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Award Number: DAMD17-03-1-0139

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

PRINCIPAL INVESTIGATOR: James R. Hebert, Sc.D.

CONTRACTING ORGANIZATION: University of South Carolina
Columbia, South Carolina 29208

REPORT DATE: May 2004

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 074-0188

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	May 2004	Annual (1 May 2003 - 30 Apr 2004)

4. TITLE AND SUBTITLE
A Diet, Physical Activity, and Meditation Intervention in Men with Rising Prostate-Specific Antigen (PSA)

5. FUNDING NUMBERS
DAMD17-03-1-0139

6. AUTHOR(S)
James R. Hebert, Sc.D.

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
University of South Carolina
Columbia, South Carolina 29208

E-Mail: jhebert@sph.sc.edu

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSORING / MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

12b. DISTRIBUTION CODE

13. ABSTRACT (Maximum 200 Words)

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 their choice, half of whom 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.

14. SUBJECT TERMS
Clinical trial, diet, nutrition, physical activity, meditation, prevention, circadian rhythm, epidemiology, prostate-specific antigen

15. NUMBER OF PAGES
48

16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	Unlimited

Army Award DAMD 17-03-1-0139

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

Annual Report: Year 1

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. 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 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 (see Appendix 1) 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 the 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 is available on the number of men contacted, the number of responses received from contacts, the number of ineligibles and the number of eligibles. Current data shows promising results; however, it is hard to make inferences in how recruitment will continue as this data only pertains to the first three weeks of recruitment.

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. Instruction sheets 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. The instruction letters are provided in Appendix 2.
- 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 (Appendix 3).
- 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 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. The coordinator's biosketch is attached as Appendix 4.
- 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.
- A chef trained in vegetarian cooking was hired in October 2003 to help develop recipes and a cookbook for the intervention group.
- 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.
- The project coordinator is in the process of hiring a graduate assistant 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 for both recruitment in order to track eligibility/ineligibility statistics as well as source of referral.
- A tracking database was also established to track participant's study compliance.

f. Develop the tracking database based on our experience with other intervention studies in the Department of Epidemiology and Biostatistics.

- Tom Hurley, biostatistian for the Department of Epidemiology and Biostatistics 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.

- A training session to prepare hired Phlebotomists for the study's first clinic in June 2003 occurred May 24, 2004.

- All other study personnel involved with data-related and clinic-based procedures are trained upon hire. Periodic updates and reviews are provided in bimonthly study team meetings. The latest training update will occur at the May 24, 2003 study meeting.

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 have been contacted. Each 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 (Appendix 5). 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 (Appendix 6).

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. The outline is attached as Appendix 7.

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 outline attached as Appendix 7 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.
  - 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 is provided as Appendix 8.
  - Provision of clear communications and expectations. A brochure was created as a tool to provide clear communications. Participants are also 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 15 May 2004. six 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, Public Service Announcement to area radio stations and newspapers (Appendix 10).
- 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.

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.

- Currently, we have been in contact with 20 men of whom 7 men and a partner of their choice met the initial eligibility of having a prostatectomy and a rising PSA. These men and their partner are currently being screened for the protocol's other exclusion criteria.

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

- Due to HIPAA regulations, previously obtained PSA levels recorded in patient medical records, which would establish a baseline PSA level, cannot be obtained until written permission is obtained from the patient. This permission will be collected during the

participant's first clinic visit. After gaining their written consent, we will 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 will begin on June 9, 2004. At this point, baseline data will be collected for the first group.

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 is scheduled for their first clinic on 9 June 2004.
- These participants will be contacted via phone and through letters. The Welcome Call script and letter were submitted to Donna Ferrandino in March 2003.

{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.
h. Randomize half of study participants to the intervention condition and half to control. Block randomization so that cases and controls are matched on age (within 5 years). If randomized to the intervention, schedule the 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.
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.
c. Establish a schedule of reminders to participants regarding the intervention.
d. Stay in contact with the control group to assure compliance with the follow-up measures.
e. Schedule clinic visits for the blood, urine, and anthropometric data collection.
f. Assure that all self-assessments are completed at follow up.

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.
b. Flag all outlier and illogical responses.
c. Verify all outlier and illogical responses, re-contacting participants, if necessary.
d. Conduct simple descriptive analyses (e.g., cross-tabulations and univariate statistics).

Task 5: Final Data Analyses, Months 30-36:

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.

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 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: Two interns have worked with the study. They included a dietetic intern from Winthrop University completing part of her community nutrition rotation by working with the study intervention manual and 24-hour recall set-up, 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. Future collaborative efforts are also being planned with Benedict College, a minority college in Columbia, SC. These efforts include accepting their students as research assistants to aid the study in our recruitment efforts within the state's minority population.

Conclusions:

At this point in the timeline the study team is actively recruiting as well as preparing for the beginning of participant baseline testing and the first intervention classes. Procedures and materials are in place for baseline testing and the intervention classes. Current recruitment data shows promising results; however, it is hard to make inferences in how recruitment will continue. 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

Appendix A.1

Statement of Work

A DIET, PHYSICAL ACTIVITY, AND MEDITATION INTERVENTION IN MEN WITH RISING PROSTATE-SPECIFIC ANTIGEN (PSA)
STATEMENT OF WORK

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

a. Inventory and finalize all assessment instruments and data collection protocols.
b. Review baseline questionnaires for completeness and for content validity.
c. Revise baseline questionnaire to assess demographic, health history, and family health history, as necessary.
d. Hire and train the Project Coordinator, Research Nurse, and other project staff.
e. Develop the study data management systems.
f. Develop the tracking database based on our experience with other intervention studies in the Department of Epidemiology and Biostatistics.
g. Train staff in all data-related and clinic-based procedures.
h. Develop and finalize all laboratory procedures to be used in the trial.
i. Finalize all biological sample collection and storage procedures to be used in the study.
j. Establish recruitment procedures for men entering the study.
k. Establish retention procedures.
l. Finalize the intervention protocol.

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.
b. Among those who say they are willing to participate, confirm eligibility using the criteria listed in section D.2. of the proposal.
c. Enroll 60 eligible men.
d. Establish baseline PSA levels through repeat measures taken before subjects are randomized to intervention.
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.
f. Schedule the first clinic appointment for the purposes of collecting all of the blood and urine specimens and taking the anthropometric measurements.
g. Abstract medical records for relevant health history and pathology data.
h. Randomize half of study participants to the intervention condition and half to control. Block randomization so that cases and controls are matched on age (within 5 years). If randomized to the intervention, schedule the 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.
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.
c. Establish a schedule of reminders to participants regarding the intervention.
d. Stay in contact with the control group to assure compliance with the follow-up measures.
e. Schedule clinic visits for the blood, urine, and anthropometric data collection.
f. Assure that all self-assessments are completed at follow up.

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.
b. Flag all outlier and illogical responses.
c. Verify all outlier and illogical responses, re-contacting participants, if necessary.
d. Conduct simple descriptive analyses (e.g., cross-tabulations and univariate statistics).

Task 5: Final Data Analyses, months 30-36:

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.

Appendix A.2

Actigraph Instruction Letters

<Date>

Dear *<name>*,

Thank you for participating in the EASE Study.

We would like you to wear the activity monitor for each of the next seven-days. We ask that you wear the monitor on your right hip both day and night. Only take the monitor off when you will be in water (bathing, showering, swimming).

Please put the monitor on before you go to bed on <Date> and wear it each day until <Date>. **You will return the activity monitor, belts and log book at your visit with the study team on <Date>.**

Instructions

- When you get up each morning, attach the monitor firmly to your right hip using the elastic belt. Make sure that the monitor is not too loose, or uncomfortably tight.
- Make sure the monitor is right side up (you should be able to see two white dots on the top of the monitor).
- The monitor is NOT waterproof. Do not wear it while bathing or swimming. When you bathe or swim, take the monitor off – but remember to put it back on!
- When you participate in water activities such as swimming or weight lifting activities you will record the information in your log book. You will also record information about your sleep on the last page.
- If you have questions about what you are supposed to do, please call Margaret Ehlers at (803) 434-1909.
- **Remember to bring the activity monitor, belts and log book with you to your visit on <Date>.**

<date>

Dear *<name>*,

Thank you for participating in the *EASE Study*.

We would like you to wear the activity monitor for each of the next seven-days. We ask that you wear the monitor on your right hip both day and night. Only take the monitor off when you will be in water (bathing, showering, swimming).

Please begin wearing the monitor on before you go to bed on **<Date >** and wear it each day until **<Date >**. **A messenger will come to your home on <Date > to pick up your activity monitor, belts and log book.**

Instructions

- When you get up each morning, attach the monitor firmly to your right hip using the elastic belt. Make sure that the monitor is not too loose, or uncomfortably tight.
- Make sure the monitor is right side up (you should be able to see two white dots on the top of the monitor).
- The monitor is NOT waterproof. Do not wear it while bathing or swimming. When you bathe or swim, take the monitor off – but remember to put it back on!
- When you participate in water activities such as swimming or weight lifting activities you will record the information in your log book. You will also record information about your sleep on the last page.
- If you have questions about what you are supposed to do, please call Margaret Ehlers at (803) 434-1909.
- **Remember a messenger will come to your home on <Date> to pick up your activity monitor, belts and log book.**

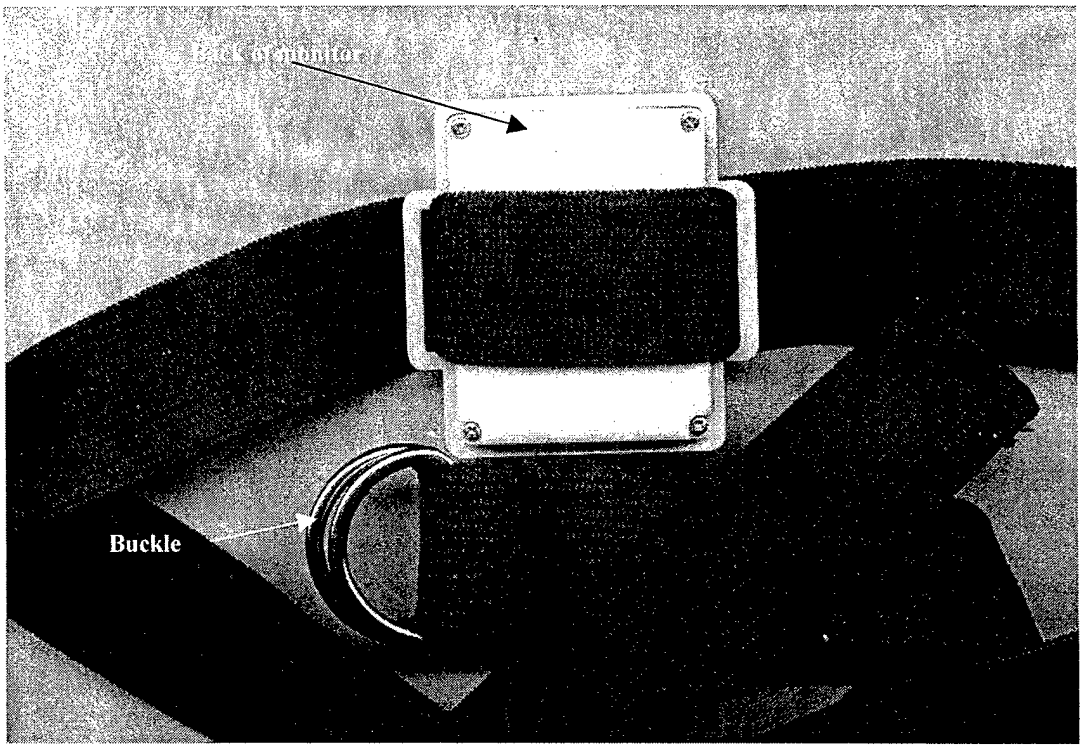
Wear the monitor so that the back of the box (screws showing) is against your hip. The word "Actigraph" should be facing away from you.

Be sure the top of the monitor is facing up (i.e., "dots" are facing up when on your waist)

It can be worn over top of, or underneath your clothes.

Attach the monitor to your waist with the elastic strap using the buckle (metal rings) on the strap to fasten the monitor.

Be sure that the monitor is snug.



Appendix A.3

24-Hour Recall Protocol

Diet Assessment Protocol

Overview

This document details the protocol for conducting 24-hour recall interviews for the purposes of collecting detailed dietary intake information. Assessments will be made by telephone-administered multiple 24-hour recalls (24HR) using the Nutrient Data System for Research (NDS-R, Version 4.06_34) software (licensed from the Nutrition Coordinating Center at the University of Minnesota). Interviewers will be registered dietitians specifically trained by USC staff in using the multi-pass approach to conduct telephone interviews. The interviews will be conducted on randomly selected days (for a 3-day sampling scheme, two weekdays and one weekend day will be selected) during a 2-week sampling frame.

The 24HR methodology relies on interviews administered on randomly selected, nonconsecutive days. As a result, the subject will not be expecting the call, and will be unable to prepare for the interview. This is by design. The rationale for this approach is that we attempt to minimize bias in reporting that can arise when a subject has time to prepare for the interview, by focusing on actual intake during the previous 24-hour period. Thus, it is important that subjects be available at specific times each day to be contacted according to the randomization schedule (i.e., no beepers, answering services, scheduling of calls or return calls from the subject are permitted).

Project Staff Responsibilities

First, when a subject is determined eligible and signs the informed consent, project staff should: 1) Collect subject contact information. This information will include the following subject specific data: first and last name, phone number, and best time to contact (for both weekdays and weekend days). This information will be entered into the study tracking database; 2) Read the "Dietary Interview Summary" (appended below) to explain to the subject how the 24HR interview process works. It is important that the subject be aware that they will be called on multiple occasions at random to be interviewed during the course of the study. The site coordinator will verify with the subject that he or she can be reached at the phone number during the times specified in the contact information. Subjects who use caller ID or call screening should be reminded that they will be receiving calls from the dietitians during the times they have specified for their availability; Provides the subject with a copy of the food portion visuals (FPV) and explain how to use the FPV to estimate portion sizes during the dietary interviews, and that they should keep the FPV by the phone for easy access during the interview.

Interview procedures

Once subject contact information has been entered into the study tracking database, call assignments will be generated (on randomly selected days as described above) and given to the dietitians. The dietitians will attempt to contact the subject to conduct an interview using the following protocol.

Dietitian Script and Methodology

1. Before beginning the interview, create a new record and enter the appropriate information into the Header section of NDS.
2. Begin the interview with, "Hello, my name is _____. Thank you for participating in the _____ study." Explain that you will be conducting a 24-hour recall interview to gather information on diet and physical activity. Ask if this is a good time to talk.
3. To initiate the recall process, explain that what we do first is to make a list of all the foods you had in the previous 24-hour period including even small tastes or samples. Then state, "I would like to know what foods you ate after midnight yesterday, which was state the day. Please tell me everything you ate or drank, including meals, snacks, beverages, candy, and alcohol. Start with the first thing you ate or drank and progress through the rest of the day. Please indicate approximately what time you had the items, whether it was a snack or a meal, and where you were. I will be entering this information directly onto a computer, so please speak slowly.
4. The control of the interview is then passed to the subject so (s)he can report food intake. Once the subject has begun to recall food intake, we try to not interrupt his/her train of thought - portion sizes, preparation information, etc. will be gathered in the next step. Some attention and encouragement are appropriate, such as "OK" or "what next." If the subject has difficulty getting started, we ask the subject to recall what (s)he did yesterday, and wait for the subject to start listing the food eaten. We always allow ample time for contemplation. When the subject has completed the 24-hour recall, the interviewer reviews the QUICK LIST and checks for snacks and alcoholic/non-alcoholic beverages and any other forgotten main food items, following the NDS prompts until the subjects responds no other foods were eaten during that meal.
5. After the subject has finished providing a description of his/her food intake, we employ standardized probing techniques as directed by the NDS system to assure that the foods are completely described, including detailed food preparation, size of portions eaten, items added to foods, etc. In addition to these on-line instructions we are aware that omissions often occur around snack items and foods taken in situations that are not typically considered eating (for example, using milk to "wash down" bed time medications). When the recall is completed, the interviewer asks the subject to hold the line while she quickly, but carefully, scans/reviews the FOOD REVIEW section of the NDS system to make sure the entries look correct (e.g., accidentally logging in "24 cups" instead of "24 ounces" of a calorie-containing beverage can produce a

major difference in calories!). The interviewer should do this verbally, as often the subject may remember additional foods or detect errors as the review is conducted.

6. The interviewer then gathers the information to complete the TRAILER of the program. (S)he then thanks the subject for her/his time. Depending on the particular study you may need to pass on specific information on meeting dates or future interviews.

Contact / missed call protocol

When attempting to contact a participant the dietitians will use the following guidelines:

1. Attempt to do a 24-hour recall on the day the call is assigned using the "best time to call" information. If you fail to reach the patient, try an additional 2 times during the available time remaining during that time slot (up until 9 pm unless requested to call later). These three interview attempts should be completed in no more than five hours, however the attempts should be spaced approximately 1 hour apart (use your judgment to optimize the chance of completing the interview).

2. If you reach the subject and they are available to be interviewed, complete an interview. If the subject is unable to complete an interview at that time, re-establish the "best time to call" (noting any period of unavailability), and call back during that time period if possible. Update any changes in the "best time to call" information in the call assignment sheet so that the project manager can update the information in the patient-tracking database. If the person is unreachable after three attempts, return the assignment to the project coordinator for subsequent reassignment. Leave a message after the 3rd call if there is an answering machine.

3. If the person has not been reached in nine (9) attempts on the three (3) consecutive days the interview is missed. Complete the assignment sheet where appropriate and e-mail the project coordinator on the evening of the third day. The tracking database will be updated and contact attempts will be stopped.

4. The dietitian will notify the data manager of problems encountered trying to reach a subject or to conduct an interview. The primary approach to resolving contact or compliance problems will be to notify the data manager who will work with the project coordinator to resolve these issues with the subject. Staff will make every effort to prevent the loss of data.

Dietary Interview Summary

The site coordinator will read this summary at the time of enrollment after contact information has been collected.

As part of the _____ Study, you will be receiving 8 phone calls from the University of South Carolina to discuss what you eat. The callers from the University of South Carolina are interested in recording what you eat; they are not counselors and will not attempt to alter your eating habits.

The 8 phone calls will be on 8 different days during 2 2-week periods, at the start of the study and at the end of the study. Each call will take approximately 15-20 minutes. The days on which you will be contacted are selected at random. Please do not keep records of your dietary intake prior to the calls, as this may alter your normal habits. If you normally use caller ID or call screening, please be aware that you will be receiving long distance calls (from area codes (803, 864, 912, 603, and 978) from the dietitians during the times you have specified for your availability. **{Review and verify the times with the patient}**

You will be given a foldout sheet of "Food Portion Visuals". These visuals should be used to help you describe the amount of food you have eaten as accurately as possible. Please keep the foldout near the phone and refer to the pictures and measurements shown when the interviewer calls you. The interviewer will be able to help you with any questions you may have in using the visuals.

Appendix A.4

Project Coordinator's Biosketch

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed for Form Page 2.
Follow the sample format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Brook E. Harmon	Project Coordinator

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
Winthrop University	BS	2001	Human Nutrition
Winthrop University	--	2002	Dietetic Internship
University of South Carolina	MS	2003	Exercise Science
University of South Carolina	Certificate	2004	Gerontology

NOTE: The Biographical Sketch may not exceed four pages. Items A and B (together) may not exceed two of the four-page limit. Follow the formats and instructions on the attached sample.

A. Positions and Honors. List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee.

Positions:

May 2000 – July 2000 Food Service Intern University of Connecticut Dining Services
Aug. 2000 – Dec. 2000 Nutrition Assistant (Corporate Wellness), Health and Sports Works, Inc.
Aug. 2001 – Dec. 2001 Research Assistant (Exercise Science), University of South Carolina
Dec. 2001 – Jan. 2003 Research Assistant (Epidemiology & Biostatistics), University of South Carolina
June 2002 – Aug. 2003 Program Coordinator (Exercise Science), University of South Carolina – Good bodies Program
Aug. 2003 – present Project Coordinator (Epidemiology & Biostatistics), University of South Carolina

Membership and Honors:

1998 – present American Dietetic Association member
2002 – present Registered Dietitian
2003 – present Columbia Midlands Dietetic Association (CMDA) member
2004 – 2005 Secretary of the CMDA
2003 – present South Carolina Cancer Alliance member
Research Task Force member
Priority Populations and Participation in Research Committee member

Appendix A.5

Clinic Script

Script for Baseline Clinic

1. **Registration Table:**

Staff Member 1:
Good morning. Are you here for the EASE study?

If you will tell me your name, we can get you checked in.
[Place a check mark by the participant's name on the Registration Log]

Did you bring your collection cup and sample with you?
If yes: *Great, as soon as you finish here someone will take it for you.*
If no: [Get Brook]

Do you have your Actigraph with you?
If yes: *Great, as soon as you finish here someone will take it for you.*
If no: [Get Brook]

Did you also bring the questionnaires we sent you in the mail?
If yes: *Thank you for bring those in. I will take them for you.*
[Check them for completeness]
If complete: [Check off "Questionnaires" on the Registration Log and participant's Clinic Form. Put the questionnaires in the participant's folder.]
If not complete: Place a note on the clinic checklist that the questionnaires need to be completed.
Thank you. I will let you talk to <Staff Member 2> *now.*

If no: *That is okay, we have an extra copy and will give you a chance to complete them before you leave today. It was nice meeting you. I will let you talk to* <Staff Member 2> *now.*

If they did not receive questionnaires in the mail: *I am sorry, but do not worry. We have a blank copy here and will give you a chance to complete them before you leave today. It was nice meeting you. I will let you talk to* <Staff Member 2> *now.*

Staff Member 2:

Hello <Mr./Ms. Last Name>. *I have two forms that we need you to read. The first form is a consent form, which explains the details of the study and is exactly like the one you received in the mail. I need you to initial every page of this form. You will also need to check one of the two boxes on the next to last page.* [Show the consent form and where they need to initial and check boxes the pages].

The second form is a release form. It explains the type of information we will be collecting during the study and how we will keep this information private. Please read this form and fill-in the last page. [Show the privacy release form and the last page where they need to sign, fill-in their address, etc.]

After you have finished reading and filling in the information on both forms, bring them back to us. You will be meeting with the study investigators so should you have any questions or concerns let them know.

This last sheet is a checklist that each person you visit will need to look at. Make sure you have each item checked off before you leave.

<Staff Member 3> *I will show you where you can take the sample you brought and where you can sit to read and fill out the forms. It was nice meeting you and I will see you in a little while.*

2. Urine Collection/Actigraph Turn-in Station

Staff Member 3

[Ask the participant to accompany you. Take them to Sue's Student Room]

Thank you for bringing your sample in. [Write the date on the label and check for a time.]

If there is a time: *Did you collect this sample at* <Time Written> *am this morning?*

If yes: [Record date and time next to the participant's Study ID number]
If I can see your checklist, I can check off this part of your visit.[Put a check next to urine sample]
Thank you for your time. If you will follow me, I will show you where you can sit and read the forms <Staff Member 2> *gave you.*

If no: [Get Brook if the time was not first thing the morning of the

clinic.]

If there is not a time: *At what time did you collect this sample?*
[Make sure it was the morning of their clinic date – if not get Brook. Write the time on the label and record the date and time next to the participant's Study ID number]

If I can see your checklist, I can check off this part of your visit.[Put a check next to urine sample]

Do you also have your Actigraph monitor?

Take it and place it in the designated box. Check off its return on the Actigraph Check-in list

Thank you for your time. If you will follow me, I will show you where you can sit and read the forms <Staff Member 2> *gave you. Snacks have are in the kitchen if you would like something to eat or drink.*[Show them to the Large Conference Room]

3. **Large Conference Room**

Staff Member 4:

Introduce yourself and show the participants to a seat. Let them know you are available if they have any questions. Once they have finished with their forms, show them back to the staff members at the Registration Desk.

4. **Registration Desk**

Staff Member 1 or 2:

Check the participant's consent and privacy forms to make sure all information is complete.

Let <Staff Member 5> know there is someone ready to meet with Sue or James.

Turn the participant over to <Staff Member 5>, who will escort the participants to the investigators.

5. **Consent Signing**

Sue and James:

Review the consent, address any questions or concerns, and sign the last page of the consent form.

Have a witness also sign the consent form (Staff Member 5).

Return both forms to the participant and have <Staff Member 5> escort the participant back to the registration desk.

6. **Registration Desk.**

Staff Member 2:

Look over the consent and privacy forms to make sure they are complete (all pages initialed, signed by James or Sue and witnessed). Check off completed consents on the participant's Clinic Form.

Check the Clinic Form to see if the participant has completed their questionnaires.

If yes: Offer them snacks in the kitchen and ask them to wait in the conference room with <Staff Member 4>. Let them know they will be called shortly to have their blood drawn and measurements taken.

If no: Give them their partially completed questionnaire packet or the blank copy from their folder. Offer them snacks in the kitchen and ask them to fill out their questionnaires in the conference room with <Staff Member 4>. Let them know that they may be called to have their blood drawn and measurements taken while they are filling out the questionnaires.

7. **Large Conference Room**

Staff Member 4:

When participant's enter, offer them a seat and let them know you are available if they have any questions about the questionnaires. Remind participants of drinks and food in the kitchen.

Using the roster of who is attending the clinic, mark the time new participants come in and if they are filling out questionnaires or just waiting for blood draws. Ask if they have had their blood drawn or measurements taken. If not, let <Staff Member 6> know.

When participants complete their questionnaires, check the questionnaires for completeness. When completed, take the questionnaire and put them in the folder provided and check off "Questionnaires" on the participant's routing slip.

Staff Member 6:
Keep track of when the Phlebotomist is free as well as Staff Member 7 taking measurements.

Try to take participants back in the order they came to the conference room, but take those who are not filling out questionnaires back first.

8. Measurements

Staff Member 7:

Take all Anthropometric measurements according to the guidelines provided. Check off the participant's Clinic Form when all measurements have been taken.

Direct the participant to Staff Member 6 who will either take them to the Phlebotomist or take them back to the large conference room to wait.

9. Blood Drawn

Phlebotomist

Take 3 vials of blood from each participant according to the protocol provided.

Record the blood draws on the Blood Draw Log provided. Also, check off by the area for blood draw on the participant's Clinic Form.

After blood draw is completed, turn participant over to <Staff Member 6> who will take the participant to have their measurements taken or return them to the large conference room.

10. 24-Recall and Actigraph Information Session; Check-out

Staff Member 4:

When at least 5 people have completed the consent process, lab work, and questionnaires, take them to <Staff Member 8> in the small conference room for information about the 24-hour recalls and check-out (information about Actigraphs as well if Clinic 2).

Staff Member 8:

(Only the men (controls and intervention) will be participating in this part of the study. Their partners will not have to do the 24-hour recalls.)

Welcome the group.

As part of the study, you will be receiving 8 phone calls from the University of South Carolina to discuss what you eat. The callers are interested in recording what you eat; they are not counselors and will not attempt to alter your eating habits.

The 9 phone calls will be on 9 different days. 3 calls will be over the next 2 weeks, 3 calls will occur at the end of 3 months and the other 3 calls will come at the end of the study. Each call will take approximately 15-20 minutes. The days on which you will be contacted are selected at random. Please do not keep records of your dietary intake prior to the calls, as this may alter your normal habits. If you normally use caller ID or call screening, please be aware that you will be receiving long distance calls (from area codes (803, 864, 912, 603, and 978) from the dietitians during the times you have specified for your availability.

You will be given a foldout sheet of "Food Portion Visuals". These visuals should be used to help you describe the amount of food you have eaten as accurately as possible. Please keep the foldout near the phone and refer to the pictures and measurements shown when the interviewer calls you. The interviewer will be able to help you with any questions you may have in using the visuals.

[Give each participant a copy of the Food Portion Visual poster]

This chart has various models on it that will help the caller understand the amounts of each food item and beverage you consumed. On Side A, you will see three spoons (A1, A2, A3) and three glasses (A4, A6, A8) with 1/4, 1/2, 3/4 and "full" marks which you might use to describe what you ate or drank. The bowls (All, A15) could be used to describe anything eaten in a bowl, such as cereal or soup. The three mounds (A12, A13, A16) will give me an idea of portions of food as they appeared on your plate. Here they are shown without the plate. The A17 model represents a scoop. We also

have a cup (A10), a mug (A9), a "shot" glass (A7), and a stemmed glass (A5). The three wedges (A14, A18, A19) could be used to describe a portion of cake or pie.

On the other side of the chart (Side B), you will see discs, squares, rectangles, a sphere, and some ruler measures. These probably do not look like any specific food item you have ever eaten, but the caller will use them to estimate portions of meat, fish, cheese, etc. To use these shapes, visualize the cooked food on your plate as though you were looking down on it. Select the food model that best represents the size of the portion you ate. You can use the ruler measures on the left side of the page to estimate how thick the portion was.

Clinic 2:

(Only the men (controls and intervention) will be participating in this part of the study. Their partners will not have to wear the Actigraphs.)

We will also be collecting information about your physical activity and sleep habits. I am handing out an instruction sheet, which will explain how to wear the monitors provided. In addition to wearing the monitors, you will record activities such as weight lifting, swimming and sleeping in a log book [show log book]. [Give each participant a copy of the "Actigraph subject instruction – Clinic 2" letter. Go over the instructions for wearing the monitors as well as ho w to track the wearing of their monitors and sleep habits in their log book. Also demonstrate how to put on, wear and take off the monitors as well as how to make entries in their log books.]

Are there any questions?

If yes: Answer them as completely as possible.

If no: Pass out the monitors and belts.

Once the 24-Hour Recall instructions (and Actigraph instructions) have been completed: Check off on each participant's Clinic Form that they received the 24-hour recall instruction session (and an Actigraph, if Clinic 2. If not Clinic 2, place a note in the Comments section to this effect).

Send participants who have everything on their clinic form checked, back to the registration desk.

11. Check-out

Staff Member 1:

- Review each participant's clinic form, if all sections are checked, provide them with their T-shirt (1 per person) and gas coupon (1 per pair).
- Fill-in each gas coupon with a number (Their study ID number backwards), expiration date (one year from the date of the clinic), and sign your name.
- On the list for the Exxon station, write in each coupon number and the date of the clinic.
- Fill-in a row for each participant on the sign-off sheet. Make sure each participant signs that they received their coupon.
- Let each pair know if they are in the control or intervention group.
- If they are in the intervention group, have them sign up for a day and time on the calendar provided. (The calendar will state that meetings will last from ½ -1 hour). If they are in the control group, provide them with the prostate cancer handout.
- Thank everyone, wish them a good day and that we will be sending them thank you gifts each week as well as reminders for their next visit.

Appendix A.6

Blood and Urine Collection Protocol

Protocol for Blood Draws and Processing

Blood Collection Supplies Available at Clinic:

1. Tiger top vacutainers (serum separators)
2. Gold top vacutainers (SST gel and Clot activator)
3. Butterfly needles
4. Vacutainer needles (23 gauge)
5. Vacutainer holders
6. Gloves (medium and large)
7. Pasteur pipettes
8. Rubber pipette bulbs
9. Marking pens
10. KimWipes
11. Tourniquets
12. Gauze
13. Bandages
14. Sharps containers
15. Biological waste containers
16. Alcohol swabs
17. Cryovials – same as used with urine
18. Quest requisition forms – filled in with participant lab ID number and birth date
19. Blood Collection Log
20. Specimen Bags from Quest

Protocol for Blood Draw:

1. Participant is received in the blood collection area.
2. Participant will be explained the procedure before taking the blood sample.
3. The Tiger top and Gold top tubes should be labeled with the participant's ID number and Date.
4. The participant is made to lie supine (face upwards) in a reclining position at 45-degree angle. The participant should remain in this position for 10 minutes. The blood sample will be collected from the right anterior cubital vein.
5. The right arm is comfortably placed supine (palm upwards) 30 degrees from the body. The elbow joint must be extended.
6. A tourniquet is tied 10 cm above the elbow joint.
7. Procedure of tying the tourniquet: Take the tourniquet from under the arm and tie the knot over the arm. The knot should be sufficiently tight so that the veins become prominent. The patient should not be caused undue discomfort. Care should be taken that the procedure be completed within 2 minutes after tying the knot.
8. The patient must be told to clench and unclench the fist a few times and then keep it in clenched position till further instructions.
9. Identify the anterior cubital vein. Palpation may be needed in some cases.
10. Then clean the area with alcohol soaked swab.
11. Now collect blood using standard sterile phlebotomy procedures. Tell the patient to unclench her fist when the vein is entered.
12. Collect into three vacutainers: a Tiger topped and two Gold topped. This should require only one needle.
13. 4-5 mL of blood needs to be collected in the Tiger topped tube. (For Quest)
14. 3-4 mL of blood needs to be collected in the Gold topped vacutainer. Directly after drawing, invert the Gold topped tubes two to three times.
15. 3-4 mL of blood to be collected in to the Gold topped vacutainers. Directly after drawing, invert the Gold topped tubes two to three times.
16. Remove the tourniquet and apply a sterile swab. Ask the patient to hold the swab in place for a couple minutes. Then, with arm raised, apply a band-aid to cover the puncture wound.
17. NOTE: If the patient is feeling uneasy or dizzy she should be asked to lie down and her blood pressure should be checked.
18. Each participant should be thanked for their cooperation and valuable time.

19. Direct patients to the Large Conference Room to finish completing their clinic appointment.

BEFORE THE NEXT PATIENT COMES IN:

20. Label each Gold topped vacutainer with the following information:
    Patient's 4 digit lab ID number
    Date blood collected

21. Store the Gold topped vacutainers in the refrigerator in Room 342.
22. Place each Tiger topped tube in a separate specimen bag along with that patient's requisition form. The form should already have the patient's lab ID number and date of birth filled in.
23. Complete the Blood Collection Log for the patient who just left.

Protocol for Blood Processing:

1. The Tiger topped tubes will be processed by Quest Laboratories. The courier for Quest will pick up the specimen bags at the end of the clinic.
2. Both sets of Gold topped tubes will be processed at the laboratory in 14 Medical Park. They need to be refrigerated for at least an hour, but no more than 4 hours.
3. Centrifuge the refrigerated specimens at 3000 rpm for 15 minutes.
4. Using pipettes and pipette bulb available in the 14 MP lab, transfer 1.5 mL of serum from the Gold topped tubes to individual cryovials for storage. Prepare 2 cryovials per Gold topped tube for each participant. (In the end each participant should have 4 cryovials of serum each.)
5. The cryovials should be labeled with the following information:
    Participant's 4-digit Lab #
    Date of collection
    Sample type –"Gold - Serum"
        ½ of the samples should also be marked "UMASS"
    Study name – EASE
6. Cryovials should be placed in the white boxes available in the 14 MP lab and stored in the freezer at – 80 degree C.
7. Also remove the clot from one of the Gold topped vacutainers. Place the clot into a 15 mL conical tube, label and freeze in the same manner as the cryovials.

Protocol for Shipping Samples

1. Once six months of samples has been collected send a shipment of cryovials to UMASS.
2. Pack one set of cryovials marked "UMASS" with dry ice and ship to:
    Department of Surgery/Division of Urology
    University of Massachusetts Medical School
    Room 540, 364 Plantation Street, Lazare Research Bldg,
    Worcester, MA, 01605-2324

3. Ship via FedEx. See the study coordinator for materials to use for shipping.

URINE PROTOCOL

Sample: Fasting morning urine sample would be appropriate for measuring hormone levels, genetic polymorphisms, or protein expression levels (e.g., PAI-2 and IL-1).

Collection: The sample will be collected by the participant the morning of their clinic visit in a standard collection cup, which contains 100 mg ascorbic acid to prevent oxidation of labile products. Participants will receive a reminder call the day before their clinic visit to help ensure they collect and bring in their sample.

Supplies

1. A Urine Collection cup with 100 mg of Ascorbic Acid.
2. Plastic bags.
3. Paper bags.
4. Labels for urine collection cup – with place for ID #, time of collection, date
5. Cryovials (2 mL) – opaque but not sterile
    - # depends on number of vials needed per participant (+2 per person just in case)
6. Pipettes (disposable, plastic) at least 240
7. Labels for cryovials
8. Urine Cups – need to order
9. Biohazard bags (black) – need to order
10. Boxes for storage in freezer (some at 14 MP)

Urine Collection

- The participant will be asked to provide a urine sample. A urine collection cup containing 100 mg ascorbic acid, a small zip-lock plastic bag and a paper bag will be provided to each participant 1 week before their clinic visit via hospital courier.
- Written instructions will be included with the collection cup. Instructions will request participants collect a sample first thing in the morning the day of their clinic visit. Participants will also be requested to record the time of collection on the collection cup label, check container lid for tightness and mix the sample container by inverting it 10 times. The sample be placed in the Ziploc bag provided, then the lunch bag and brought to their clinic visit.
- Upon check-in a study personnel will label the container with the participants ID number and the date. The collection cup will then be placed in a cooler to be taken to 14 MP for processing and freezing within 24 hours of collection.

Processing Urine Samples

1. A fasting urine sample will be collected by participants on the morning of their clinic visit.
2. The sample will be collected by a study team member upon the participant checking-in at the clinic.
3. Urine samples will be stored in a provided cooler during the clinic.
4. At the end of the clinic, urine samples will be transported to 14 MP for processing and freezing.
5. Using Pasteur pipettes and bulbs provided, 2 mL of urine is to be pipetted into cryovials for freezing. A clean pipette must be used for each participant.
6. Each participant will have 3 cryovials of urine prepared per clinic visit.
7. Each cryovial will be labeled with the following information:
   Participant's 4-digit Lab #
   Date of collection
   Sample type –"Urine"
   Study name – EASE
8. All cryovials will be stored in white boxes available in the 14 MP lab.
9. All samples will be processed and stored within 24 hours at – 80 degree C (freezer available at 14 MP).

Protocol for Shipping Samples

4. Once every six months a shipment of cryovials will be sent to the Bassett Research Institute.
5. Pack one set of cryovials with dry ice and ship to:
   Laboratory of Chrono-Neuroendocrine Oncology
   Bassett Research Institute
   Attn: Leslie Davidson
   1 Atwell Road
   Cooperstown, NY 13326

6. Ship via FedEx. See the study coordinator for materials to use for shipping.

Appendix A.7

Recruitment Outline

EASE Study Recruitment Outline

- Potential participants in the urologist/oncologist offices are identified by the Nurse Navigator (member of Palmetto Health).
- Either the physician discusses the study with the identified patient and informs them of their eligibility or tells the patient the Nurse Navigator will be contacting them about their eligibility for a research study.
- Once the patient is told about the study and states they are interested in learning more:
    - The patient is either instructed to contact the EASE study recruitment coordinator (member of Palmetto Health) OR
    - The recruitment coordinator is given the patient's contact information and the patient is told they will be contacted in the next few days by a member of the study team.
- The letter from Drs. Heiney and Hebert sent to the patient.
    - This letter is sent to all patients - those who contacted the study and those whose contact information was provided by the Nurse Navigator.
- After allowing a couple days for the letter to reach the patient, a phone call will be made by the recruitment team (Lynne Bridges or Dr. Heiney – both with Palmetto Health). Eligibility will be discussed with the patient and their partner, and the pair will be sent the eligibility cover letter and checklist in the mail.
- Within a week, as indicated in the cover letter, the recruitment team will call the potential participant and partner to confirm they are eligible for the study.
- After eligibility is established, the pair will be sent the consent form to read and sign. A cover letter will be attached with the recruitment team's contact information should the potential participants have questions.
- Once the recruitment team receives the signed consent form, the names are passed on to the project coordinator (Brook Harmon – USC/SCCC employee).
- The project coordinator makes a welcome call to set up the participants' first clinic appointment and inform them that they will be receiving questionnaires and a urine sample cup, which they should bring with them to their first clinic.
- A second call will be made by the project coordinator the day before the participant's clinic visit to remind them to bring the questionnaires and urine sample to the clinic.
- At the first clinic visit, a formal consent signing session will take place before witnesses and will include the participants meeting with study investigators to further clarify any questions they may have.

Appendix A.8

Incentive List

Incentives

Incentive 1: T-shirt (2 per participant pair)

Incentive 2: Small Notebook (2 per participant pair)

Incentive 3: Pen and Magnet

Incentive 4: 4" Bag clips (3 per participant pair)

Incentive 5: Sport Tote

Incentive 6: Arts and Healing Book

Incentive 7: Memo Board

Incentive 8: Apron

Incentive 9: Paper clip and Pencil (3 clips and 2 pencils per participant pair)

Incentive 10: Eyeglasses/Sunglasses Holder

Incentive 11: Arts and Healing Cards

Incentive 12: Seat Cushion

Incentive 13: Bumper Sticker & "To Do" List

Incentive 14: Flashlight Car Key

Incentive 15: Plants

Incentive 16: Sports Bottle (2 per participant pair)

Incentive 17: Magnet Frames (2 per participant pair)

Incentive 18: Clock

Appendix A.9

Intervention Diet Sheet for Potential Participants

Eating with EASE

If you decide to join our team and are randomly (like flipping a coin) assigned to the intervention group, the following are some of the foods you will be eating, some of the foods you will be asked to avoid, and some examples of recipes you will learn to cook.

Foods You Will Be Enjoying:

- All the vegetables you like.
- All the fruits you like.
- All the grains you like (rice, bread, grits, oatmeal, etc.)
    - We encourage and will show you recipes using whole grains (brown rice, whole-wheat bread, bran, etc.)
- All the beans or peas you like (black-eyed peas, boiled peanuts, lima beans, etc.)
- All the nuts or seeds you like (almonds, cashews, sunflower seeds, etc.)
- Any type of fish you like (salmon, sardines, trout, tuna, etc.)
- Any soy product you like – This includes tofu as well as a list of meat and dairy substitutes (Soy milk, cheese, and yogurt ; Veggie hotdogs, "ground beef," sausage and bacon)

Foods You Will Be Asked to Replace:

- Foods made with poultry (chicken, turkey or other bird).
- Foods made with meat (beef, pork, or other animal).
- Foods made with dairy (cow's milk, yogurt, ice cream, etc.).
- Foods made with eggs, butter or lard.
- Cookies, cakes and other desserts you buy in the store that have hydrogenated oils (a type of fat).

Some of the Tasty Recipes You Will Learn to Make:

- Pecan Crusted Flounder
- Chocolate Brownies
- Whole-wheat Pizza
- Creamy Cole Slaw
- Ice Cream Sundaes
- Down South Cornbread
- Southern Baked Beans
- Cranberry-Walnut Waffles
- Peach Cobbler
- Plus a 70 Recipe Cookbook

Appendix A.10

University of South Carolina Public Service Announcement

Public Service Announcement

Volunteers needed for a USC, Palmetto Health study on prostate cancer

Volunteers are needed for a study that will help determine treatment options for men with prostate cancer.

The study, which is funded by the U.S. Department of Defense, seeks men who have been treated for prostate cancer and have been told that their prostate specific antigen (PSA) levels have increased.

The study will include free medical tests and surveys about eating habits, physical activity and stress. The results will help doctors and health care professionals determine how to prevent an increase in PSA levels after surgery or radiation.

The study is under the direction of the University of South Carolina's Arnold School of Public Health, in cooperation with Palmetto Health's S.C. Cancer Center and the Comprehensive Prostate Center. Researchers include Dr. James Hebert, a USC public health professor, and Dr. Sue Heiney, manager of psychosocial oncology at the S.C. Cancer Center.

For information, call Lynne Bridges at 238-1975 or 1-800-775-2287 or email, ease@palmettohealth.org.