

**Statement of Work
For
Research Study Entitled
*Garlic and the Prevention of Cancer***

Background:

The Clinical Nutrition Research Program at Weill Cornell Medical College has been involved in research on garlic and prevention of prostate, breast and colon cancer for a number of years. Early studies have shown that alliums derivatives from garlic contained in Kyolic inhibit human prostate cancer cells in cell culture and in animals bearing transplants of human prostate cancer. Two independent reports have shown that individuals within a population group consuming more garlic have lower rates of prostate cancer prevalence.

Beaufort-Jasper-Hampton Comprehensive Health Service Centers, Incorporated (BJHCHS), a section 330 designated community health center, has been participating in prostate cancer research programs since 1995. Men living in the three counties served by the eight health centers providing primary care services have been participating in the studies over the past 12 years. South Carolina has one of the highest rates of prostate cancer in African American men in the nation and the three counties included in this study reflect the severity of the disease.

The Clinical Nutrition Research Program at Weill Cornell Medical College and Beaufort-Jasper-Hampton Comprehensive Health Service Centers have agreed to work together to conduct a research study including 24 African American men.

Objectives of the Relationship:

The Clinical Nutrition Research Program at Weill Cornell Medical College will work with Beaufort-Jasper-Hampton Comprehensive Health Service Centers to conduct a study to evaluate the potential of a garlic derivative, Kyolic, on Prostate Specific Antigen (PSA) levels in African American men taking capsules with the garlic derivative for fifteen months.

The research objectives include:

- PSA (prostate specific antigen) is one indicator of the potential of prostate cancer. PSA levels can be measured by a simple blood test along with other laboratory tests from blood samples that combined with other information about the participant's family history and health history may provide some clues regarding a man's potential for prostate cancer.
- The effectiveness of garlic (selenium) in reducing the known indicators of prostate cancer as measured in laboratory tests and DRE (Digital Rectal Exam) may suggest that additional larger scale research could prove useful in defining the role of selenium (and garlic) in prostate cancer prevention.

The clinical objectives include:

- The clinical objective of this research study is to recruit 40 African American men into the study between the ages of 35-80 years of age with PSA levels between 2.0 and 8.0. For the sake of patient safety, certain health requirements are defined in the inclusion and exclusion criteria of the proposed study.
- Men enrolled in the study will be divided (randomized) into two groups – 1 group will be receiving capsules containing a known concentration of garlic. The second group will receive placebo capsules containing no garlic. They will be asked to take these capsules for 15 months. Only two people will know which men, identified only by a study number received the garlic capsules and who received the placebo capsules. No one at BJHCHS will know the randomization.
- Blood will be drawn from the participants 5 times during the study to measure the biomarkers, including PSA, through laboratory tests to measure the affect of garlic on those markers.
- In order for the study to be effective, at least 24 of the 40 men selected to participate in the study must take six capsules a day for 15 months.

Scope of Work:

Essential elements of the study include: research definition of the study; biostatistical definition and evaluation of the study; Kyolic capsules; protocols; approved consent process, IRB reviews and approvals; clinical facilities to evaluate participants, trained staff to recruit participants and evaluate patients; laboratory facilities to analyze samples defined in the protocol; a HIPPA compliant system for collecting, storing, and managing data generated by the study; funding to offset expenses incurred during the study.

When the study was initiated through the auspices of the Stang Institute for Cancer Prevention, the preliminary work for the study was completed:

- an initial research study was defined
- biostatistical perimeters were defined
- an initial budget was developed
- protocols were developed, patient consent processes were developed and approved
- IRB approval at Strang Institute for Cancer Prevention and Beaufort Memorial Hospital (under the direction of Duke University)
- Kyolic capsules were secured
- an electronic database was developed and tested
- arrangements were made with laboratory facilities for analysis
- some staff was trained in the protocol

The following work remains to complete the study:

Clinical Nutrition Research Program at Weill Cornell Medical College will:

- Provide notification of an approved current IRB review
- Provide a final approved budget for the program
- Provide financial management with the funding agencies
- Participate in a monthly conference call or video conference
- Provide a biostatistical analysis of the data collected on the men who completed the study. Provide the full analysis with Beaufort-Jasper-Hampton Comprehensive Health Service Centers, Incorporated
- With the support of Beaufort-Jasper-Hampton Comprehensive Health Service Centers, Incorporated prepare a final report on the study
- With the support of Beaufort-Jasper-Hampton Comprehensive Health Service Centers, Incorporated prepare an abstract on the study
- Identify an opportunity for publication of an article on the study with a peer review journal and with the support of Beaufort-Jasper-Hampton Comprehensive Health Service Centers, Incorporated prepare the article
- With Beaufort-Jasper-Hampton Comprehensive Health Service Centers, Incorporated, identify opportunities for poster presentations and jointly prepare the presentation

Beaufort-Jasper-Hampton Comprehensive Health Service Centers, Incorporated will:

- Train clinical staff on the purpose and protocols of the Garlic and the Prevention of Prostate Cancer study
- Manage the recruitment of men who qualify for the study
- Establish a clinical interface with men recruited into the study
- Manage the interface with the laboratory conducting the analysis defined in the protocols of the study
- Collect and store data gathered at each step of the protocol within HIPPA standards
- With the support of Clinical Nutrition Research Program at Weill Cornell Medical College prepare a final report on the study
- With the support of Clinical Nutrition Research Program at Weill Cornell Medical College, prepare an abstract on the study
- Identify an opportunity for publication of an article on the study with a peer review journal and with the support of Clinical Nutrition Research Program at Weill Cornell Medical College prepare the article
- With the assistance of Clinical Nutrition Research Program at Weill Cornell Medical College, identify opportunities for poster presentations and jointly prepare the presentation

Compensation:

Clinical Nutrition Research Program at Weill Cornell Medical College will provide \$xxxxx to Beaufort-Jasper-Hampton Comprehensive Health Service Centers, Incorporated to recruit 40 patients into the study, and provide clinical support and data management as defined in the protocol.

- Each quarter, reimbursement will be made by Weill Cornell Medical College for expenses incurred by Beaufort-Jasper-Hampton Comprehensive Health Services Inc, associated with the personnel cost of individuals managing the clinical aspects of the Garlic and Prevention of Cancer study, as well as, patient recruitment, participation, and retention, laboratory expenses, travel cost, and indirect cost. The total amount reimbursed shall not exceed the amount budgeted for each category and the entire budget amount. Reimbursement is contingent upon the timely receipt of an invoice detailing the expense by the above mentioned categories.
- A no-cost extension will be granted to complete the parameters of the study as defined in specific aims of the study and the progress towards completion of recruiting and retaining at least 20 men through the protocols defined by Beaufort-Jasper-Hampton Comprehensive Health Service Centers, Incorporated and Clinical Nutrition Research Program at Weill Cornell Medical College.