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14. ABSTRACT African Americans (AA) are disproportionately affected by prostate cancer (PCa) for reasons including, biologic tumor differences, genetic predisposition, differential exposures, lack of access to prostate specific antigen (PSA) testing, inadequate access to health care, paucity of minority PCa investigators, and low accrual of AAs in clinical trials. We propose a research team at an HBCU to study the molecular, genetic, dietary, and body fat patterns in the pathogenesis of PCa disparity among AA and African men. There is substantial urology, oncology, epidemiology, nutrition and other expertise in both institutions, now developing this program at MMC, by training new and junior minority investigators, maintaining lasting partnership with mentors, and establish viable community network ties. One project will investigate health care seeking behavior of AA, another will investigate the role of lycopene in PCa risk, a third will look at genetic risk factors, and two studies will study the growth inhibitory effect of Thalidomide and other agents on PCa cell lines. The program has attracted graduate students, has identified, and is currently in the process of hiring a second post-doctoral fellow.					
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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 Prostate Cancer Research Program (PCRP) has 12 members at Meharry Medical College (MMC), and 6 mentors/collaborators from Vanderbilt University Medical College (VUMC) who are working on partially overlapping PCa topics at the genetic, molecular, clinical and epidemiological levels. 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 PCRP at the completion of this Department of Defense (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.

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 (1-3 months)**

Meetings with PCRP members, principal administrative officers at Meharry, selected community leaders:

(A) Planning Meetings:

The Inaugural Executive Committee (EC) meeting was held in April, 2005, in the office of Dr. Robert Matusik to set up guidelines for organizing and evaluating the PCRP. The three main groups of the PCRP were to remain as follows:

Table 1

Research Team	Mentor
Basic / Laboratory Science Research	Dr. Robert Matusik
Translational Research	Dr. Michael Cookson & Dr. Jason Morrow
Clinical Research	Dr. Robert Dittus
Outreach Core	Dr. Margaret Hargreaves & Dr. Flora Ukoli (Program PI)

Evaluation of progress will be conducted at the research team level, and opportunity to present progress to the PCRP will be scheduled twice a year.

Main outcomes of this meeting:

Guidelines for evaluating pilot projects was established:

1. Establishment of Trainee PI / Mentor relationship: The PI should meet with the Mentor at least once every month, and more often as necessary, to receive directives from the mentor and to present pilot project progress update.
2. Present progress report at PCRP seminar/meetings to be held twice annually.

Inaugural PCRP meeting: Individual meetings were held between the PI and the various members of the group, and their working plan, and time lines were discussed. These meetings

served as the starting point of active collaboration, and it was agreed that our first annual meeting should serve four purposes:

- i) An official inaugural meeting of the PCRCP
- ii) A forum to exchange ideas about strategies to succeed as a team
- iii) A forum for the PIs (and mentor) of all program pilot projects to present their progress to the PCRCP. This meeting was held on October 26, 2005, it was well attended (only 2 were absent), and the presentations were excellent. The very close working relationship between the PIs and their mentors was demonstrated. Quarterly seminars were scheduled to begin in the second year of the program.
- iv) Announcement of cancer and related seminar series in both institutions that are open to all PCRCP members. All those who were not already on the mailing lists of such series will be included immediately.

Main outcomes of this meeting:

1. Members of the PCRCP officially met each other by the self-introduction.
2. The goals and objectives of the PCRCP was presented by the PI, Dr. Ukoli, and clarification was provided as requested by members.
3. Trainee PI/ Mentor pairs were officially introduced.
4. 4 pilot projects were presented by the trainee PIs. The presentation included a brief introduction, aims and objectives and methods. Each presentation was scheduled for 15 minutes. PCRCP members made comments and provided useful input.
5. Pilot progress update:
 - a. Dr. Ukoli's project: Completed protocol and consent forms etc. Received MMC and UBTH IRB approvals. Submitted application to DOD HSRRB, and awaiting their approval.
 - b. Dr. Stewart's project: Completed study protocol, and to submit to MMC for IRB exemption.
 - c. Dr. Washington's project: To complete protocol, consent forms etc., and to submit MMC IRB application.
 - d. Dr. Ogunkua project: To complete protocol and submit to MMC IRB for exemption.

Pilot project group inaugural meetings were held between the designated mentor and trainee PI in the mentor's office. This was then followed by research group meetings in the offices the individual pilot project PIs.

Dr. Ukoli's group: This group was made up of a Post-Doc, a research assistant and a research associate. This is a community-based study, and the focus was on IRB training, community outreach activities, and data collection skills with questionnaires, handling of study samples, and creating of database and data entry techniques.

Dr. Stewart's group: This group was made up of a graduate student and a research assistant. This is a laboratory-based study, and the focus was on the development of laboratory skills and techniques.

Meetings:

- i) Inform group members about the objectives of the project, their roles in the project, and to begin to train them to carry out their individual responsibilities. All those who required IRB training were shown how to take the online training.
- ii) Subsequent meetings involved updating the PI about activities carried out.

Dr. Washington and Dr. Ogunkua did not have a group at this time, and so did not hold group meetings.

Other business meetings:

Meharry Medical College administration:

Separate meetings were held with the Vice-President, Research (Lee Limbird, Ph.D.), the Associate Vice-President, Grants Management & Compliance (Peter J. Dolce, Ph.D.), and the Dean, School of Graduate Studies (Maria F. Lima, Ph.D.), who are now conversant with the program objectives. The aim of these meetings was to ensure that everyone was on the same page regarding the program. At these meetings the PI explained in detail what was expected to be accomplished by the program.

In February 2006, Dr. Dolce called a special meeting of all pilot project PIs in the PCRCP in order to facilitate collaboration between the individual groups. This was to ensure the understanding that the PCRCP, although made up of 5 research groups, can only succeed when there is strong inter-group collaboration. This meeting became necessary because none of the PIs had secured IRB approval from DOD. Besides the program had recruited a new PI, Dr. Cui, and Dr. Ogunkua had decided to change his pilot project to involve animal studies, rather than just animal cells.

Main outcomes of this meeting:

- 1 All PIs need to complete their protocol within 2 weeks and submit to MMC IRB for approval. Those who already have MMC should ensure that they provide all necessary documents to HSRRB so as to secure their approval as well.
- 2 All PIs should work closely with their mentor.
- 3 Dr. Ukoli should intensify efforts to replace her research group by advertising, interviewing and hiring a new post-doc and a new research assistant immediately.

In May 2006, the PI held a meeting with the Director of the Clinical Research Center (CRC) at Meharry, and was assured of their support in participant recruitment efforts, and the provision of phlebotomy services.

Interdenominational Ministers Forum (IMF):

The PI and the outreach coordinator met with the executive of the Interdenominational Ministers Forum in Nashville, and 50 other clergy ministers to intimate them about our program, to solicit their cooperation in planning health education forums at their churches, and permitting the distribution of study flyers / brochures to their congregation.

(B) Program Staff:

Research associate, Mariam Ladipo, MPH., was identified to coordinate the activities of the outreach core, and to later assist with participant recruitment and data collection.

Graduate student, Jennifer Murphy was hired part-time to begin training under the supervision of Dr. Ukoli. A second graduate student was hired through the work-study program to begin training under the supervision of Dr. Washington.

Resident Doctor, Emeka Amaefuna, M.D., in the Department of Preventive Medicine at Meharry was identified to assist with prostate cancer screening activities, to train to collect epidemiological data, is registered in the Meharry MSPH program, and is currently developing a thesis to compare the fatty-acid profile of African-American and African men.

Post-doctoral fellow, Jean Dessources, M.D., was interviewed and hired for the program. He completed training like the above, and was required to start developing a quality of life proposal to be submitted for a career development award. To facilitate this process, he was required to attend a course in epidemiology and biostatistics. He however decided to resign his appointment so as to enroll in a full-time masters program in public health. The response to a new advertisement for this position was encouraging with 5 candidates from outside the United States, 8 from the United States, including 2 from Meharry Medical College. After careful deliberations two candidates were invited, and interviewed by members of the PCRPP, and by the Dean of Graduate studies. They were both found suitable for appointment, and are going through the process of being hired. Contact is maintained with two other candidates to be interviewed if the need should arise.

Graduate student, Amy Oringi, was recruited by Dr. Washington to work on the development of his pilot project protocol, consent forms, and IRB application process. This student was funded as a work-study student.

All staff members completed an online Human Subjects Protection Training offered by the CITI online program, after attending a training workshop offered by the Ms. Cynthia Weaver, Meharry IRB administrator. Staff members were provided with appropriate reading materials to increase their knowledge about Human Subject protection. The staff was also trained by Dr. Flora Ukoli to recruit, consent, and interview study participants, and to manage specimens and data. This was a hands-on (role-play) process conducted by the PI as follows:

- Staff members were involved in health fairs where they assisted the PI, and understudied the process of introducing research subject to potential participants. They actively participated in recruiting participants.
- PI asked staff to pretend to be a participant, and be consented and interviewed by the PI. The staff was asked to observe what the PI did and was free to ask questions as needed.
- The staff then consented and interviewed the PI as a participant.
- Staff members interviewed each other in the same way.
- Staff members watched the PI consent, and interview real study participants in an existing study.
- Staff member then started interviewing study participants in the existing study.
- All staff were trained to collect data, handle samples, enter data under close supervision by the PI, Dr. Ukoli.

Product: (This phase of the program has been completed)

Meetings to foster collaborative strength.

Full-time post-doctoral fellow hired part of the first year.

Two part-time graduate research assistants (GRA) hired.

Resident doctor developing a PCa dietary risk factor related thesis for MSPH degree.

Table 2:

Position	Name	Comments
Research Associate	Mariam Ladipo, M.P.H.	Coordination of Outreach Core activities.
Graduate Student	Jennifer Murphy	Training under Dr. Ukoli
Graduate Student	Amy Oringi	Training under Dr. Washington
Resident Doctor	Emeka Amaefuna, M.D.	Enrolled in the Masters of Science in Public Health (MSPH) program Conducts prostate cancer screening To train in collecting epidemiological data
Postdoctoral Fellow	Jean Dessources, M.D.	Trained under Dr. Ukoli. Candidates are being interviewed to replace him because he resigned.

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

The Outreach Core is made up of the PI, Margaret Hargreaves, Ph.D., and an outreach coordinator, Marian Ladipo, MPH. It was therefore important to hold meetings with leaders of other outreach cores within both institutions to solidify plans for cooperation. This was achieved in a meeting with Dr. Margaret Hargreaves (Meharry Outreach), Pamela Hull (Tennessee State University Outreach), and Elizabeth Williams (Vanderbilt-Meharry Alliance Outreach). This program will develop its own community network strategies in line with the activities of other outreach and cancer coalition activities in Nashville to avoid duplication of efforts, and possible mixed messages in the community. The PI intends to make use of existing contact in a previous program with lay representatives (Ron Weathersby, Folusho Micah), who have been active in expanding our community networking base.

Outreach Committee:**Table 3:**

Individual members	Position or Organization
Margaret Hargreaves, Ph.D.	Committee Chair
Flora A.M. Ukoli, MBBS., MPH	Program PI
Jennifer Murray	Graduate Student
Gordon Bonnyman, Jr.	Tennessee Prostate Cancer Coalition
Samuel Scales	Tennessee State University Outreach
Tene Franklin	National Association for the Advancement of Colored People
Victor Singletary, Rev.	Minister
Folusho Micah	Lay Minister
Ron Weathersby	Community Representative
Patricia Albrecht	Prostate Research International Mission in Education (Non-profit)

Results of these meetings:

- 1 Each member agreed to be included in this committee
- 2 Members were willing to introduce the PI to groups and organizations in the Nashville community that they were associated with, and to facilitate the process of participant recruitment when the study takes off.
- 3 Members also agreed to look for other organizations that can be approached in the same way to increase the outreach community network.

List of physicians:

William Hughes, M.D.	Urologist
Michael Cookson, M.D.	Urologist
Emeka Ikpeazu, M.D.	Oncologist
Alphonse Pasipanodya, M.D.	Surgeon
B. Bamigboye, M.D.	Primary Care
Havey Latimer, DDS.	Dental Surgeon

Results of these meetings:

- 1 The doctors were receptive to the PI's plan to distribute flyers at their office, and to speak with patients who were waiting to consult about the proposed study.
- 2 None of the doctors was able to confirm that their office staff will talk to patients about the study.

This list will be expanded as more physicians and surgeons in the Nashville area who see African American (AA) and African patients commit to supporting the program. Their support is limited to allowing information about this program to be displayed or distributed in their office.

Health Institutions:

Nashville General Hospital
Mathew Walker Comprehensive Health Center
Vanderbilt Medical Center

Community Groups and Organizations:

These groups have agreed to support program activities, and help to develop the most appropriate way of reaching the members of their community.

Interdenominational Ministers Fellowship (IMF)

Churches (10) List to be expanded.

The Church of Christ at Buena Vista Pike
Cleveland Street Baptist Church
The Church of God Sanctified, Inc. (Trinity Lane)
Greater St. John Missionary Baptist Church
Born Again Church
Jefferson Street Missionary Baptist Church

15th Street Baptist Church
Fairfield Missionary Baptist Church
Nashville's Corinthian Missionary Baptist Church
First Baptist Church Capitol Hill,
Chapel of Peace, Inc

100 Black Men of Nashville

NAACP

Newspapers:

Urban Journal

TN Tribune

Nashville pride

Globe and Mail

The Tennessean

News Channel 5 (Television): "Urban Outlook"

TN State Cancer Control Coalition

List of barbers shops contacted around Meharry (available)

Prostate Cancer support groups:

American Cancer Society: Man-to-Man

USTOO International

PRIME (Prostate Research International Mission in education, Non profit organization)

Products: (This Phase of the project has been completed)

Individual telephone conference with 3 members of the Outreach committee.

One Outreach Core working meeting, attended by 4 members

Contact listing of African-American churches in Nashville.

Individual meeting with 2 urologist, 1 oncologist, and 1 family physician.

Individual meetings with physicians at Meharry Medical College

(Family physicians, Internal Medicine & Surgery)

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

Training:

Members of the PCRCP attended and completed training in the following:

Human subject protection (All Members)

Data collection by interview (Post-doctoral fellow, Research Assistant)

Other lectures:

Epidemiology of cancer

Epidemiology of prostate cancer

Practical experience:

These activities were conducted within the PI's on going DOD funded study, "Dietary Fat and Vitamin E in Prostate Cancer Risk among African Americans and Africans: A Case-Control Study," Proposal Number PC010092, Award Number DAMD17-

02-1-0068, HSRRB Log Number A-11105.a. Data collection has not been initiated in the current study.

- Participant recruitment, making professional calls, consenting participants
- Collection of quality research data using the study instruments and FFQ
- Samples/specimens collection, handling, labeling, storage and shipping.
- Medical records abstraction has not yet been addressed.

Products: (This Phase of the Program has been completed)

People undergoing training in prostate cancer research:

4 faculty members (new prostate cancer investigators)

1 resident doctor, 1 post-doc, 2 graduate students, and 1 research associate.

Outcome:

The PIs, resident doctor, and the post-doc acquired competences, confidence and cultural sensitivity to recruit and retain study participants.

Graduate students have demonstrated interest, and are beginning to developed ideas about PCa research.

Deliverables:

- Training program lecture schedule (See Appendix C).
These lectures are planned to begin in the second year of funding.
- Bi-weekly tutorial and learning contact with respective mentors has been initiated and is ongoing.

Task 3b. Development of Consent & HIPAA Forms, Submission of IRB application

Table 4.

Pilot Project PI	IRB	HSRRB
Dr. Ukoli	Initial approval received MMC May 2005 UBTH May 2005	Submitted two revisions (Nashville). Submitted one revision (Nigeria)
Dr. Washington	Initial approval received from MMC	Application submitted, first revision received.
Dr. Stewart	MMC IRB Exemption received	HSRRB Exemption approved.
Dr. Cui	MMC IRB Exemption received	Application submitted, first revision received.
Dr. Ogunkua	MMC IRB Exemption for cell study. To Submit to IACUC (Institutional Animal Protection Office)	Notice to submit application to Animal care & Use office (ACURO)

HIPAA and consent forms for the two studies that require human subject protection have been developed by Dr. Ukoli and Dr. Washington.

The PIs of all the 5 pilot projects have submitted their IRB application to Meharry IRB as applicable.

IRB initial approvals received:

Dr. Ukoli: From Meharry and from UBTH (Nigeria)

Dr. Washington: From Meharry

Dr. Stewart: From Meharry. IRB Exemption status received.

Awaiting IRB exemption status approval: Dr. Cui & Dr. Ogunkua

HSRRB approval received: Dr. Stewart

Awaiting HSRRB approval.

Dr. Ukoli: Already submitted 2 revisions each for the Nashville and Nigerian study sites.

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

Seminar Series Attendance:

Vanderbilt

Epidemiology Seminar series (Weekly): Members who attend will include Dr. Ukoli, Dr. Malin, Dr. Washington, Dr. Cui, Post-Doc fellow, and graduate student who has selected an epidemiological study for their MSPH thesis.

Urological Workshop on Research (Weekly): Members to attend include Dr. Stewart, Dr. Ogunkua, Dr. Cui, Post-doc, and interested graduate student who has selected a basic science topic for their MSPH thesis.

VICC Seminar series (Weekly): All members of the PCRCP will attend when a topic of interested related to their interest area is being presented.

Meharry

Grand rounds in surgery, and internal medicine (Monthly): All members of the PCRCP will attend especially when a topic relevant to their research interest is being presented.

Center for Health Research TN State University (Weekly): All members of the PCRCP will attend especially when a topic relevant to their research interest is being presented.

Mathew Walker Surgical Symposium: Presentation by PI.

“Recruiting Minorities for Prostate Cancer Research with Respect, Beneficence, and Justice”

All members of the PCRCP is expected to attend seminars and conferences, especially when a topic relevant to their research interest is being presented. His process has started

and is ongoing. Each member of the PCRCP is advised to attend at least one relevant seminar weekly.

Workshops and Conferences:

TN State Cancer Coalition
Nashville Community Health Disparity Summit

Pilot Project Progress Report:

Each PI made a PowerPoint presentation at one of the meetings, and received constrictive criticisms from PCRCP members. PIs are expected to present updated versions at the proposed DOD site visit scheduled for May 2006.

It is expected that all pilot projects will be initiated within the first half of 2006. Dr. Stewart has initiated her own pilot study.

Deliverables:

Seminars: 2 in the 1st year.

Products:

5 Pilot project presentations

Annual program report.

(This Phase of the Program has started and will continue throughout the study duration)

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

Schedule and Organize PCa symposium/screening

IMF/ Churches: 8

Fraternity: 1

Association: 1

Housing complexes)

Recreation centers) To be scheduled:

Work places)

Radio Program: Fisk University Radio: Recorded and aired PCa program. (PI, urologist and Co-PI)

Television Program: News Channel 5: Recorded PCa research program at Meharry. This was aired 12 times weekly for 3 weeks.

Distribution of flyers/brochures: (This Phase of the program has not started)

No pilot project has been initiated. The program PI is however actively recruiting participants into another prostate cancer study, and is therefore distributing prostate cancer information and flyers at several churches, Meharry Medical College clinics, 3 doctor's offices, 5 stores, Nashville airport taxi-drivers stand, and at an African workers' party. People are informed that this is just one in a series of prostate cancer related studies, and that participating in one study may not exclude them from participating in another study.

Deliverables:

Community-based PCa health education presentation	8
Community-based PCa screening activity	1 (Senior Expo)
MMC-based PCa screening (available daily)	Appointments
Radio/Television program recorded	2
Study brochures, Study flyers	Developed.

Products:

Men who attended community outreach education (Approximate) 200

Although 108 men have been screened for PCa through our outreach activities, this cannot be reported as a product of this program

Task 5 b. Subject Recruitment and Data Collection. Research Projects: (6 – 36 months)

This PCRP started off with three pilot projects (PIs, Ukoli, Stewart, & Washington), a 4th project (PI Ogunkua) was added in August 2005, and a 5th project (PI Cui) in November 2005.

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

A HSRRB review of the PCRP was received, and all comments about the program were addressed in September 2005, including the submission of biographical information of the two additional new investigators, evidence of human protection training by all investigators and mentors, and a training plan for the post-doctoral fellow, graduate students, and new investigators in the program. The PI awaits comments from the HSRRB.

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.

Nashville Site:

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

IRB application was submitted to Meharry IRB, and approval was received in May 2005. The post-doctoral fellow (Jean Dessources, M.D.) resigned before completing this process. The PI did not submit a revision of this protocol to the HSRRB for review as our plan was to allow the program post-doctoral fellow to process the HSRRB application as part of a training process. We have interviewed two candidates for this position, and we are yet to hire a new post-doctoral fellow. By November 2005 it became mandatory to process this application, and the PI submitted all documents with the requested revisions to HSRRB in December 2005. Once the final review is received from HSRRB, the comments will be reflected in the protocol, consent forms, and the recruitment materials, and the revised documents will be submitted a second time to the Meharry IRB for their approval.

The PI has been informed by Jo Collins, M.S.A., Human Subjects Protection Scientist (AMDEX Corporation) to expect further information in due course.

Nigerian Site:

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

The collaboration with our colleagues at the University of Benin remains strong, and an additional urologist has joined the group. IRB approval was received from the University of Benin, but because their registration with NIH expired, this document was rejected by HSRRB. Revised protocol, consent forms, and the recruitment materials have been submitted to HSRRB, and once their final review is received, a new IRB application will be submitted a second time to the University of Benin, Nigeria, for their approval. The IRB of the University of Benin has now been registered with NIH. The Benin team is still directed by Prof. Usifo Osime, and includes two urologists, Dr. Philip Akumabor and Dr. Temple Oguike.

The PI has been informed by Jo Collins, M.S.A., Human Subjects Protection Scientist (AMDEX Corporation) to expect further information in due course.

Products: Recruitment has not started.

Deliverables:

Database and survey instrument development from the office of Dr. Dittus:

In collaboration with Mr. Wande Guo (Vanderbilt), a computer-based data collection tool has been designed to collect and store research data. This instrument is currently being tested.

Presentation:

A description of the study was presented to the PRCP at the annual meeting that was held in October 2005.

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 joined the PCRCP team in November 2005 to conduct basic science research, has written a protocol, and submitted an application for Meharry IRB approval of an exempt status on 03/09/06. An HSRRB application will be submitted in the first week of April 2006. Dr. Cui will be conducting genetic analysis on stored blood samples of cases and controls, without identifiers. He will be working with blood samples from 100 prostate cancer cases and 200 controls from Washington DC, and Nigeria, with a tentative start date of April 2006. Dr. Cui will be mentored by Dr. Dittus, and also by Wei Zheng, M.D., Ph.D. of Vanderbilt University with whom he has established very cordial and productive working relationship. This is very important as Dr. Cui will be able to work from Dr. Zheng’s laboratory until he develops his own laboratory at Meharry.

[Dr. Cui replaces Dr. Olufemi Adegoke who is no longer on Meharry faculty because of illness.]

Products: Blood samples from 300 Africans and African Americans stored without identifiers by Dr. Ukoli are available for this project.

Deliverables: The research protocol has been developed. Dr. Cui can start DNA extraction in Dr. Zheng's laboratory at Vanderbilt University.

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

“Prostate Cancer Health Care Seeking Behavior of African American Men.”

Dr. Washington will be interviewing 200 African American men, has developed a survey tool, consent form, a proposal, and has applied for Meharry IRB approval. He received comments from the IRB that has been addressed, and is waiting for an approval letter before submitting a HSRRB application in the first week of April 2006. Dr. Washington has also received guidance from Dr. Dittus, and will be working with the program Outreach Core to develop strategies to find potential study participants, with a tentative start date of May 2006.

Products: Recruitment has not started.

Deliverables: Survey instrument has been developed.
A description of the study was presented to the PRCP at the annual meeting that was held in October 2005.

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

“Inhibition of Prostate Cancer Growth by Thiazolidinediones”

Dr. Stewart will be working with commercial prostate cancer cell line, has written a protocol, submitted an exempt status application to Meharry IRB, received Meharry IRB approval, and an HSRRB application was submitted 03/09/06, and approval received 03/13/06. The tentative start date for this project will be March 2006. There is very close working relationship between Dr. Stewart and her mentor, Dr. Matusik.

Products: Prostate cancer cell line has been purchased.

Deliverables: Research protocol has been developed.
IRB approval obtained from MMC.
HSRRB approval received March 2006.
Dr. Stewart's laboratory is functional.
A description of the project was presented to the PRCP at the annual meeting that was held in October 2005.

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

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

Dr. Ogunkua joined the PCRP in August 2005, will be working with commercial mouse prostate cell line, has written a protocol, has received exempt status from Meharry Institutional Animal Care and Use Committee (IACUC), and the documents for the Animal Care & Use Office, ACURO) is to be prepared and submitted immediately. The tentative start date for this project will be the May 2006. There is very close working relationship between Dr. Ogunkua and his mentor, Dr. Matusik.

Products: Animal prostate cell line has been purchased by mentor.

Deliverables:

Research protocol has been developed.

IACUC exempt status received.

Pending HRSSB approval.

Dr. Ogunkua will run his experiments in Dr. Matusik's laboratory until his own laboratory is set up at Meharry.

A description of the project was presented to the PCRP at the annual meeting that was held in October 2005.

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

-Create database for pilot projects in SAS, SPSS or EXCEL, enter demographic, quality of life, health behavior, anthropometric, genetic, laboratory, dietary, and other epidemiological data into database as they become available, analyze specific data as applicable, calculate odds ratio for each risk factor for both ethnic groups separately and for the combined group. Complete other statistical analysis.

Deliverables:

A database has been created in SPSS for pilot project 1, and a computer-based electronic data collection program has been developed in ACCESS for this project.

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

A. Poster presentation by PIs at program seminars once a year, at EC meetings once a year and at scientific conferences at the 16- and 32-month time points.

B. Manuscript preparation presented at local and external seminars and communicated to peer-reviewed journals and scientific meetings for publication.

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

This part of the program is Not Due at this time.

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

This part of the program is also Not Due at this time, and will be addressed starting from January 2007.

KEY RESEARCH ACCOMPLISHMENTS:

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

1. A prostate cancer research program (PCRP) has been formed at Meharry Medical College, prostate cancer research is being conducted actively, and the program is geared to sustainability.
2. Five vibrant research teams have been formed in collaboration with investigators from Vanderbilt University.
The teams are made up of 4 new prostate cancer investigators, 3 junior investigators, and 2 graduate students.
3. Dr. Stewart has submitted a DOD New Investigator Award, and an NIH Career development Award.
4. This program has an international component in collaboration with the University of Benin, Nigeria, and plans to expand this endeavor.
5. The program has developed one research laboratory, and in the process of developing two other research laboratories.
6. Identified another faculty member at Meharry whose laboratory can be expanded to run the assays for pilot project 1.
7. The program is developing a strong network with the community, now has a functioning outreach committee, and have delivered prostate health and research related presentations at the community level:
Flora Ukoli. “Recruiting Minorities for Prostate Cancer Research with Respect, Beneficence, and Justice” Symposium at Meharry.
Flora Ukoli. Taking Control of Your Prostate Health: The Importance of Early Detection on Prostate Cancer. 8 community-based events
Flora Ukoli. Participating in Prostate Cancer Research. 6 community events
8. Graduate students have been exposed to prostate cancer research, and are receiving supervision and exposure from program PIs by using sections of data collected in the PI’s ongoing study, and in this program.

Emeka Amaefuna, M.D. is studying the pattern of essential fatty acid profile among African-American and Nigerian men.
Esiri Esin, M.D. is studying the tobacco and alcohol use pattern among Nigerians and African migrants living in the United States.
Mariam Abayomi-Cole is looking at dietary patterns and colon cancer prevention.
9. Pilot Projects:
Pilot project 1
Computer-based data collection tool developed

IRB obtained. Awaiting HSRRB approval.
 Community network established
 Infrastructure to start recruiting participants is ready.
 Pilot project 2
 300 samples available for pilot project 2
 IRB Exemption obtained.
 Pilot project 3
 Survey tool developed
 IRB obtained. Awaiting HSRRB approval.
 Infrastructure to start recruiting participants is in place
 Pilot project 4
 IRB and HSRRB approvals obtained
 Cell line purchased
 PI's laboratory is running. Project has been initiated.
 Pilot project 5
 Project involves the use of animals.
 Obtained IACUC approval, and to submit ACURO application.
 Mentor's laboratory is available and ready.

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) 10 church communities
 - iii) A local prostate cancer non-profit organization
 - iv) Two local African American fraternities
 - v) 100 Black Men of America.
 - vi) NAACP
2. The clinical research center (CRC) at Meharry is actively involved in the process of supporting the program regarding participant recruitment and phlebotomy services.
3. Maintained partnership with the Nigerian research collaborators that includes an experienced general surgeon and two urologists.
4. Established very strong collaborative partnerships between Meharry investigators and their mentors and other collaborators at Vanderbilt.
5. Obtained IRB approval from TN state cancer registry.

CHALLENGES:

PCRP Membership:

There has been movement of faculty members at Meharry, leading to some interruption in activities, so new members have taken over the responsibilities of those that left, bringing with them new perspectives and enthusiasm, contributing positively to the development of the program. The program welcomes new members:

Derrick Beech, M.D. (Chair of Department of Surgery at Meharry): Co-PI

Olugbenga Ogunkua, M.D., Ph.D.
Young Cui, M.D., MSPH.

Outreach Core:

Establishing contacts with neighborhoods has been problematic as it has been difficult to identify community leaders at that level. The church listing we purchased appear to be outdated with several non-functioning telephones. In addition some of the ministers are hardly available and fail to return calls. Therefore we plan to concentrate on just 10 churches as a starting point.

Barbers shops have not been particularly responsive as the owners feel that the presence of a study personnel may be unwelcome by their clientele.

Only one of 9 grocery store managers was responsive to our desire to distribute flyers and information from their facility.

Urologist at Meharry:

Meharry is in the process of hiring a urologist, but in the mean time we have resident doctors from Vanderbilt seeing urology patients here at Meharry, and we still have the strong support of Vanderbilt urologists on the program.

Development of Laboratories:

Dr. Ogunkua continues to work out of his mentor's laboratory.

Dr. Cui will be working out of his mentor's laboratory.

Dr. Ukoli is in the process of arranging collaboration with another faculty at Meharry Medical College who can run immunoassays for pilot project 1. Budget plans need to be made for a laboratory technician for this program

Pilot Project 1.

Nashville Site:

1 Recruiting cases: Our experience from ongoing prostate study reveals the difficulty to secure the support of private physicians or urologists in the community, and this is a process we are still working on. It may be necessary to budget some administrative fee for physician office staff to encourage them to pass out study information to African American patients who are 40 years and older. Cases identified from the cancer register does not include new cases as the register is current up to 2003. Recruiting more recently diagnosed prostate cancer cases will depend on the support of local urologists, physicians, and oncologists.

2 Recruiting controls: There is need to pay more attention to outreach, offering more information and hoping that men will realize that research is not just for people who do not have health insurance, the poor, or the underserved. It appears as if the importance of research is not understood by many, such that they are not willing to make any sacrifice to participate for \$30.00 or \$40.00 incentive as they probably hear of people who receive a lot more for research.

It is possible that such incentive will attract only the unemployed, the very enthusiastic full-time employed men, while those who are on wages cannot miss a day's work for such an amount.

3 Research staff: It has been difficult to recruit a post-doctoral fellow, but 4 have been lined up for interview. It will not be cost effective to hire a RA until the post-doc is in place, so the program plans to fill both positions at the same time. The outreach assistant position was planned to be part-time, and this may pose a challenge unless the other half of funding is provided from a sister program or the institution. It will benefit the program to actually hire a fulltime program manager to provide administrative support, and coordinate both outreach and research activities.

Nigerian Site:

- 1 Biopsy in Nigeria:
 The urologists would like the program to provide them with an ultrasound guided biopsy equipment so that they can collect the standard 8-12 biopsy samples for review by the pathologist.
- 2 Dry ice:
 Sample shipping can be done quarterly because dry ice is only available in Lagos.
- 3 Graduate students:
 Collaborators in Nigeria would like to have resources to have include young investigators on their team. This was not in the budget.

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.]

This program includes 5 pilot projects that will generate a lot of pilot data that will form the basis for applying for independent research funding. This program has started on the right foot, laying the foundation for close collaboration with experienced investigators, so as to be in a position to conduct state of the art research. The collaboration between Meharry and Vanderbilt investigators is growing strong, and respective mentors have provided guidance as expected. Pilot project 4 has received both IRB and HSRRB approval at this time, and has ready started data collection. Pilot project 1 is receiving a second HSRRB review. All other pilot projects have received approval from the Meharry IRB/IACUC, have completed all HSRRB protocols, and once approvals are received will be able to start their projects by April/May 2006. The scientific objectives of these studies can be met, and the infrastructure for success is in place.

This program plans to facilitate the community cancer education effort in our research site in Nigeria. Many people accept to participate in research, and the fear of the unfamiliar prostate biopsy procedure can be overcome with time and patience. In Nashville, the program will develop a strategy to actively solicit the support of other private urologists, and physicians who have African-American patients so as to have access to inform them about the epidemiological studies in this program. Plans to continue to educate the community, to network with the people, and to gain their

trust continue to be our focus via media exposure, distribution of informational materials, and health presentations at public locations.

Given the enthusiasm of members of this team, the guidance of the experienced mentors from Vanderbilt University, the support of the new chairman of the department of surgery, and the good will expressed by the administration of both institutions, the prostate cancer research program at Meharry will certainly succeed in training and producing minority prostate cancer investigators who can submit competitive research grants.

There are no publications at this point in time, and data is yet to be collected. The state of all program tasks is summarized below.

Task 1	Months 1-3	Completed
Task 2	Months 2-6	Completed
Task 3a	Months 3-8	Completed
Task 3b	Months 3-12	Almost Completed.
Task 4	Months 3-36	Started
Task 5a	Months 6-36	Initiated: Outreach and Network in place
Task 5b	Months 6 – 36	One pilot project has started data collection 2 Grant applications submitted.
Task 6	Months 6 – 36	Initiated. Data collection tools in place.
Task 7	Months 12 – 36	Not Due
Task 8	Months 24 – 36	Not Due

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

APPENDIX A: **Updated List of PCRP Members**

Name	Institutional Affiliation(s)	Role(s) on Proposed Project or Perceived Conflicts of Interest
Meharry Medical College	HBCU INSTITUTION	
Flora A.M. Ukoli, MBBS, MPH.	Meharry Medical College	Principal Investigator
Derrick Beech, M.D.	Meharry Medical College	Co-PI
LaMonica Stewart, Ph.D.	Meharry Medical College	Investigator
Yong Cui, M.D., MSPH.	Meharry Medical College	Investigator
William Washington, DPA., MPH	Meharry Medical College	Investigator
Ben O. Ogunkua, M.D., Ph.D.	Meharry Medical College	Investigator
Alecia Malin, Ph.D., CHES	Meharry Medical College	Investigator
Emeka Amaefuna, M.D.	Meharry Medical College	Resident Doctor
Margaret Hargreaves, Ph.D.	Meharry Medical College	Member
Emeka Ikpeazu, M.D.	Meharry Medical College	Member
Billy Ballard, M.D.	Meharry Medical College	Member
Usifo Osime, MBBS, FRCS	University of Benin, Nigeria	Consultant
Philip Akumabor, MBBS, FRCS	University of Benin, Nigeria	Investigator
Temple Oguike, MBBS, FRCS	University of Benin, Nigeria	Investigator
Vanderbilt University Medical College	PARTNER INSTITUTION	
Robert J. Matusik, Ph.D.	Vanderbilt University	PI / Mentor
Robert S. Dittus, MD	Vanderbilt University	Mentor
Jason Morrow, M.D.	Vanderbilt University	Mentor
Michael Cookson, M.D.	Vanderbilt University	Mentor
Jay H. Fowke, Ph.D.	Vanderbilt University	Investigator
Marcia Wills, M.D.	Vanderbilt University	Investigator
Susan Kasper, Ph.D.	Vanderbilt University	Member

APPENDIX B:

Possible Projects Topics for Trainees:

Basic / Laboratory Science Research: (genes, cells, or animals)

- The role of neuroendocrine cells in the progression of prostate cancer to androgen independence.
- Effect of lycopene on isoprostane levels in prostate cancer prevention.
- The role of insulin growth factors in prostate cancer risk: A case - control study.
- Genetic indices of urinary system biota in prostate cancer.
- Glitazones as preventive agents for prostate cancer.

Translational Research: (diagnostic or therapeutic interventions)

Clinical Trials (Efficacy, dose, toxicity)

- Phases I - IV Clinical Trials

Intervention studies

- Lycopene and prostate cancer survival: A randomized placebo-controlled trial.
- The role of Lycopene in prostate cancer prevention among high-risk African Americans & Africans with elevated PSA

Clinical Research (disease treatment and prevention: Effectiveness, QOL)

Treatment related research

- Quality of life studies.
- Urinary Incontinence
- Erectile dysfunction

Health services research

- Prostate cancer education program for AA & minority communities in Nashville.
- Clinical, social, economic, and lifestyle determinants of quality of life after prostate cancer treatment among black and white men living in Nashville.
- Informed decision making for prostate cancer screening at community health centers in Nashville.

APPENDIX C: **Training Program Schedule**

Training Plan for Post-Doctoral Fellows and Graduate Students in the PCRP at Meharry

Career Development Committee:

Each trainee/candidate will be supervised and guided by a Career Development Committee consisting of the candidate's sponsor, the mentor, and appropriate faculty members from both institutions, and will be composed of faculty with broad expertise relevant to the trainee's research training plan. Mentors are already listed within the membership of the PCRP. Senior investigators within the PCRP and other Meharry faculty who wish to directly supervise candidates will act as sponsors. These individuals will contribute greatly to helping the candidate acquire a broad range of research skills relevant to his/her career goals.

While a sponsor will directly work with and supervise the candidate on a day-to-day basis, the mentor will meet with the candidate once a month. The Career Development Committee will meet on a scheduled basis twice per year to hear a work-in-progress discussion by the candidate and provide critical feedback. Members of the committee will contribute to the candidate's career development on a more frequent informal basis. Appropriate committees will be constituted for each candidate to meet the needs of that research domain.

Research Domains:

Potential research topics are listed as guides for candidates

1. Basic / Laboratory Science Research: (genes, cells, or animals)

- The role of chromatin A (NE marker) differentiation in prostate cancer progression.
- Effect of lycopene on isoprostane levels in prostate cancer prevention.
- The role of insulin growth factors in prostate cancer risk: A case - control study.
- Genetic indices of urinary system biota in prostate cancer

2. Translational Research: (diagnostic or therapeutic interventions)

Clinical Trials

- Phase II Clinical Trials

Intervention studies

- Lycopene and prostate cancer survival: A randomized placebo-controlled trial.
- The role of Lycopene in prostate cancer prevention among high-risk African Americans & Africans with elevated PSA

3. Clinical Research (Treatment and prevention: Effectiveness, QOL)

Treatment related research

(No topics suggested at this time)

Health services research

- Prostate cancer education program for AA & minority communities in Nashville.
- Clinical, social, economic, and lifestyle determinants of quality of life after prostate cancer treatment among black and white men living in Nashville.
- Informed decision making for prostate cancer screening at community health centers in Nashville.

Each mentor or sponsor will provide their candidate with structured and practical research training activities that are specific to their research area on a day-to-day basis within an ongoing research project.

Example:

Dr. Matusik: Metastatic tumor research training activities on NE-10 mouse model.

Dr. Ukoli: Prostate cancer dietary risk research training activities in minority communities.

Educational Training Activities:

This plan will be built on four training modalities that will come together to produce a well rounded research experience for the candidate.

A) Practical Training activities

The candidate will receive hands-on experience, and develop specific skills and competences by working within an existing research project under direct supervision of the sponsor or mentor. The scope of such activities will depend on the research domain. While basic science projects will involve expertise in laboratory techniques, methods, and measurements, lifestyle and treatment effect research will focus on participant recruitment and data collection skills.

Data management, analysis and interpretation will be important in the training of all candidates. Preparing and submitting IRB applications, developing consent and HIPPA forms, negotiating and obtaining letters of support from other collaborators will cut across all domains of research.

B) Workshops, Seminars and Conferences

Seminars:

In addition to these practical and intensive research activities, candidates will attend seminars and listen to guest presentations in both institutions and other research colleges in Nashville, such as the Tennessee State University. Current relevant seminar series on campus are run by the clinical research center at Meharry, the Epidemiology department of Vanderbilt, the Urology Research Unit Department health research seminar series. This is an important way of getting adequate and broad exposures to the world of research. It is hoped that candidates will attend 2 seminars a week. There are two aspects to this section. The trainee will learn from other experienced researchers by attendance at their presentation, and will also participate as presenters when scheduled.

Seminar series at Meharry:

-Bridges to Independence

-Clinical research center Biometrics Core series at Meharry

- Departmental Noon Conference and Grand-rounds (Department of family practice, OB/GYN, Internal medicine, and surgery)
- Department of biological sciences
- Prostate cancer research program seminar series

Seminar series at Vanderbilt:

- Department of Epidemiology
- General Clinical research center (GCRC) research skills workshop series
- Urologic surgery department: Prostate cancer lab meetings and journal club
- SPORE and other grants and Vanderbilt
- Vanderbilt-Ingram Cancer Center seminar series

Workshops, Conferences and Retreats

Arrangements will be made for candidates to attend pertinent workshops and scientific meetings that will broaden their research exposure, and provide the opportunity to network and establish relationships with other investigators all over the world. All relevant local events will be attended and the candidate will attend at least one external workshop in the year.

Example:

- Health Disparity Summit organized by the Meharry EXPORT grant.
- American Association for Cancer Research (AACR) annual workshop on the “Pathology of Cancer”, a series of lectures on the pathophysiology of cancer
- Society for Basic Urologic Research (SBUR) meeting held in conjunction with the American Urology Association
- American Public Health Association and the American College of Epidemiology are just a few of the annual meeting that include basis research, clinical studies, and poster presentations.
- U54 MMC/VICC partnership annual retreats and conference on cancer

The candidate trainee will be expected to present a poster / presentation at one local and one external meeting in the second and third year of the grant.

C) Course Attendance

There are several programs within the Meharry and Vanderbilt systems that offer courses that will be of interest to trainees, especially if they had not attended such a course in the past. Candidates may be expected to audit certain courses will provide them with a critical exposure to the subject area that is directly relevant to their proposed research work, and for their overall academic growth. This will include courses in the following areas:

Cancer Biology [4 hours] – *Advanced concepts in Cancer Biology.*

Human Genetics [3 hours] – *Background and latest advances in human genetics.*

Biostatistics [3 hours] - *Modern multivariate analyses*

Epidemiology II [3 hours] – *Concepts, principles and practices*

Special attention will be placed on the area of conduct of research especially as issues of research misconduct in the past have been identified as one of the important factors responsible for negative response towards research among minorities. This program plans to offer courses and training activities in this regard.

Responsible Conduct of Research. (Vanderbilt University and Meharry): a two-day retreat format, with lectures on a range of topics. This material is supplemented by a series of on-line tutorials that require a test to document completion. This certification is required of all investigators, predoctoral and postdoctoral research trainees supported by NIH or DOD training grants. Sponsors and mentors will engage in discussion of critical issues relating to the ethical conduct of research less formally and more regularly.

D) Development and Submission of a Grant Proposal

Candidates in this program, either pre-doctoral, post-doctoral, or faculty will be expected to develop and submit an appropriate grant proposal. The knowledge, skills and experience gained from both practice and theory will be used to achieve this end. Grant writing workshops are offered on Meharry campus through NCI, through our EXPORT grant. Our trainees will attend at least one of these workshops. Each mentor will closely supervise the trainee in developing their grant proposal at the informal and regular basis. Each trainee will be scheduled to present their proposal at the program seminar within the second half of second year of this grant, in preparation for submitting that proposal, giving time for revisions and final submission in the final year of the grant.

Pre-doctoral grant

Career development grant for post-doctoral fellows and junior faculty.

Idea award grant, R03 and R01 for other faculty.

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