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Following surgery or radiation of primary early-stage prostate cancer (PrCA), one in three patients will experience an elevation in serum prostate antigen (PSA) within 10 years. This rises to one in two at 15 years. After such evidence of recurrence, the most common treatment is androgen ablation. We hypothesize that the host-PrCA balance in asymptomatic men with biochemically recurrent PrCA, as reflected by the PSA rise, is favorably affected by an intensive, vegetable-based diet, plus physical activity and mindfulness-based stress reduction. This randomized trial will enroll 60 men with rising PSA levels along with a partner of his choice. Half of enrollees will be randomized to the intervention and half to usual care. The intervention will continue for 3 months, followed by monthly booster sessions for 3 months. Data will be collected on main study outcomes, protocol compliance and adherence, and potential effect modifiers, mediators, and confounders of treatment effect.

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A Diet, Physical Activity, and Meditation Intervention in Men with Rising Prostate-Specific Antigen (PSA)

Table of Contents

Introduction:

Prostate cancer (PrCA) is the most commonly occurring cancer, excluding skin cancer, in Western male populations (1). South Carolina, an area of high prostate cancer incidence, has the highest mortality rate of the disease in the world (2, 3). Generally, patients who present with prostate cancer are treated with either radical prostatectomy or radiation therapy or both. However, biochemically defined recurrence, marked by a rise in prostate-specific antigen (PSA), and the development of metastatic disease is common. No curative therapy exists for metastatic prostate cancer (4). Androgen ablation, the most commonly used management strategy, produces side effects whose severity has motivated a search for new strategies that could retard tumor progression and postpone such therapy (5-7). Epidemiologic and laboratory studies suggest that environmental influences may be the most important modifiable PrCA risk factors. A more complete discussion of these issues can be found in the complete study protocol.

This randomized trial will evaluate the effects of such environmental influences on PSA rise, quality of life, and circadian organization. The focus will be on the effects of a vegetable-based diet, circadian-timed physical activity and mindfulness stress reduction. Previous studies suggest that these factors promote favorable outcomes in the host-prostate cancer balance. Asymptomatic men with rising PSA values following primary prostate cancer treatment along with a partner of choice are being recruited from the Palmetto Health system and the greater Columbia, SC area. Results from this study will add to our body of knowledge of the modifiable risk factors associated with the progression of prostate cancer.

Specific Aims:

Previous studies with both animal and human models suggest diet, physical activity and mindfulness-based stress reduction produce favorable results within the host-prostate cancer balance in asymptomatic men with rising concentrations of prostate-specific antigen (PSA) following primary prostate cancer treatment. This study will evaluate how the host-prostate cancer balance, as reflected by PSA rise, the span until symptom appearance, the robustness of circadian activity/sleep and melatonin patterns, and quality of life, is affected by an intervention consisting of:

- a whole-grain diet rich in soy products, other beans and vegetables
- a physical activity regimen aimed at increasing fitness and general well-being and establishing and maintaining the circadian coordination of the subject's sleep/activity cycle; and
- a mindfulness-based stress reduction aimed at increasing the coping resources of participants in dealing with difficult emotional reactions to a prostate cancer recurrence and related physical symptoms, and to increase compliance with other components of the intervention (i.e., to use meditation and other stress reduction techniques to increase self efficacy or the belief in the subject's own ability to change his other health-related behaviors for the better).

The purpose of this study is to test the effect on PSA levels of an intensive intervention combining diet, physical activity, and mindfulness-based stress reduction in prostatectomized men after biochemical recurrence of prostate cancer. In order to assess the effect of the intervention on PSA

rates of change and doubling times from the pre-recruitment period to the end of the intervention, subjects will be compared to age-matched controls randomized to usual care.

Body:

The approved Statement of Work (On File) categorized the work objectives for the project into 5 distinct tasks, each with indications for the months from the study timeline in which these tasks will be accomplished. Due to unforeseen delays in getting Human Subjects approval from the Institutional Review Boards of the three bodies governing this research (i.e., U.S. Army, University of South Carolina, and Palmetto Health), the original study timeline was revised. The original timeline started in May 2003 (month 1) and participant recruitment was scheduled to begin in August 2003 (month 5). Final approval from all three institutions was not obtained until late March 2004, with recruitment for the first wave of participants beginning immediately after.

With the start of recruitment, data are available on the number of men contacted, the number of responses received from contacts, the number of ineligibles, and the number of eligibles. We had promising results in the beginning of recruitment with the referrals from urologists. But currently, we have to explore other avenues in order to recruit participants. We have been focusing our recruitment efforts on advertisements and health fairs, along with expanding our efforts to the surrounding Midlands areas. We have also been focusing our efforts on recruitment of men from the African-American population through various publications widely read in that population.

In the following sections, each individual sub-task outlined in the Statement of Work is indicated in bold text and by an alphabetic indicator (e.g., a, b, c,...). Our work to accomplish these sub-tasks follows in bulleted form. Where applicable, problems encountered in completing tasks are described and our plans for overcoming these barriers are outlined.

Task 1: Run-in Phase, Months 1-4:

a. Inventory and finalize all assessment instruments and data collection protocols.

- Actigraphs were purchased from MTI Actigraph. Analysis programs have been provided by Dr. Chuck Matthews to analyze the Actigraph data for physical activity involvement at baseline and six months. An instruction sheet for the proper use and return of the Actigraphs has been prepared for participants. To ensure we receive the Actigraphs in a timely fashion, half of the participants will bring their Actigraphs to us, while the other half of the group will have their Actigraphs picked up by a courier service. (Instruction letters - On File)
- The collection of 24-hour recall data at baseline and six months was added to the protocol and approved in March 2004. The protocol for this data collection is based on similar recalls done in previous studies by members of the study team (On File)
- All questionnaires and data collection protocols are housed in the study's Procedures Manual.

b. Review baseline questionnaires for completeness and for content validity.

- A baseline questionnaire packet was reviewed and compiled. All questionnaires were submitted to the Department of Defense on November 14, 2003. The packet includes the following sections:

- Demographics
- Food Frequency Questionnaire
- The Community Health Activities Model Program for Seniors (CHAMPS)
- Medical/Family History
- Personal Reaction Inventory (also known as the Marlowe Crowne Social Desirability Scale)
- Martin-Larsen Approval Motivation scale (to measure social approval)
- Perceived Stress Scale
- Anger Expression Scale

- The Perceived Stress Scale was approved to be added to the baseline questionnaire packet. This questionnaire allows for better assessment of how individuals react to stress versus simply listing the number of potentially stressful events to which they have been exposed.

c. Revise baseline questionnaire to assess demographic, health history, and family health history, as necessary.

- Questionnaires were reviewed by Dr. Wilcox and Dr. Heiney to assess for readability in this population.
- On their recommendation, the font of all questionnaires was changed to Times New Roman, type size 14.

d. Hire and train the Project Coordinator, Research Nurse, and other project staff.

- A Project Coordinator trained in nutrition and exercise science was hired in August 2003. In the fall of 2004, the role of Project Coordinator was divided into two part time positions. The original project coordinator transitioned into the role of class instructor for the intervention group and a new project coordinator, Wendy McKenzie was hired to handle the everyday operations of the study. The coordinator's biosketch is attached (Appendix A.5 – Biosketch).
- Due to HIPAA compliance, the Nurse Navigator system at Palmetto Health is being used instead of a Research Nurse. The Nurse Navigator system uses a nurse trained in patient education, who is also an employee of the Palmetto Health system, to act as liaison between the urologist/oncologist offices, possible participants and study staff. This system has been of limited use in recruitment and we have found going straight to the urologist office and their staff has produced better results.
- A chef trained in vegetarian cooking was hired in October 2003 to help develop recipes and a cookbook for the intervention group. This individual completed her duties to the study in 2004.
- An instructor trained in mindfulness-based stress reduction was hired in January 2004 to prepare class materials and teach the meditation portion of the intervention classes. Trained phlebotomists have been hired to perform blood draws at each clinic and handle the preparation and shipment of biological samples collected.
- Two Benedict College (a Historically Black College in Columbia) students and one graduate assistant from the University of South Carolina have been hired to aid in data entry and other study duties.

e. Develop the study data management systems.

- Under the supervision of Dr. Sue Heiney and Mr. Tom Hurley, Microsoft Access databases have been created to monitor recruitment, track eligibility/ineligibility statistics, and as a source of referral.
- A tracking database also was established to track participants' study compliance.

f. Develop the tracking database based on our experience with other intervention studies in the Cancer Prevention and Control Program.

- Tom Hurley, epidemiologist/biostatistian for the **Cancer Prevention and Control Program** with extensive experience in creating and managing Access databases, oversaw the development of the tracking database used by the study.

g. Train staff in all data-related and clinic-based procedures.

- Training sessions are held periodically to train Phlebotomists for the study's clinic.
- All other study personnel involved with data-related and clinic-based procedures are trained upon hire. Periodic updates and reviews are provided in our ongoing study team meetings.

h. Develop and finalize all laboratory procedures to be used in the trial.

- Dr. Shuk Mei Ho at the University of Massachusetts and Dr. Blask with the Bassett Research Institute provided protocols for the collection and shipment of the specimens they will analyze, i.e., blood and urine, respectively.
- A clinic route with directions for team members assisting in the clinic appointments has been established (On File). The clinic route and script are maintained in the study's procedures manual.

i. Finalize all biological sample collection and storage procedures to be used in the study.

- A blood collection, processing and shipping protocol along with a urine collection, processing and shipping protocol were developed and are housed in the study's procedures manual (On File).

j. Establish recruitment procedures for men entering the study.

- A bulleted recruitment outline was provided to Department of Defense contact Donna Ferrandino on March 10, 2004. (On File)

k. Establish retention procedures.

- The following retention procedures were outlined in the protocol:
  - Establish a project identity. The study identity EASE – Eating, Activity, and Stress Education was created along with a logo to support the identity. The logo was submitted in March 2003 to Donna Ferrandino.
  - Multiple contacts leading up to consent. The bulleted recruitment outline details the multiple contacts the study team makes with the potential participant before the individual consents. These contacts include mailings as well as phone calls. (On File)
  - Provision of meaningful incentives. $10 gas coupons as well as other incentives will be provided to participants each week they are enrolled in the study. The list of incentives participants will receive was submitted last year and is currently on file.

- Provision of clear communications and expectations. A brochure was created as a tool to provide clear communications. Participants also are provided with an overview of the intervention from section D.10 of the protocol as suggested by Donna Ferrandino and a more detailed description of the intervention diet (Appendix 9). Projected dates of the intervention and clinic appointments are provided during recruitment and are finalized in the welcome call and reminder letter to the participants. The welcome call script and reminder letter were submitted in March 2004 to Donna Ferrandino.
- Maintenance of between-assessment and intervention contacts. This maintenance includes weekly incentives to both intervention and control participants, thank you notes included with each incentive and phone calls to remind them of clinic appointments.

l. Finalize the intervention protocol.

- An intervention manual was created with an outline, handouts, menu and recipes for each intervention class. A copy of the manual's table of contents was submitted in March 2004 to Donna Ferrandino.
- Personnel to run the intervention were hired (dietitian trained in exercise science, instructor trained in mindfulness-based stress reduction) and a chef trained in specialized vegetarian cooking.

Task 2: Recruitment, Months 5-18:

a. Identify men who could be eligible for the study from the tumor registry and patient records at the collaborating urology practices in Columbia, SC.

- The tumor registry is not being utilized at this point.
- As of 30 April 2005, thirty patients have been referred to the study by collaborating urologists in the Columbia, SC area.
- Dr. Heiney also sent a general mailing to the 430 PrCA patients with whom she works at Palmetto Health Richland.
- The University of South Carolina's public relations department provided, and IRB approved, a Public Service Announcement to area radio stations and newspapers (On File).
- In addition to the above recruitment efforts, various cancer advocates around the state have been given the study brochure and are distributing them at area events and doctor's offices. Brochures were provided at the South Carolina Cancer Alliance (SCCA) annual meeting, cancer presentations in Greenville, South Carolina, area members of the American Urological Association (AUA), and Dr. Thomas Keane's (Chief of Urology) office at the Medical University of South Carolina (MUSC). Dr. Keane asked specifically to be able to refer eligible patients and distribute the study brochure to interested patients in his practice.
- We will also begin utilizing the South Carolina Central Cancer Registry in the late spring/summer of 2005 with letters being mailed to potentially eligible participants in the eight counties that comprise the Midlands region of South Carolina.
- We also have focused recruitment efforts on health fairs, conferences, and minority populations via publications targeted for their communities.

b. Among those who say they are willing to participate, confirm eligibility using the criteria listed in section D.2. of the proposal.

- To aid in confirming eligibility of participants. Dr. Heiney and Lynne Bridges developed a checklist, which is mailed to participants. Ms. Bridges then calls potential participants and reviews the checklist with them. All checklists and phone scripts were submitted to Donna Ferrandino on March 2, 2004.

c. Enroll 60 eligible men.

- To date, we have been in contact with 120 men of whom 31 were eligible and agreed to participate, along with their partners.

d. Establish baseline PSA levels through repeat measures taken before subjects are randomized to intervention.

- Due to HIPAA regulations, it is not possible to access patient medical records in order to obtain a history of PSA levels. Therefore, establishing a baseline PSA level cannot be achieved until written permission is obtained from the patient. This permission is collected during the participant's first clinic visit. After gaining their written consent, we obtain previous PSA levels recorded in their medical charts as well as collect a blood sample during our baseline clinic for PSA testing by Quest diagnostics.

e. Collect data on diet, physical activity, other aspects of lifestyle, demographic, and health (family and personal history), and other factors as outlined in D.4.

- Data collection began on 9 June 2004 and we continue to collect the baseline data from each group enrolled.

f. Schedule the first clinic appointment for the purposes of collecting all of the blood and urine specimens and taking the anthropometric measurements.

- The first group recruited into the study had their first clinic on 9 June 2004.
- These participants were contacted via phone and through letters. The Welcome Call script and letter were submitted to Donna Ferrandino in March 2004.

{Task 2, items g and h, and Tasks 3-4 have not been reached at this time; delays in Institutional Review Board/ Human Use Committee reviews and revisions are the underlying cause of the delays}

g. Abstract medical records for relevant health history and pathology data.

- This is currently being conducted as each wave of participants is recruited.

h. Randomize half of study participants to the intervention condition and half to control by SAS program.

- Block randomization is done so that cases and controls are matched on age (± 5 years). If randomized to the intervention group, the participants are scheduled to have individual and group sessions with the interventionist.

Task 3: Intervention / Passive Follow Up in the Controls, Months 8-30:

a. Ensure that the intervention is delivered according to the protocol.

- This is being done by conducting 24-hour diet recall interviews (24HR) and the recalls being reviewed by a member of the staff.

b. Establish a schedule of incentives and provide incentives on regular basis to encourage men who are randomized to intervention and their significant other to attend group sessions and other intervention methods.

- A schedule of incentives has been developed (On File). We currently provide incentives on a regular basis according to the schedule.

c. Establish a schedule of reminders to participants regarding the intervention.

- This is done on a regular basis. We use a reminder call script which is attached. (Appendix A.4)

d. Stay in contact with the control group to assure compliance with the follow-up measures.

- Contact with the control group is done on an as needed basis and when scheduling meetings for follow-up measures.

e. Schedule clinic visits for the blood, urine, and anthropometric data collection.

- This is being done as planned.

f. Assure that all self-assessments are completed at follow up.

- A regular check of database and a clinic check list is done in order to ensure that all data needed have been collected. Two staff members review all the questionnaires by hand before scanning them to insure each tool is complete.

Task 4: Data Entry, Verification and Interim Analyses, Months 6-31:

a. Assure that all data are immediately read into the tracking and analytic databases.

- This is currently being done for each participant's data.

b. Flag all outlier and illogical responses.

- This is currently being done.

c. Verify all outlier and illogical responses, re-contacting participants, if necessary.

- This is currently being done as needed.

d. Conduct simple descriptive analyses (e.g., cross-tabulations and univariate statistics).

- We conduct such analyses after each intervention cycle.

Task 5: Final Data Analyses, Months 30-36: We will be ready for this when data collection is complete.

a. Perform all exploratory analyses to test for adherence to model assumptions.
b. Perform all necessary data manipulations (e.g., log transforming all non-normal and heteroschedastic data).
c. Test study hypotheses.

d. Conduct post-hoc analyses of study data.
e. Prepare manuscripts.
f. Archive datasets for future analyses and future patient follow-up.
f. Plan for future studies.

Key Research Accomplishments:

In our first year of funding, we have created an intervention manual with twelve weeks of lessons combining instruction in nutrition, mindfulness-based stress reduction (MBSR), physical activity and behavior change methods. To aid in at-home compliance with the intervention, study personnel have created a cookbook and an instructional MBSR audio CD set. Additional accomplishments include the study and procedure manuals, the study's questionnaire packet and study databases. We will begin our 4th wave of participants in July 2005. We are also beginning to utilize the South Carolina Central Cancer Registry and building a database of prostate cancer patients. This also will aid in the recruitment of future participants to other studies, building necessary infrastructure that is recommended by the South Carolina Cancer Alliance (of which Dr. Hebert is Chair of the Research Task Force).

Reportable Outcomes:

Study products: The study's intervention manual and procedures manual have been completed. The study efforts thus far have also produced a vegetarian cookbook and MBSR instructional CD set. Recruitment efforts have aided participating doctor's offices with establishing databases capable of tracking their patients.

Funding applied for and received based on this award: Study epidemiologist/ biostatistian, Tom Hurley, was awarded a grant by the South Carolina Research Authority and the South Carolina Nutrition Consortium entitled "Self-Reporting of Dietary Data: Influence of Bias and Imprecision on Intervention Effect Estimates." This will allow us to conduct three 24-hour dietary recall interviews for each of the study periods. This is a huge plus for the study, as this is the deluxe method of dietary assessment (8-10) and is provided at no cost.

Training opportunities: Four interns have worked with the study. They included three dietetic interns from Winthrop University completing part of their community nutrition rotations by working with the study intervention, and a masters student in the Health, Promotion, Education and Behavior department at the Arnold School of Public Health completing his degree's practicum requirement. Collaborative efforts have begun with Benedict College, a Historically Black College (HBCU) in Columbia, SC with the hiring of two students. These efforts include accepting their students as research assistants to aid the study in our recruitment efforts within the state's minority population. Also, we have provided training opportunities for two additional Winthrop University dietician interns.

Conclusions:

At this point in the timeline, the study team is actively recruiting for the 4th wave of participants as well as completing the third wave of participants. We continue to utilize the procedures and materials that were put in place for baseline testing and the intervention classes. Current recruitment data shows that we have exhausted our efforts with the Midlands urologists and we have moved out side of the midlands in order to recruit. To continue a strong recruitment effort and reach as many potentially eligible men as possible, the study team is strengthening and creating collaborative efforts statewide.

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Appendices

A.1 Advertisement for study published in publications in the area
A.2 Medical Records Form
A.3 South Carolina Cancer Registry letters
A.4 Reminder Call Script
A.5 Bio-Sketch of Project Coordinator

Appendix A.1

Rising PSA After Prostate Cancer?

New Treatment Choice

Help us advance knowledge about prostate cancer treatment. This study provides coupons for gas, thank you gifts and free tests including PSA. You personally may not benefit, but cancer research will definitely benefit.
If you have been treated by surgery or radiation for prostate cancer and have had a rise in your PSA, you may be eligible.
To find out more about the study

visit our web site at www.palmettoresearch.info

or call 1-803-238-1975 (toll free 1-800-775-2287).

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Appendix A.2

Medical Record Data Collection Form

Gleason Score: ____________________ **Date:** ______________

Stage: ____________________ **Date:** ______________

Date of Prostatectomy: ________________

Radiation Treatment: _______ **YES** _____ **NO**

If yes, Dates: __________________ _________________________

__________________ _________________________

Androgen Receptor Information:

____

____

____

ALL PSA VALUES IN RECORD

PSA:		**Date:**		**PSA:**		**Date:**	
PSA:		**Date:**		**PSA:**		**Date:**	
PSA:		**Date:**		**PSA:**		**Date:**	
PSA:		**Date:**		**PSA:**		**Date:**	
PSA:		**Date:**		**PSA:**		**Date:**	
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Study ID: ___________

Appendix A.3

7230105222

Prostate Health Survey

(All questions are voluntary. Thank you for your help filling this out)

1. Since learning that you had prostate cancer, how many times have you returned to the doctor who told you that you had prostate cancer? ☐ please write in the number, write 0 if never

2. Since being treated for prostate cancer, how many times have you seen another doctor or other health care provider for Prostate Cancer (for example, a nurse)? ☐ please write in the number, write 0 if never

3. What kind of treatment did you get when you were first diagnosed with prostate cancer (fill in the bubble for all that apply)?

- ○ Surgery
- ○ Radiation
- ○ Chemotherapy
- ○ Hormone Therapy
- ○ No Treatment (Watchful Waiting)
- ○ Don't Know

4. Besides the treatment you got when you were first diagnosed with prostate cancer, please indicate other treatment(s) you received after the initial therapy (for example, radiation or hormone after surgery) - list as many types as you got:

Month Year

Type of treatment _____ When ☐☐ \ ☐☐☐☐

Type of treatment _____ When ☐☐ \ ☐☐☐☐

5. Has your PSA level changed since your cancer treatment? ○ Yes ○ No ○ Don't Know

If yes, has your PSA level increased at least once? ○ Yes ○ No ○ Don't Know

6. Since being told that you had prostate cancer, has your weight changed? ○ Yes ○ No

If yes, by how much: ☐☐ pounds Have you ○ lost or ○ gained

7. Since being told that you have prostate cancer, has your diet changed? ○ Yes ○ No

If yes, briefly explain how: _____

8. Since being told that you have prostate cancer, has your level of physical activity changed? ○ Yes ○ No

If yes, has your activity level ○ increased or ○ decreased

9. Do you live with your wife or partner? ○ Yes ○ No

10. Besides you, how many other people live with you in your home? ☐☐

11. Do you ever have trouble getting to your doctor visits? ○ Yes ○ No

If yes, briefly explain why: _____

UNIVERSITY OF SOUTH CAROLINA

DEPARTMENT OF EPIDEMIOLOGY AND BIOSTATISTICS
ARNOLD SCHOOL OF PUBLIC HEALTH

Dear Mr. Patient Name:

Prostate cancer is the most common type of cancer diagnosed among men in South Carolina. You have been identified by the South Carolina Central Cancer Registry as being eligible to complete a survey on prostate cancer. I am the leader of a research team at the University of South Carolina's Arnold School of Public Health that is very interested in learning about what men do for their health after hearing that they have prostate cancer. Currently, by law, the state of South Carolina collects information about men who are diagnosed with cancer. However, we do not have information on what happens to men after they have received treatment for their cancer. Choices made after prostate cancer diagnosis can impact the length and quality of life, which has an affect on family and friends.

In order to improve our understanding of what men do for their health, I am asking you to take part in a research survey. Your choice to participate, and the answers that you provide, will have no affect on your medical care. Your name, and all other identifying information, will not be revealed to anyone nor will they be revealed in any publication resulting from this work.

On the reverse side of this letter, is the survey that we would like you to complete. This should take less than 15 minutes to fill out. Even though all of the questions are voluntary (you may choose not to answer them), your choosing to do so will help us learn how we can improve the lives of men who have had prostate cancer. By completing this form you are agreeing to participate in this survey. Although the research may be of no direct benefit to you, results from the survey will help us to understand how prostate cancer affects the way men manage their health. Completion of this survey will end your participation in this project. If you have any questions about this survey, please do not hesitate to call me at 803-434-6009.

Sincerely Yours,

James R. Hebert, MSPH, ScD
Professor, Arnold School of Public Health, University of South Carolina
Director, Statewide Cancer Prevention & Control Program, Hollings Cancer Center

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Information from this survey may make you eligible to take part in a prostate cancer research study entitled, *A Diet, Physical Activity and Meditation Intervention in Men with Rising Prostate Specific Antigen.* This is an intervention study and may be of direct benefit to you.

Would you be willing to have us contact you if you were eligible to participate in this additional research study?

○ Yes ○ No If you answered Yes, please sign your name below:

Name _____ and fill in the date _____

Are you willing to be contacted for any additional research studies of which you may be eligible?
o Yes o No If you answered Yes, please sign your name below:

Name _____ and fill in the date _____

If you answered No, to both of these questions above, you will not be contacted.

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Appendix A.4

EASE Clinic Reminder Call Script

Hi, could I speak to ___Subject name___.

My name is ____Your name____ . *I am calling on behalf of the EASE Study at the University of South Carolina. In our conversation last week you agreed to participate in the study and we sent you (and your partner) a packet containing questionnaires, directions to your clinic visit and a sample collection cup.*

Did you receive these items?

If response is no:

We will be sending the packet to you (both) today. Are there any questions I can answer today?

If response is no:

I will be calling you back in a few days to make sure you have received everything. Thank you (both) for taking the time to help in the fight against prostate cancer. I look forward to speaking to you again. Goodbye

If response is yes:

What can I clarify for you?

[After answering questions - *I will be calling you back in a few days to make sure you have received everything. Thank you (both) for taking the time to help in the fight against prostate cancer. I look forward to speaking to you again. Goodbye*]

If response is yes:

[Move to next question]

Have you had a chance to look through the questionnaire?

If response is no:

As you review the survey, if you have any questions please feel free to contact a member of our staff at 434- 1628. [Move to next question]

If response is yes:

Did you have difficulty with any part of the questionnaire?

If yes, ask the following: *Is there anything we can clarify for you*?

Are you comfortable with the directions we provided?

If response is no:

Is there a part I can clarify for you?

If response is yes:

[Move to sample reminder]

Remember to collect a urine sample as soon as you wake up the morning of your clinic visit. You and your partner are schedule for you clinic visit on ___date and time of clinic visit___. Please bring your urine sample as well as your questionnaire packet to this clinic.

Are there any questions or concerns you have at this point?

If response is no:

If at any point you have questions or concerns, please feel free to contact a member of our staff. Our number again is 434-1628.

If response is yes:

What can I clarify for you?

Thank you (both) for taking the time to help in the fight against prostate cancer. We are looking forward to meeting you on __date and time of clinic visit__. Have a good evening/day. Good-bye

If participant is not available, use the following script or Voice Mail Message:

My name is ____Your name____. I am calling on behalf the EASE study at the University of South Carolina. We have sent __Subject name__ a packet of information and want to make sure everything was received. Could you tell me when is the best time to reach him at home? If he would like to contact us, please have him call (803) 434 - 1628. Thank you for you help.

Voice Mail Message:

This message is for __Patient's Name__. My name is __Your Name__ and I work for the EASE study at the University of South Carolina. Please call our study coordinator, Wendy McKenzie, at (803) 434-1628. If she is not in, please leave your name and a time when it

would be convenient for her to call you. Thank you and we look forward to hearing from you.

Again, the number is (803) 434-1628.

Appendix A.5
Bio-sketch of Project Coordinator

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed on Form Page 2.
Photocopy this page or follow this format for each person.

NAME	POSITION TITLE
Wendy Bush McKenzie	Program Manager

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training).*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Francis Marion College, Florence, SC University of South Carolina, Columbia, SC	B.S.	1990 2000-2002	Sociology Public Health

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list, in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List, in chronological order, the titles, all authors, and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. If the list of publications in the last three years exceeds two pages, select the most pertinent publications. **DO NOT EXCEED TWO PAGES.**

Professional Experience:

January 2000 – August 2002	Project Coordinator, College of Nursing, University of South Carolina
August 2002-present	Program Manager, Department of Epidemiology and Biostatics, University of South Carolina