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TITLE: Development of the Meharry Medical College Prostate Cancer Research Program

PRINCIPAL INVESTIGATOR: Flora A. M. Ukoli	Robert S. Dittus
Yong Cui	Robert J. Matusik
William Washington	Jason Morrow
LaMonica Stewart	Michael Cookson
O. Ogunkua	Jay H. Fowke
EmekaAmaefuna	Susan Kasper
Alecia Malin	Marcia Wills

CONTRACTING ORGANIZATION: Meharry Medical College
Nashville, TN 37208

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14. ABSTRACT There is substantial urology, oncology, epidemiology, nutrition and other expertise at Meharry and Vanderbilt to address issues relating to prostate cancer (PCa) disparity among African-American (AA) men. Six new/junior minority investigators have initiated pilot projects, continue to maintain partnerships with mentors at VU, and two PIs have established viable community network ties. Dr. Ukoli has recruited 64 participants into the lycopene study, sent 200 stored plasma samples for lycopene analysis, and developed a lycopene clinical trial to be submitted in June. Dr. Washington has recruited 14 participants into the PCa health care seeking behavior study. 300 blood samples of AA and Nigerians will be sent to the GCRC at VU for DNA extraction and genotyping for Dr. Cui's study in collaboration with Dr. Marshall (new investigator). Dr. Ogunkua has dosed/sacrificed 40 mice recording data at all time-points. Dr. Stewart has received independent funding for the PCa cell lines Thalidomide growth inhibitory study, and two students have submitted pre-doctoral grants from her laboratory. Dr. Abu, post-doctoral fellow, has developed a career development award proposal to look at quality of life following PCa treatment to be submitted in June. 2 MSPH graduate students have selected related topics for their thesis.						
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 Meeting with the Advisory Board and Executive Committee**

Appendix E: Descriptive Analysis of Study Participants (Project 1)

Abstracts Submitted

INTRODUCTION:

[Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.]

The reason for African-Americans (AA) being disproportionately affected by prostate cancer (PCa) may include biologic tumor differences, genetic predisposition, differential exposures, lack of access to prostate specific antigen (PSA) testing and inadequate access to health care. The paucity of minority PCa investigators and low accrual of AAs in clinical trials also contribute to the lack of progress in reducing this disparity. This proposal includes research initiatives to study the genetics, pathogenesis and epidemiology of PCa disparity among AA men. The genetic similarity between AAs and Africans, disparity in the degree of admixture, differences in dietary style and body fat patterns provide opportunity to study genetic and environmental causes of PCa in black men. The PCRCP has 12 members at MMC, 6 mentors/collaborators from VUMC who are working on partially overlapping PCa topics at the genetic, molecular, clinical and epidemiological levels, and an additional collaborator, Dr. Dana Marshall, from MMC Department of surgery. There is substantial urology, oncology, epidemiology, nutrition and other expertise in both institutions to successfully develop this program at MMC and train minority investigators in the field of PCa.

The program goals are to:

- 1). Develop an Outreach Core to sustain communication network with AA communities in Nashville, address PCa needs and facilitate recruitment into PCa early detection programs and research studies.
- 2). Develop a PCa research training program for junior faculty, new PCa investigators, and graduate students.
- 3). Conduct pilot projects, accumulate preliminary data, submit independent proposals, and generate new research ideas to sustain the PCRCP at the completion of this DOD award.

The scientific aims of the program are to:

- 1). Conduct research of biomarkers and lifestyle risk factors of PCa development and progression in African-Americans and Africans.
- 2). Study the role of specific genes, gene-gene interactions, gene-environment interactions in PCa initiation and progression in these populations.
- 3). Conduct investigator-initiated clinical trials with emphases on nutritional interventions and molecular therapeutics.
- 4). Use mass spectrometry and proteomic-based approaches to identify predictive factors of PCa aggressiveness, treatment response and metastasis and develop molecular classifications and/or biomarkers of aggressive PCa.

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BODY:

*[This section of the report shall describe the research accomplishments associated with each task outlined in the **approved** Statement Of Work. Data presentation shall be comprehensive in providing a complete record of the research findings for the period of the report. Appended publications and/or presentations **may** be substituted for detailed descriptions but **must** be referenced in the body of the report. If applicable, for each task outlined in the Statement of Work, reference appended publications and/or presentations for details of result findings and tables and/or figures. The report shall include negative as well as positive findings. Include problems in accomplishing any of the tasks. Statistical tests of significance shall be applied to all data whenever possible. Figures and graphs referenced in the text may be embedded in the text or appended. Figures and graphs can also be referenced in the text and appended to a publication. Recommended changes or future work to better address the research topic may also be included, although changes to the original Statement of Work **must** be approved by the Grants Officer. This approval must be obtained prior to initiating any change to the original Statement of Work.]*

Statement of Work:

Task 1 Start-Up Phase

This task was completed in the last period. The program retains an Executive Committee to oversee its scientific merit. This committee is made up of senior faculty from MMC and VUMC.

MMC Faculty

Derrick Beech, MD.
Flora A. M. Ukoli, MD, MPH.
Margaret Hargreaves, Ph.D.
Billy Ballard, DDS, MD.

VUMC Faculty

Robert Matusik, Ph.D.
Michael Cookson, MD.
Susan Kasper, Ph.D.
Robert Dittus, MD., MPH.

After the DOD site visit, the program decided to set up an Advisory Board made of senior and administrative faculty external to the program charged with the responsibility to ensure the smooth running of the program. This Board is has been constituted as follows:

Lee E Limbird, PhD.	Vice President for Research, MMC. (Committee Chair)
John J. Murray, MD. PhD.	Associate Vice President for Clinical Research, MMC
Andrea Baruchin, PhD.	Assistant Vice Chancellor for Research, VUMC
Gordon Bernard, MD.	Assistant Vice Chancellor for Research, VUMC

2nd. Meeting of the Advisory Board & The Executive Board: (March 9, 2007)

This was a joint meeting of The Executive Committee and the Advisory Board (Agenda attached). The meeting was very successful, as each pilot project PI was able to demonstrate their successes, and also discuss any challenges they were experiencing. Each program member was able to contribute to a rich discussion to over come such perceived challenges. The Board and Executive committee then met with the Dr. Ukoli (PI; MMC) and Dr. Matusik (PI; VUMC) for an hour to address all major concerns.

The major comments that needed to be addressed were as follows:
Salary support for all pilot project PIs: Increase percent effort
Budget for preliminary data collection for all pilot projects
Adequate participant incentive for both community-based studies.

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Laboratory technician & Participant recruiter (Preferable a PCa survivor).

The Advisory Board suggested an application for supplemental funding, and this information was sent to the program director, Teresa Miller, Ph.D. The PI is in the process of submitting application for supplemental funding.

Task 2. Development of Program Outreach Core (2 – 6 months)

The Outreach Core has been set up during the last report period, and continues to provide support to each of the PIs as needed. At the last meeting the Chairman suggested very careful workings with the community so as not to make them think that we outreach them just because we want to recruit them into studies. The team from the Office of Minority Affairs (VUMC) headed by Dr. Elizabeth Williams, and Ms. Tonya Micah continue to conduct very good community outreach work, but it may be counter productive to try and start recruiting study participants at their events. Both of them being members of this Outreach Committee will always be there to let us know the best time introduce such activities.

Dr. Pam Hull of Tennessee State University, also a member of the core, is PI of a DOD funded prostate cancer education project in the committee. The PI, Dr. Ukoli, is on her project Steering Committee, and since the TSU group has worked successfully with about 50 churches in the community, this program will intensify collaborative links with them. They also are in charge of the Meharry U-54 Outreach Core, making it very convenient to work collaboratively.

Task 3 Initial Training: Investigators, Trainee-PIs, Post-Doc, GRA (2-8 months)

This task was completed in the last period, and those hired since then, post-doctoral fellow (Abu K. Taher, M.D., MPH), the Research Assistant (Libnir Telusca, MSPH) and the graduate student (Fanesia Whitney) have completed training in human subject protection.

Deliverables:

1. Bi-weekly tutorial and regular learning contact with respective mentors as needed
2. HIPAA and consent forms for 2 studies that require human subject protection documents. (PIs: Dr. Ukoli, Dr. Washington)
3. IRB and HSRRB approvals obtained by Drs. Ukoli & Washington.

Task 4: Continuing Medical Education in Prostate Cancer Research (Month 3 – 36)

Seminar Series Attendance:

Vanderbilt

Epidemiology Seminar series	(Weekly)
Urological Workshop on Research	(Weekly)
VICC Seminar series	(Weekly)

Meharry

Grand rounds in surgery, and internal medicine	(Monthly)
Prostate Cancer Seminar Series	(Quarterly)
Center for Health Research TN State University	(Weekly)

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Workshops and Conferences:

TN State Cancer Coalition
Nashville Community Health Disparity Summit
TN Cancer Coalition Annual Summit

Pilot Project Progress Reports:

PowerPoint presentations were presented on March 9, 2007 by each pilot project PI.

Deliverables: Seminar presentations:

1. Ram Dasari, M.D. (Urologist), Urology Associates, Nashville. “PSA Failure after local treatment of prostate cancer: What next?” Friday February 16th, 2007 at 12:00pm.
2. Omer Kucuk, M.D. (Oncologist), Wayne State University, Detroit. “Lycopene in the etiology and control of prostate cancer progression”. March 5th, 2007 at 12:00noon.
3. Harvey Murff, M.D., MPH., Vanderbilt University, Nashville. “Data Safety and Monitoring in Clinical Research”. Monday March 26th, 2007.

Products:

Annual program report.

Task 5. Subject Recruitment and Data Collection. (6 – 36 months)

A: Outreach:

Each pilot project PI is now following up the contacts that have been made for them, and have started recruiting study participants. Meanwhile the program continues to maintain support of the Interdenominational Ministers Fellowship (IMF) and has initiated new contacts:

Churches:	4	Lake Providence, Christ Church, St. Bartholomew, Friendship Baptist
Associations:	3	Somali Association & Ethiopian Association, and Hispanic Community Association
Support group:	2	USTOO International Men’s Health Network
Doctor’s office:	1	Urology Associates (28 Urologists)

Distribution of flyers/brochures:

The two pilot projects have been initiated and flyers are now being distributed in appropriate locations. (See pilot study reports).

Deliverables:

Community-based PCa health education presentation	2
Community-based PCa screening activity	2
MMC-based PCa screening (available daily)	Appointments
Study brochures, Study flyers	Developed.

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Products:

Men screened for PCa: 232
Men who attended community outreach education (Approximate) 125

B: Research Projects:

HSRRB Log No. A-13323.0 (Proposal No. PC041176) Award No. W81XWH-05-1-0229 -

Project 1: (Dr. Ukoli, PI / Dr. Dittus, Mentor)

“Lycopene in Prostate Cancer Risk among African-Americans and Nigerians: A Case-Control Study”

This study has a site in Nashville and a site in Nigeria, and will be a continuation of Dr. Ukoli’s ongoing prostate cancer dietary risk study funded by DOD, Award Number DAMD17-02-1-0068, titled Dietary Fat and Vitamin E in Prostate Cancer Risk among African Americans and Africans: A Case-Control Study. Identifying, contacting and recruiting prostate cancer cases is a challenge. So far we have demographic and diet history information, and stored blood samples for a good number of controls from both study sites. Effort will be directed mainly to meet the recruitment goal of prostate cancer cases in the next year.

Nashville Site:

HSRRB Log No. A-13323.1a (Proposal No. PC041176) Award No. W81XWH-05-1-0229

Data collection has been initiated with 25 new participants recruited in Nashville. 200 samples from stored participants who consented to have their samples used in related studies have been shipped to Dr. Gross’s laboratory for lycopene analysis.

Nigeria Site:

HSRRB Log No. A-13323.1b (Proposal No. PC041176) Award No. W81XWH-05-1-0229

42 participants have been recruited at this site, and we received samples and questionnaires of 20 participants in March 2007. The collaboration with our colleagues at the University of Benin remains strong, and two new investigators who just completed their residency, Dr. Okoro (General Surgery) and Dr. Obarisiagbon (Urology) are interested in joining the Benin team.

Products:

1. Stored blood samples from 67 participants
2. Support from Nigerian urologists continue to be strong
3. Support from two sets of urologists in Nashville beginning to strengthen
 - a. VUMC Urology clinics
 - b. Urology Associates, Nashville
4. Meharry hired urologist Rodney Davis, M.D. to start in May 2007.
5. Entered 40 food assessment information (FFQ) into new ACCESS data base.

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Deliverables:

1. Lycopene analysis: First batch of 200 stored samples from participants from the parent study shipped to Dr. Gross's laboratory
2. Data analysis started in January 2007. Population description data attached.
3. Graduate student (Nicole Johnson): "Dietary pattern of African-Americans and Africans: Implication for prostate cancer risk"
4. Grants:
 - DOD Clinical Trial Development Award Funded for 1 year
Proposal to be submitted for funding in June/July 2007.
6. NIH CNP Pilot project Submitted in partnership with Margaret Hargreaves, Ph.D.
"Integrated Prostate Health Program for Low-Income African-Americans: CBPR Approach"

Pilot project 2: (Dr. Cui, PI / Dr. Dittus, Mentor)

"Genetic Indices of Steroid Hormone Synthesis and Metabolism in Prostate Cancer: A Pilot Study."

Dr. Cui will be joined by Dana Marshall, Ph.D., department of surgery, Meharry, as a collaborator. She is a new faculty with interest in cancer, and now including prostate cancer as one of her research interests, and with expertise in various laboratory methods. (Biosketch attached). The efficient strategy to move this pilot project forward will be working through the VUMC GCRC for DNA extraction and genotyping. Dr. Matusik has initiated the application process with the GCRC, and Dr. Cui / Dr. Ukoli will follow-through with an application to use that facility. Pilot project progress is as follows:

1. Laboratory set up already, and awaiting equipment & Hire laboratory technician
2. Collaboration: Dr. Dana Marshall (Surgery Dept.)
 - a. Supplies ordered for DNA extraction at Meharry
 - b. 13 samples to Dr. Marshall's laboratory to try-out DNA extraction kit.
3. Samples shipped from Washington DC:
 - a. ~ 500 stored at Meharry, ready for DNA extraction
 - b. 300 to be shipped to GCRC at VUMC once application process is completed
4. Developing IRB modification to allow use of samples being collected at this time to be included in this pilot.

Products:

1. Stored blood samples from 500 participants (Parent study)
2. Stored blood samples from 276 participant (Collected since 2005)

Pilot project 3: (Dr. Washington, PI / Dr. Dittus, Mentor)

"Prostate Cancer Health Care Seeking Behavior of African American Men."

HSRRB Log No. A-13323.3 (Proposal No. PC041176) Award No. W81XWH-05-1-0229

An MSPH graduate student, Fanesia Whitney, has been identified for this pilot project. She will be trained by Dr. Ukoli, and work with Dr. Washington on this project. They have recruited 14

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participants into the study. Distributing questionnaires and expecting men to complete and return them has not worked well. Interviewing men appears to be a better strategy, but this cannot take place after a church service. There is need to schedule 10-20 men to week-day and weekend evenings or to Saturday mornings for this purpose. Providing an incentive towards transportation cost will be a good way to encourage participation. The PI has proposed a minimum of \$20 that will need to go back for IRB and HSRRB approvals, once funds are identified.

The PI is developing a proposal to be submitted as a DOD IDEA AWARD in June 2007. This will provide independent PI with a budget for at least 25% salary effort for the PI, a part-time R/A (Data collection, data management), and adequate participant incentive (\$20-\$35 cash and or gift certificate)

Products:

1. IRB approval from MMC & HSRRB

Deliverables:

1. Graduate student included in project (Fanesia Whitney, MSPH)
 - Working on part of the material for thesis
 - Data collection: Recruiting and interviewing participants.
2. Used for Epidemiology II field practice experience
 - 9 MSPH students to recruit 90 men total from local churches
3. Database developed by Dr. Ukoli for this pilot project
 - Used for MSPH Data Management course activity (*8 students)
4. Period IRB renewal submitted to MMC and HSRRB in March 2007.
5. Recruitment: 14 participants recruited

Pilot project 4: (Dr. Stewart, PI / Dr. Matusik, Mentor)

“Inhibition of Prostate Cancer Growth by Thiazolidinediones”

This pilot has been initiated and completed. Dr. Stewart has now received independent funding and has gone on to submit new grants, and is training graduate students in her research area. She has set up two research committees to oversee the graduate work of her two doctoral students, each committee including two faculty from Meharry and 2 faculty from VU.

Products:

1. 3 distinct research findings demonstrated.
2. 2 Graduate students submitted applied for the Ruth L. Kirschstein NRSA Program for NIGMS MARC Pre-doctoral Fellowships in December 2006.
3. NCI K01 Mentored Career Development Award: 7/1/06 to 6/30/11, titled "Regulation of Prostate Cancer Growth by PPAR γ ligands".
4. DOD New Investigator Award received in September 2005.

Deliverables:

1. Two grant awards.
2. Two pre-doctoral grants submitted.

Pilot project 5: (Dr. Ogunkua, PI / Dr. Matusik, Mentor)

“Benzopyrene B(a)P Induced Activation of Prostatic Specific Genes”

Dr. Ogunkua has started active laboratory experiments, and has also been working on grant proposals seeking external funding. He is working very closely with his mentor, Dr. Matusik, having completed training in the following techniques

1. Breed transgenic mice, tail clip, DNA isolation, and identify transgenic mice.
2. Establish tissue collection procedures for gene expression and pathology assessment of the prostate.
3. Assess proliferation and apoptosis in the prostate.
4. RNA isolation and qRT-PCR.
5. Establish immunohistochemistry for markers such as AR, PB, Foxa1, Foxa2, p63, Nkx3.1.
6. Establish Western Blot Analysis.

Products:

1. MMC Institutional Animal Care and Use Committee (IACUC) approval received.
2. 40 mice sacrificed for experiment. Dosing of CD1 mice tissue collection and analysis in progress.
3. Data tabulated for all tissues and at all study time-points

Deliverables:

1. ARCH Pilot Project funded: “Benzo(a)Pyrene [B(a)P] and Prostate Cancer Progression in Transgenic LPB-Tag Mice.”
2. Abstract submitted for the 46th annual meeting of the society of toxicology March 25-29, 2007 Charlotte NC.

Pilot Project 6: (Post-Doctoral Fellow Dr. Taher / Dr. Cookson & Dr. Ukoli, Mentor)

Dr. Taher opted to conduct a population (clinical) study rather than a laboratory based study. He has undergone human subject protection training, and is working on Dr. Ukoli’s project as part of his training. He is conversant with participant recruitment & consenting, data collection by interview, processing of study specimens, and is involved in tutoring MSPH students in epidemiology and data management. He has developed a proposal “Quality of Life among African-American Men Following Treatment for Organ-Confined Prostate Cancer”.

Products:

1. Developing study SOP (Standard Operating Procedure) for the parent study
2. Blood collection and storage protocol
3. Modified FFQ interview: Food models and Consumption pattern
4. List of Molecular Weight of relevant fatty-acids

Deliverables:

1. DOD Career development award grant to be submitted in June 2007.

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“Quality of Life among African-American Men Following Treatment for Organ-Confined Prostate Cancer”.

2. Lecture notes: Epidemiology Methods, Sampling Techniques, ANOVA
3. Manuscript development:
“Fatty-Acid profile differences between African-Americans and Africans”

Task 6. Interim, On-going and Final Data Analysis (6 - 36 months)

This database has been developed in SPSS, and data entry is ongoing as collected. Some of the demographic summaries from the parent study are attached. Participants recruited from this pilot project will be added on to the same database. Lycopene data will be included in this database once available.

Deliverables:

SPSS database.

ACCESS data collection software program for dietary assessment.

Task 7. Report Writing and Presentations (12 - 36 months)

Deliverables: One poster presentation per pilot study and a manuscript draft per pilot study.

Dr. Ogunkua Abstract: Submitted for the 46th annual meeting of the society of toxicology March 25-29, 2007 Charlotte NC.

Dr. Ukoli Presentation:

1. Dietary Determinants of Prostate Cancer in Black Populations.
July 2006. LSU. New Orleans.
2. Response to Prostate Biopsy by Nigerian men: Community and Hospital Experience.
July 9 -12. 2006. UICC World Cancer Congress, Washington DC.

Dr. Ukoli & Dr. Fowke: Publications:

1. F.A. Ukoli, E Egbagbe, F. Akereyeni, E. Iyamu, T. Oguike, P. Akumabor, and U. Osime. Response to Prostate Biopsy by Nigerian men: Community and Hospital Experience. Proceedings of the UICC World Cancer Congress, Washington D.C.(USA), July 8-12. 2006. Pgs 341- 347. Medimond. International Proceedings.
2. Flora A. Ukoli, Eruke Egbagbe, Barbara B. Zhao, Efosa Iyamu, Dale Young, Philip Osime, Usifo Osime, Lucile L. Adams-Campbell. Anthropometric Body Fat Predictors of Elevated Prostate Specific Antigen among Rural and Urban Nigerians: A Population-Based Study. West African J of Med.(2006 in press.)
3. Fowke JH, Signorello LB, Underwood W 3rd, Ukoli FA, Blot WJ. Obesity and prostate cancer screening among African-American and Caucasian men. Prostate. 2006;66(13):1371-80.
4. Fowke, J.H., Signorello, L, Chang, S, Matthews, C.E, Buchowski, M., Cookson, M. Ukoli, F., Blot,W. Effects of Obesity and Height on PSA and Percent Free PSA Levels Among African-American and Caucasian Men. Cancer. 2006; 107(10):2361-7.
5. Ukoli, F.A., Barlow Lynch, Lucile Adams-Campbell. The effect of radical prostatectomy on patient quality of life in African Americans. Ethn Dis. 2006;16:988-993.

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6. Odedina FT, Ogunbiyi JO, Ukoli FA. Roots of prostate cancer in African-American men. J Natl Med Assoc. 2006 Apr;98(4):539-43.

Dr. Cui & Dr. Hargreaves: Abstract Presentation:

Hargreaves MK, Cui Y, Zhao B, Peterson NB, Fowke JH, Blot WJ. Cancer screening among low-income African-American and Caucasian-American women. The National Leadership Summit on Eliminating Racial and Ethnic Disparities in Health. Jan. 9-11, 2006, WA DC.

Task 8. Developing Grant Proposals for Independent Funding (24-36 months)

Dr. Stewart and Dr. Ogunkua have submitted proposals for funding. Dr. Ukoli and Dr. Taher (post-doc) have developed proposals to be submitted for funding June 2007, two graduate students have submitted pre-doctoral grants, Dr. Washington and Dr. Cui have stated the process of developing their own proposals.

KEY RESEARCH ACCOMPLISHMENTS:

[Bulleted list of key research accomplishments emanating from this research.]

1. The prostate cancer research program (PCRP) has been established at Meharry Medical College, and prostate cancer research is being conducted actively both in the clinical and basic science areas. The program investigators and mentors continue to give their full attention to this program, giving it sustainability.
2. Five strong research teams are in place in collaboration with investigators from Vanderbilt University, and a 6th team headed by Dr. Cookson as been added.
3. The international component in collaboration with the University of Benin, Nigeria, continues to be maintained.
4. The program has developed one research laboratory, (Dr. Stewart's lab), and is in the process of developing two additional research laboratories for Drs. Ogunkua and Cui. Another faculty member at Meharry, Dana Marshall, Ph.D. is willing to join the program, and her laboratory can do manual DNA extraction.

The program continues to develop a strong network with the community. Derrick Beech, M.D., now conducts prostate cancer education in churches, and offers free screening in collaboration with the program pilot project.

5. Graduate student Exposure:
 - a. MSPH students in the first and second years have been exposed to prostate cancer research, receiving exposure to community networking and participant

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- recruitment, 2 of whom have selected prostate cancer related topics for their thesis.
 - b. Two doctoral students from Dr. Stewart's laboratory have submitted pre-doctoral grants for funding, and will be developing their thesis in the area of prostate cancer.
6. Pilot Projects:
- Pilot project 1
 - 67 participants recruited
 - 200 samples sent for lycopene analysis.
 - Pilot project 2
 - 300 samples available for DNA extraction.
 - Pilot project 3
 - Graduate assistant trained, 4 churches identified, 14 participants recruited, database developed.
 - Need to include \$20 participants incentive.
 - Pilot project 4
 - Goal achieved, independent funding secured.
 - Pilot project 5
 - Experiments in progress. 40 mice sacrificed, and tissues harvested.
 - Pilot project 6
 - Proposal first draft ready. Awaiting DOD grant announcement.

REPORTABLE OUTCOMES:

[Provide a list of reportable outcomes that have resulted from this research to include:]

1. Partnership established/initiated in Nashville:
 - i) Interdenominational Ministers Forum (IMF)
 - ii) 16 church communities
 - iii) 3 local prostate cancer non-profit organizations
 - iv) Two local African American fraternities
 - v) 100 Black Men of America.
 - vi) NAACP
 - vii) World Baptist Center
 - viii) Academy for Educational Development (AED)
2. The clinical research center
 - i) CRC at Meharry is actively involved
 - ii) GCRC at VU agreed to support program.
3. Maintained partnership with the Nigerian research collaborators: Usifo Osime, (Director), Philip Akumabor and Temple Oguike (urologists), Patrick Okoro, and Obarisiagbon (junior investigators in general surgery and urologist) have indicated interest to start training.
4. Maintained very strong collaborative partnerships with mentors and other collaborators at Vanderbilt.

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CHALLENGES:

PCRP Membership:

This is a very ambitious and optimistic program. In the second year of the program it is important to mention the need to increase the salary effort of all investigators to at least 10% to increase performance. PIs such as Drs Cui, Ogunkua, Stewart, and Washington will be able to perform even better if this is done.

Participant Incentive:

It has come to our notice that participants cannot commit to this study with such limited incentive. There is need to increase participant incentive to at least \$80, to offset lost wages for a day spent taking part in a research study. Several potential study participants cannot miss work, and miss wages for a research study, especially when they hold jobs that do not offer adequate health insurance. The men in our study population tend to be medically underserved and any call for their time should include adequate incentive as part of respect for their time. For studies that require participants to present themselves for interviews, a minimum of \$35 will be needed, especially as other similar studies have offered that much in this and other areas. These sums have not been budgeted for, and there is need to source for money to cover these costs and boost participation.

Outreach Core:

Distributing flyers at grocery stores on senior citizens days have been very good forum for health education. Managers have only allowed one such visit a month, making continuity problematic.

It is no unlikely that difficulty in locating community leaders is as a result of persons not willing to stick their head out for a research program with no immediate benefit to participants. Church leaders continue to be a reasonable starting point, and we plan to continue to use them.

Urologist at Meharry, Vanderbilt, and Urology Associates:

Meharry has hired a urologist to start in May 2007, and this should improve recruitment of prostate cancer cases here at Meharry. In general urologists will rather inform their patients about this study rather than allow us approach their patients directly because of confidentiality concerns. We need to develop a way of going around this as it is possible that some minority patients may be more responsive to a request from a minority investigator/research assistant/ recruiter.

Development of Laboratories:

Dr. Ogunkua and Dr. Cui continue to work out of his mentor's laboratory while their own laboratories are being developed. As investigators and teachers they need to have a laboratory technician conducting some of the experiments to free their time for other responsibilities. We propose hiring one full-time laboratory technician to serve this purpose.

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Dr. Ukoli can continue to run her study assays as a fee-for-service from other laboratories until full collaborative ties are arranged with another faculty at Meharry Medical College who can run immunoassays for pilot project 1. Budget plans must be made to include a minimum of 25% effort towards supporting a laboratory technician for this purpose.

Program Coordinator:

There is need for a full-time experienced program coordinator to take over all program administrative responsibilities to free the PI for the scientific study goals. Currently the PI is overloaded with these additional responsibilities.

Nashville Site:

- 1 Recruiting cases: It may be necessary to budget some administrative fee for physician office staff to process patients in their practice, identify potential participants, and process them for possible recruitment. Cancer register cases are two years in arrears, and so new cases continue to be difficult to recruit without the full support of the office administrators in local urologists, physicians, and oncologists.
- 2 Recruiting controls: Increase the incentive to \$80 will probably encourage minority men who earn wages to miss a days job for this activity.

Nigerian Site:

Prostate biopsy in Nigeria:
This site still requests an ultrasound equipment for facilitate adequate prostate biopsy by ultrasound guided technique rather than the 'blind' technique where the biopsy needle is 'digitally-guided' by the index finger.

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CONCLUSIONS:

[Summarize the results to include the Importance and/or implications of the completed research and when necessary, recommend changes on future work to better address the problem. A "so what section" which evaluates the knowledge as a scientific or medical product shall also be included in the conclusion of the report.]

The collaboration between Meharry and Vanderbilt investigators continues to grow strong, and respective mentors continue to provide guidance as expected. The Advisory Board has been very efficient in providing adequate solutions to program challenges. Two PIs have received funding, a third has submitted a proposal, the 4th has initiated data collection, the 5th is expected to take-off in full swing in the next month after completion of the GCRC application and the post-doctoral career development award will be submitted this June. The goals of this program have been met, and the scientific objectives of the individual pilot projects are all feasible.

The underlying causes for lack of operational support from urologists need to be studied so as to find lasting solution for recruiting newly diagnosed prostate cancer patients. This program will need supplemental funds to meet its optimistic objectives but over-ambitious goals as enumerated at the onset. Potential participants, community leaders, and health providers will require continuous education to eliminate the real challenges of recruiting study participants. This program has successfully produced minority prostate cancer investigators who are submitting competitive research grants, and who have attracted graduate students to the field, and adequate salary support for each of them is necessary. The enthusiasm of program members and mentors, and the first time program PI, will be further lifted with the provision of supplemental funds to meet the existing budget gaps. This request has been submitted to the program grants manager.

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REFERENCES: *[List all references pertinent to the report using a standard journal format (i.e. format used in Science, Military Medicine, etc.).]*

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List of Appendix:

Appendix A: Agenda 2nd PCRCP Meeting with Advisory Board and Executive Committee

Appendix B: Educational Training Activities

Appendix C: Dana Marshall, Ph.D. Biosketch

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Advisory Board and Executive Committee

Appendix E: Descriptive Analysis of Study Participants (Project 1)

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APPENDIX A: Agenda for PCRP 2nd Advisory Board / Executive Committee Meeting

Development of a Prostate Cancer Research Program at Meharry
A Department of Defense HBCU Partnership Award
PCRCP 2nd Executive Committee / Advisory Board Meeting

Friday, March 9, 2007

Agenda

- 3:30pm. Welcome PI (Flora A. M. Ukoli)
- 3:32pm. Opening remarks by the Chairman of the Advisory Board: Lee Limbird, Ph.D.
- 3:35pm Project Updates:
- Dr. LaMonica Stewart Followed by Q & A
- 3:45pm Dr. Ben Ogunkua Followed by Q & A
- 3:55pm. Dr. Flora Ukoli Followed by Q & A
- 4:05 Dr. Yong Cui Followed by Q & A
- 4:15pm Dr. William Washington Followed by Q & A
- 4:25pm Dr. Abu Taher (Post-Doc) Followed by Q & A
- 4:35pm Program progress summary by Flora Ukoli (PI).
- 4:40pm Comments by the program Mentor & PI VU (Robert Matusik, Ph.D.)
- 4:45pm. Discussion: Executive Board & Advisory Board Members
Andrea Baruchin, Ph.D. Chief of Staff, Office of Research, VUMC
Gordon R. Bernard, MD. Assistant Vice Chancellor for Research, VUMC
- 5:05pm Response and General Discussions
- 5.15pm. Closing.

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APPENDIX B: Educational Training Activities:

A) Practical Training activities

Hands-on experience, and develop specific skills and competences working within existing research project under direct supervision of the sponsor or mentor.

Dr. Matusik:

1. Training in the Following Techniques
2. Breed transgenic mice, tail clip, DNA isolation, and identify transgenic mice.
3. Establish tissue collection procedures for gene expression and pathology assessment of the prostate.
4. Assess proliferation and apoptosis in the prostate.
5. RNA isolation and qRT-PCR.
6. Establish immunohistochemistry for markers such as AR, PB, Foxa1, Foxa2, p63, Nkx3.1.
7. Establish Western Blot Analysis.
8. Development and submission of grant proposals

Dr. Ukoli:

1. Community outreach
2. Participant recruitment, consenting & interviewing
3. Human biological sample collection, handling, processing, and storage
4. Development of study questionnaires and flyers
5. Development of SPSS database
6. Development and submission of grant proposal

B) Workshops, Seminars and Conferences

Seminar series at Meharry:

1. Bridges to Independence Series (Obtaining independent funding)
2. Clinical research center Biometrics Core series at Meharry
3. Departmental Noon Conference and Grand-rounds (Department of family practice, OB/GYN, Internal medicine, and surgery)
4. Department of biological sciences
5. Prostate cancer research program seminars

Seminar series at Vanderbilt:

1. Department of Epidemiology
2. General Clinical research center (GCRC) research skills workshop series
3. Urologic surgery department: Prostate cancer lab meetings and journal club
4. SPORE and other grants and Vanderbilt
5. Vanderbilt-Ingram Cancer Center seminar series
6. Workshops, Conferences and Retreats
7. Health Disparity Summit organized by the Meharry EXPORT grant.
8. American Public Health Association & The American College of Epidemiology annual meetings.
9. U54 MMC/VICC partnership annual retreats and conference on cancer

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Dana R. Marshall		POSITION TITLE Associate Professor, Dept of Surgery	
eRA COMMONS USER NAME		Director of Surgical Research, Dept of Surgery	
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
U of Delaware, Newark DE	B.S.	1979	Animal Science
North Carolina State University, Raleigh, NC	M.S.	1983	Veterinary Microbiology Minor: Physiology
U of Delaware, Newark DE	Ph.D.	1990	Animal Science (Virology)

A. Positions and Honors.**Positions and Employment:**

1990-92	Postdoctoral Research Associate, USDA/ARS, Avian Disease and Oncology Laboratory, East Lansing, Michigan
1993	Postdoctoral Research Associate, Department of Infectious Diseases, St. Jude Children's Research Hospital, Memphis, Tennessee
1993-1997	Post-doc Research Associate, Department of Virology and Molecular Biology, St. Jude Children's Research Hospital, Memphis, Tennessee
1998-2001	Associate Investigator, Department of Immunology, St Jude Children's Research Hospital, Memphis, Tennessee
2002-2003	Section Leader, Clinical Applications Core Technology Laboratory (Affymetrix Core Facility), Hartwell Center for Bioinformatics and Biotechnology, St. Jude Children's Research Hospital
1997-2005	Adjunct Faculty, Dept of Natural Sciences, Southwest Tennessee Community College, Memphis, TN
2003	Self-employed genomics analyst and scientific writer and editor for functional genomics-based research projects.
2003-2006	Assistant Research Faculty, Department of Surgery, Transplant Division, University of Tennessee Health Science Center, Memphis, Tennessee
2004-current	Research Biologist, VAMedical Center, Research Division, Memphis, TN
2006 (June 1)	Associate Professor and Director of Surgical Research, Department of Surgery, School of Medicine, Meharry Medical College, Nashville, TN

Other Experience and Professional Memberships:

Association of Biomolecular Resource Facilities (ABRF)

American Association for the Advancement of Science (AAAS)

Honors:

University of Delaware, Graduate Women of Excellence, 1987, 1988, 1989

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USDA Certificate of Appreciation “For Volunteering Time and Expertise In Support of the EEO Program” February 1991

USDA Certificate of Appreciation “For Volunteering Time and Expertise with the Summer Intern and Apprenticeship Students”, July 1992

USDA Certificate of Merit “For Dedication and Commitment to Teaching Young People Science and Excellence in Performing Ancillary Duties in the Laboratory”, July 1992

B. Selected peer-reviewed publications (in chronological order).

Marshall DR, Simmons DG, Gray JG. Evidence for adherence dependent cytotoxicity of *Alcaligenes faecalis* in turkey tracheal organ cultures. *Avian Dis.* 28:1007-1015, 1984.

Marshall DR, Simmons DG, Gray JG. An *Alcaligenes faecalis* isolate from turkeys: pathogenicity in selected avian and mammalian species. *Am J Vet Res.* 46:1181-1184, 1985.

Marshall DR, Reilly JD, Liu X, Silva RF. Selection of Marek’s disease virus recombinants expressing the *Escherichia coli* gpt gene. *Virology.* 195:638-648, 1993.

Gong-Y-F, **Marshall DR**, Srinivas RV, Fridland A. Susceptibilities of zidovudine-resistant variants of human immunodeficiency virus type 1 to inhibition of acyclic nucleoside phosphonates. *Antimicrob Agents Chemother.* 38:1683-1687, 1993.

Robbins BL, Connelly MC, **Marshall DR**, Srinivas RV, Fridland A. A human T-lymphoid cell variant resistant to the acyclic nucleoside phosphonate 9-(2-Phosphonylmethoxyethyl)adenine shows a unique combination of a phosphorylation defect and increased efflux of the agent. *Mol Pharmacol.* 47:391-397, 1995.

Marshall DR, Sample CE. Epstein-Barr virus nuclear antigen 3C is a transcriptional regulator. *J Virol.* 69:1689-1694, 1995.

Zhao B, **Marshall DR**, Sample CE. A conserved domain of the Epstein-Barr virus nuclear antigens- 3A and -3C binds to a discrete domain of Jκ. *J. Virol.* 70:4228-4236, 1996.

Marshall D, Sealy R, Sangster M, Coleclough C. T_H cells primed during influenza virus infection provide help for qualitatively distinct antibody responses to subsequent immunization. *J Immunol.* 163:4673-4682, 1999.

Zhong W, **Marshall D**, Coleclough C, Woodland D. CD4⁺ T cell priming accelerates the clearance of Sendai virus in mice, but has a negative effect on CD8⁺ T cell memory. *J Immunol.* 164:3274-3282, 2000.

Marshall DR, Turner SJ, Belz GT, Wingo S, Andreansky S, Sangster MY, Riberdy JM, Liu T, Tan M, Doherty PC. Measuring the diaspora for virus-specific CD8⁺ T cells. *Proc Natl Acad Sci.* 98:6313-8, 2001.

Coleclough C, Sealy R, Surman S, **Marshall DR**, Hurwitz J. Respiratory vaccination of mice against influenza virus: Dissection of T and B cell priming functions. *Scandinavian Journal of Immunology* Jul;62 Suppl 1:73-83, 2005.

Marshall D, Sabek O, Fraga D, Kotb M and Gaber AO. Examination of the molecular signature associated with islet dysfunction. *Transplantation Proceedings.* 37:3441-3, 2005.

Marshall DR, Olivas E, Andreansky S, LaGruta NL, Neale G, Gutierrez A, Wichlan DG, Wingo S, Cheng C, Doherty P, Turner SJ. Effector CD8⁺ T cells recovered from an influenza pneumonia differentiate to a state of focused gene expression. *PNAS.* 26;102(17):6074-9, 2005.

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Gerling IC, Singh S, Lenchik NI, **Marshall DR**, Wu J. New data analysis and mining approaches identify unique proteome and transcriptome markers of susceptibility to autoimmune diabetes. Mol Cell Proteomics. 5(2):293-305, 2006.

Sabek OM, **Marshall DR**, Minoru O, Fraga DW, Gaber AO. Gene expression profile of nonfunctional human pancreatic islets:predictors of transplant failure? Transplant Proc. 37:3441-3, 2005.

C. Research Support.

Ongoing Research Support

Career Development Award DAMD17-02-1-0482 Marshall(PI) 6/1/2002-6/31/2006
MCMR-AAA-R

Gene-Gene and Gene-Environment Interactions in the Etiology of Breast Cancer

This grant is directed towards the redirection of Dr. Marshall's research from that of the immune response in autoimmune and infectious diseases to one that incorporates the epidemiology of breast cancer and the role of the immune response in breast cancer.

R25 CA102209-02 Beech(PI) 8/1/2004-7/31/2009
NCIG

Student Research: Stimulus for Academic Research Careers

This goal of this program is to expose medical students to cancer research so that they may experience, first hand, the scientific process and inspire them to look at research as a possible avenue for their future as physicians.

D. Time and Effort Statement.

Research-75%, Teaching-5%, Academic Service-10%, Administrative and Other-10%.

E. Significant Life Events (OPTIONAL)

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APPENDIX D: Supplemental Fund Rationale and Needs: Summary of the Meeting with the Advisory Board and Executive Committee

The main points from the 2nd PCRPA Advisory Board/Executive Committee Meeting: Presentations by each pilot project PI was followed by very fruitful and exhaustive deliberations, with lots of useful comments, observations and advice from members. The main observation was that PIs have made appreciable progress since the DOD site visit, and that the program did not have enough funds to meet all its goals.

It was suggested that the DOD be approached for possible supplemental funds.

1

- a) The program did not have salary support for the basic science members of the group. Each PI will need at least 10% salary support to protect their time for this program.
- b) One full-time laboratory technician to support Dr. Ogunkua and Dr. Cui.
- c) Funds required for pilot project 3 DNA extraction and Genotyping=

3 Epidemiology Projects: (3 pilot projects)

- a) Dr. Ukoli's project:
 - i. 200 additional lycopene analysis
 - ii. 50% increase for 100 case participant incentive
 - iii. Physician/urology office staff time-effort for processing records for potential participant eligibility.
- b) Dr. Washington's project:
 - iv. Increase salary support to 10%
 - v. 200 participant cash incentive
- c) Special strategy to improve participation of prostate cancer survivors
 - vi. Full-time recruiter, Prostate cancer survivor
 - vii. UsTOO Meharry (support group start off funds)

* Supplement by 2007/2008 of

APPENDIX E Description of Study Participants: Preliminary Analysis (Project 1)Table 1: Number of Participants Recruited Per Year by Study Site

Study Site	STUDY YEAR			Total N	%
	2005 Parent Study	2006 Parent Study	2007 Current Study		
Nashville	85	76	25	186	56.5
Nigeria	82	19	42	143	43.5
Total	167	95	67	329	100.0
%	50.8	28.9	20.3	100.0	

Table 2: Prostate Diagnosis of Study Participants by Study Site

Diagnosis (Prostate)	Study Site		Total	
	Nigeria	Nashville		
CASES	37(25.9)	23(12.4)	60	18.2
CONTROLS	33(23.1)	131(70.4)	164	49.8
Elevated PSA (Normal DRE)	24(16.8)	8(4.3)	32	9.7
Elevated PSA + BPH	18(12.6)	0	18	5.5
BPH only	23(16.1)	17(9.1)	40	12.2
Not Recorded*	8(5.6)	7(3.8)	15	4.6
	143	186	329	

* No stored blood sample or Incomplete data

Table 3: Age Distribution of Study Participants by Study Site

Age Group (years)	Study Site		Total	
	Nigeria	Nashville		
< 55	23(17.3)	104(58.1)	127	40.7
55 - 64	43(32.2)	53(29.6)	96	30.8
65 - 84	61(45.9)	22(12.3)	83	26.6
> = 85	6(4.5)	0	6	1.9
Total	133	179	312	
Not Recorded	10(7.0)	0	10	3.1
Total	143	179	322	

Table 4: Educational Status of Study Participants by Study Site

Educational Status	Study Site		Total N	%
	Nigeria	Nashville		
< 6 years	25(18.9)	0	25	8.0
6 – 11 years	48(36.4)	21(11.7)	69	22.2
12 Years (High School)	19(14.4)	80(44.7)	99	31.8
Some college	15(11.4)	12(6.7)	27	8.7
College Degree	20(15.2)	51(28.5)	71	22.8
Post-Graduate Degree	4(3.0)	15(8.4)	19	6.1
Total	132	179	311	
Not Recorded	11(7.7)	0	11	
Total	143	179	322	

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Table 5: Current Job Status of Study Participants by Study Site

Job Status	Study Site		Total	
	Nigeria	Nashville		
Unemployed	5(3.8)	36(20.1)	41	13.2
Retired	68(51.1)	30(16.8)	98	31.5
Part-Time	7(5.3)	27(15.1)	34	10.9
Full-Time	53(39.8)	60(33.6)	113	36.4
Disabled	0	26(14.5)	26	8.4
Total	133	179	312	
Not Recorded	10		10	

Table 6: History of Urinary Symptoms by Study Site

Urinary Symptoms	Study Site		Total	
	Nigeria	Nashville		
Absent	24(18.0)	109(60.9)	133	42.6
Present	109(82.0)	70(39.1)	179	57.4
Total	133	179	312	

Table 7: History of Physical Examination Including DRE by Study Site

DRE History	COUNTRY		Total	
	NIGERIA	USA		
Never	73(54.9)	70(39.1)	143	45.8
Yes	60(45.1)	109(60.9)	169	54.2
Total	133	179	312	

Table 8: Prostate Status at Previous DRE by Study Site

Prostate Status	Study Site		Total	
	Nigeria	Nashville		
Normal	1(1.6)	81(74.3)	82	48.5
Enlarged (Benign)	10(16.7)	10(9.2)	20	11.8
Abnormal (? Cancer)	3(5.0)	5(4.6)	8	4.7
Prostatitis	0	1(0.9)	1	0.6
Don't Know	45(75.0)	7(6.4)	52	30.8
Total	60	109	169	

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Table 9: Current Prostate Status at DRE by Study Site

Prostate Health	Study Site		Total	
	Nigeria	Nashville		
Normal	30(30.3)	108(85.0)	138	61.1
Enlarged No Symptom	10(10.1)	8(6.3)	18	8.0
Enlarged With Symptoms	37(37.4)	7(5.5)	44	19.5
Abnormal Cancer Suspected	22(22.2)	4(3.1)	26	11.5
Total	99	127	226	
Not Recorded*	34(25.6)	52(29.1)	86	27.6
	133	179	312	

* Refused DRE, Already diagnosed with cancer, DRE not done

Table 10: Type of Health Insurance of Participants by Study Site

Health Insurance	Study Site	
	Nigeria	Nashville
Private Insurance/HMO	N/A	49(27.4)
Medicare	N/A	35(19.6)
Medicaid	N/A	16(8.9)
Veteran	N/A	18(10.1)
Employer Reimburse	2(1.5)	5(2.8)
None (Self-Pay)	131(98.5)	56(31.3)
Total	133	179

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