what is called "Prevention Clinical Trials"

One of the ways being studied is whether eating foods with vitamin E, the mineral Selenium, Tomatoes, or Soy can keep prostate cancer from happening

There is no such prevention trial close to North Carolina. However, Dr. Marva Price wants to know if there were such a prevention trial going on for prostate cancer, and was offered at Duke University Medical Center

Do you think you would participate?

- ☐ Yes
- ☐ No
- ☐ Maybe

APPENDIX D. STUDY PERSONNEL

Marva Price, DrPH, RN, FAAN, Family Nurse Practitioner Investigator	Principal
Cary N. Robertson, MD, PhD	Co-Investigator
Seronda Jackson, MS PhD/c Assistant	Research

APPENDIX E. PI CONTACT INFORMATION

Marva M. Price, DrPH, RN, FAAN, Family Nurse Practitioner
Assistant Professor
Duke University School of Nursing
Box 3322 DUMC
Durham, NC 27710-3322

Phone: 919-684-3786 ext. 245

Fax: 919-684-8770 or 919-681-8899

Email: marva.price@duke.edu

APPENDIX F. Duke University Medical Center IRB Report, May 2005

DUKE UNIVERSITY HEALTH SYSTEM

INSTITUTIONAL REVIEW BOARD RESEARCH PROTOCOL

RENEWAL RESEARCH STUDY PROTOCOL SUBMISSION

Submit original + 2 copies of all materials to IRB Office

FOR IRB USE ONLY:

Assigned IRB Reviewer: _____	IRB Registry # _____
Check only one: <input type="checkbox"/> Approved (ER Category _____, if applicable) <input type="checkbox"/> Modifications Required <input type="checkbox"/> Deferred <input type="checkbox"/> Disapproved	
IRB Chair _____	Date _____

Study Title: _____	IRB# <u>3497-02-2ER</u>
Increasing Sustained Participation in Free Mass Prostate Cancer Screening Clinics	
Does Study Involve: Good Clinical Practice: _____ Good Manufacturing Practice: _____ Gene Transfer: _____	
Review Preparatory to Research or Waiver filed for this Study? (circle one) <u>Y</u> <u>N</u> If yes, please attach.	

1. Principal Investigator: Marva Price, DrPH, RN MD/PhD DUHS
Faculty? : _____ Mail Box: 3322
Email: Marva.price@duke.edu Pager: _____ Phone: 684-3786 ext 245 Fax: 681-8899 Dept. & Dept: Sch. Nursing

2. Co-PI: Cary Robertson, MD MD/PhD DUHS Faculty? : Yes
Mail Box: 3833
Email: rober010 Pager: _____ Phone: 681-6768 Fax: 681-8074 Dept. & Division: Urology

3. Study Coordinator: Marva Price, DrPH, RN (PI) MD/PhD DUHS Faculty?: x
Mail Box: 3322 Email: Marva.price@duke.edu Pager: _____ Phone: 684-3786 x245 Fax: 684-8770 Dept. & Division: Sch of Nursing

4. Duke Sponsor: n/a MD/PhD DUHS Faculty? : _____
Mail Box: _____
Email: _____ Pager: _____ Phone: _____ Fax: _____ Dept. & Division: _____

5. Personnel: Please use page 3 of this form to list all Key Personnel for this study.

Funding Source: U.S. Army, Department of Defense Drug/Device Source: _____

Protocol Source, if other than PI: _____

Date human subject contact began: 9/21/2002

IF NIH funding, is it: _____ Competing Renewal* _____
_____ Non-competing renewal**

Certification Deadline to NIH: _____ **Attach: *Complete Grant Application ** Progress Report**

Indemnification Letter on File: _____ Date: _____

☐ Investigational drugs/devices: IND# _____ If so, Sponsor held? _____
_____ PI held? _____ IDE # _____ CMS: A _____ or B _____

Attachments – check and include all that apply:

- ☐ Federal Grant/Contract Annual Progress Report (if applicable)
☒ Consent form(s)
☐ Risk Assessment by Dept. of Pediatrics Chair – required if minors are used
☐ Additional information PI considers important for review by IRB

Subject Populations/Procedures/Costs - check and complete all that apply:

- ☒ Adults ☐ Patients ☐ Students ☒ Pregnant Women were acceptable for Focus
Groups only; study is focused on males and
sustaining regular prostate cancer screening
☐ Minors ☐ Controls ☐ Employees ☐ Fetuses
☐ Prisoners ☐ Cooperative sites ☐ Subjects incapable of giving consent

*employees/students over whom Key Personnel have a supervisory role may **not** be enrolled in the study

*controls (healthy volunteers) must be given Notice of Privacy Practices

screening participants enrolled Year 2004= 508 screening participants

☒ Exclusion of pregnant women (Male only screening for Prostate Cancer; in Year 1 pregnant females were appropriate for the physician's or ministers focus groups for discussion of the subject matter. However, there were no pregnant subjects in any phase of the study.)

☐ Blood: maximum amount to be drawn in any 8-week period Prostatic Specific Antigen (PSA) samples were drawn as a part of the screening program, but is not a part of this study. PI's involvement with the PSA screening program is only to store screening test results in locked files in the Duke University School of Nursing. Results, and afterwards recommendations for follow up of abnormal results are provided to participants through the Duke Univ. Comprehensive Cancer Center which facilitates the free screening.

☐ Extra costs to patients/insurance as a result of the research (e.g., tests, hospitalization) **NONE**

☐ Genetic testing **NONE**

☐ Gene Transfer Therapy **NONE**

☐ DNA Banking **NONE**

☐ HIV testing **NONE**

☐ Human cell banking **NONE**

☒ Subject compensation: travel/lost-income expenses **NONE**

Subcommittee Reviews – check and obtain approvals as appropriate before submission to department reviewer. Check all that apply.

Check ALL that apply.

Signature / Date

☐ Cancer Related – CPRC: _____

☐ Center for Living: _____

☐ Davis Ambulatory Surgery Center: _____

☐ Duke Health Raleigh Hospital Comm: _____

☐ Durham Regional Hospital Comm: _____

☐ Gen.Clin. Res. Ctr-GCRC: _____

☐ Hypo/Hyperbaric Unit – Safety Comm: _____

☐ Institutional Biosafety Comm: _____

☐ Operating Room/Anesthesia Time – Minutes required: (for research purposes only): _____

☐ Other Hospital Comm: _____

☐ Radiation – Radiation Safety Comm: _____

☐ VA Hospital-VA IRB: _____

V. Certification of Principal Investigator/Faculty Sponsor: Signature certifies that all Investigators have reviewed the proposed protocol and grant, if HHS sponsored, that the documents are in agreement (or if not, an explanation is attached), and that the research will be conducted in full compliance with federal/state regulations and DUHS procedures/guidelines. It is understood that: 1) continuing IRB review is required in order to maintain the approval status and that the investigator must submit a progress report for this review; 2) all changes in the study must be approved by the IRB prior to implementation; and 3) serious, unexpected study related adverse events must be promptly reported to the IRB. . **In addition, signature below certifies that, to the best of his/her knowledge, the investigator has no conflict, financial or otherwise, in serving as Key Personnel on this study.**

Signature of Principal Investigator:

(original signature is on the form submitted to IRB) June 20, 2005

Date

Signature(s) of Co-PI/Faculty Sponsor:

(original signature is on the form submitted to IRB) June 28, 2005

Date

Certification of Departmental Review (by other than PI/Faculty Sponsor): The department IRB member's signature signifies that the protocol has been reviewed and is ready for presentation to the Department Chairperson who is responsible for scientific review of the proposed research. The Chair's signature certifies that the proposed research study has been so reviewed and is recommended for submission to the IRB.

Signature of Dept IRB Member (*clinical depts. only*):

Signature of Department Chairperson (*all depts.*):

Date

Date

Please list all Key Personnel for this study. Key Personnel are research personnel who are directly involved in conducting research with human subjects, or who are directly involved with the handling of protected health information related to those subjects in the course of a research project.

[illegible]

Annual Review Summary

1. Provide a summary of your protocol for the upcoming year.
2. Answer the following questions
 - a) Discuss any study related adverse events or unanticipated problems involving risks to human subjects since the last IRB review. Have these events changed your current risk/benefit assessment? **None**
 - b) Discuss any complaints about the research since the last IRB review. **None**
 - c) Discuss any substantive changes in the research since the last IRB review. **None**
 - d) Discuss any proposed substantive changes to the research. **None**

Do these changes require changes in the consent?

- e) Discuss any new information or literature on possible risks to human subjects associated with this research topic.

There is no new information on the possible physical risks or harms, but more vigorous debate continued in 2003-2004 on to screen or not, and discussion that screening include an emphasis on informed decision making process between the man and his health care provider. In addition, in 2004 the National Cancer Institute released new findings that a significant number of men with normal PSA levels had biopsies which show varying stages of prostate cancer.

- f) Discuss any preliminary results of the research, if available.

The overall objective of this study is to determine factors associated with sustaining regular participation among African American men, particularly lower-income men, in free nurse-run prostate cancer screening clinics. From those factors, a risk profile is being developed to determine which men are less likely to return for regular prostate cancer screening. The expected outcome will be to define a set of intervention strategies that can be conducted at the community level.

Across the study years 2002-2004, consistent marketing strategies have been used by the nurse-run team who organize the free screening clinics:

- Consistent marketing of the screening clinics in community newspapers, 500 Durham churches, and area ethnic radio stations.
- Letters to screening participants from two previous consecutive years to announce the screening dates and invite their continued participation.
- To increase participation by men who are uninsured or low-income in each of the study years, the nurse supervisor at Lincoln Community Health Center mailed letters to 1,000 non-white male patients 40 years and older. These were clinic patients who had not been formally informed of the screening in

previous years. Lincoln is a comprehensive health center located in a Durham low income inner city neighborhood.

- The free screening clinic has been scheduled on a consistent weekend and consistent time over the three years of the study (third weekend of September).

A continuing observation is that African American participants tend to start prostate cancer screening close to age 40, but decrease in regular screening as they age into the 60 and older range when this cancer is more prevalent. Contrastingly, White screening participants tend to increase in screening practices as they age into the 60 and older range.

For this overall study, the goal has been met for a sample size of 614 prostate cancer screening participants (307 sustainers) plus 307 non-sustainers. A one year extension was requested from the Department of Defense for continued marketing of the screening clinics in African American faith based organizations, and data analysis. During this time, comparison will be made between the rise in clinic attendance over the 2002-2004 study years and the free clinic attendance in the final study year 2005, completion of the final report, and dissemination of findings.

- g) Was the study audited in the past year by internal or external auditors and were copies of the audit report sent to the IRB and to the Clinical Trials Quality Assurance (CTQA) office, School of Medicine? No
- h) If your study was reviewed by the CTQA office since the previous IRB review, please attach a copy of the review report.

Provide a subject status report:

During the Past Year

Number of subjects enrolled/participating to date: # 508

Number of subjects who refused to participate: # 1

Number of subjects terminated early: # 0

Number of subjects who completed the study: # 508

Has enrollment ended? _____ X No

Are any subjects still receiving study drug? _____ Yes _____ No n/a, no study drug are used

Are any subjects receiving protocol required follow-up procedures not otherwise
____ Yes x No

done as standard care and which involve more than minimal risk (such as involving radiation exposure or injection of radiographic contrast material)?

Are any subjects still active in the protocol? (Such as follow-up visit, follow-up questionnaire or follow-up phone contact).___Yes __x__ No

Cumulative Accrual by Race/Ethnic Group

	African Am.	Caucasian	Am. Indian	Hispanic	Asian	Others	Totals
2004							
Males	293	162	0	43	5	5	508
Females	n/a	n/a	n/a	n/a	n/a	n/a	
Totals	293	162	0	43	5	5	508

Appendix G. Consent Form

DUKE UNIVERSITY
Duke University MEDICAL CENTER
SCHOOL OF NURSING

Consent For Research

PROSTATE CANCER FREE SCREENING INFORMATION AND CONSENT FORM **IRB Protocol #3497-02-2ER**

Location:

- ☐ Lincoln Comm. Health Center
☐ Duke University Medical Center

Participant # _____

Last Name _____

First Name _____

This free prostate cancer screening clinic uses tests and procedures that are standard medical care. However, the results of your PSA, DRE, and your questionnaire are kept in locked files maintained by Dr. Marva Price of the Duke University School of Nursing through a research grant provided by the United States Department of Defense. Parts of Dr. Price's and her research staff's salaries are being paid by this grant.

Today you are also being asked to be part of a research study in the School of Nursing at Duke University Medical Center. The purpose of this study is to find out the best way to encourage men to get regular prostate cancer screening. Approximately 300 men who are getting today's free prostate cancer screening will be asked to participate in the research study about how to encourage men to get screened.

You maybe mailed a survey by Dr. Marva Price or one of her prostate study staff at the School of Nursing, and receive a reminder from Dr. Price for the next September free screening date. There are no known physical risks to being in this study. You may choose not to be in the study or if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes. You may withdraw your authorization for us to use your data that has already been collected (other than data needed to keep track of your withdrawal,) but you must do this in writing. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke or Lincoln Health Center. If you decide to withdraw, we ask that you contact Dr. Marva Price in writing and let her know that you are withdrawing from the study. Her mailing address is Marva Price, DrPH, RN, Duke University School of Nursing, Box 3322, Durham, N.C. 27710. At that time we will ask your permission to continue using all information about you that has already been collected as part of the study prior to your withdrawal.

Any new findings about prostate cancer screening in general could be made known in local newspapers and scientific reports. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Duke University Health System (DUHS). For records disclosed outside of DUHS, you will be assigned a unique code number. The key to the code will be kept in a locked

file in Dr. Price's office. Your study records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives of the U.S. Army Medical Research and Materiel Command (also known as the U.S. Department of Defense), which has funded this study, and the Duke University Health System Institutional Review Board.

The study results will be retained in your research record for at least six years or until after the study is completed, whichever is longer.

statement of consent

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have additional questions. I have read this consent form and agree to be in this study with the understanding that I may withdraw at any time. I have read the attached information and have been given the opportunity to discuss it and ask questions. I have been informed that I may contact Dr. Marva Price (919-684-3786 ext. 245) to answer any questions I may have about this study. I may also contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111 for any questions concerning my rights as a participant." I have been told that I will be given a signed copy of this consent form.

Participant's

Signature _____ Date _____

Permanent Address (please print):

Signature of Person Obtaining Consent

_____ Date _____