

# **ProCap Trial - A Prostate Cancer Prevention Trial**

**(Does Inflammation Reduction Decrease Prostate Cancer Risk?)**

**Date of Proposal:** January 10, 2016

**Format:** Randomized, Double blind, Placebo Controlled, Age-Matched and PSA Matched

**Trial Accrual:** 1000-2000 patients without evidence of prostate cancer will be randomly divided between the placebo and the active formula. Study will be performed at multiple Veterans Administration Clinics in Florida (actual number of entrants will depend upon a statistical analysis associated with the projected outcome that the study is powered to measure)

**Trial Entry:** Men aged 35 – 69 years old, (four decades represented).

## **Trial Qualifications:**

- No evidence of prostate cancer based on digital rectal exam
- Men with a PSA of 4 ng/ml – 9.9 ng/ml will also qualify if there is a preceding biopsy that validates a lack of cancer.
- IPSS-Index (International Prostate Symptom Score Index)
- 3T MRI

## **Trial Variables:**

1. Prostate-specific antigen (PSA) using Quest Diagnostics
2. Digital rectal exam
3. International Prostate Symptom Score Index (IPSS)
4. Biopsy specimens will be interpreted by pathologists who routinely evaluate biopsy specimens at the VA; Second opinions will be sent to Bostwick Laboratories under the auspices of David Bostwick, M.D.
5. 3T MRI

**Frequency of Office Visits:** Every six months. (Evaluate and record all variables.)

**Study Trial Endpoint:** Prostate cancer diagnosis

**Length of study trial:** 3-5 years is the anticipated time frame to reach statistical significance, albeit, 3 years is very realistic.

**Study Guideline:** In the event that men evaluated note a change in PSA (velocity change) or digital rectal findings that support suspicion for prostate cancer, a prostate biopsy will be performed following a complete consented disclosure. In the event the biopsy is negative, the patient will be returned to the previously assigned treatment arm while a diagnosis of prostate cancer will prompt immediate termination options with subsequent implementation. The entirety of the study tenets represented will be usual and customary to the protocols normally practiced by urologists in a community setting.

**Funding:** Private resources are requested, albeit, this offering presents an opportunity to “Create a legacy” through a foundation donation or business opportunity.

**Premise:** Prostate disease is the number one health risk that an adult male will face with 90 men dying daily from this menacing disease while a new case of prostate cancer is diagnosed every three minutes, according to the American Cancer Society. Based upon scientific data, it is believed that a worldwide patented prostate nutritional formula (Peenuts®) will provide a major health care benefit. Specifically, Peenuts® is expected to decrease the pool of prostate biopsy candidates based on eradication of prostatitis as a sentinel disease that many experts believe is associated with the evolution of prostate cancer, according to the American Association of Cancer Research, AACR. Improvement in prostatitis will be noted by a reduction in PSA (prostate-specific antigen), a surrogate marker for prostatitis. Therefore, it’s believed that a reduction in prostatitis (a non-bacterial inflammatory condition) will lead to a decrease in the diagnosis of prostate cancer. To reiterate, the expectation is noted for the health care system to benefit through a reduction in unnecessary prostate biopsies associated with a reduction in PSA, improved patient health anticipated with improvement in voiding abilities, a reduction or resolution of signs and symptoms associated with inflammation as well as an ultimate decrease in the incidence of prostate cancer (validated by study design).

**Background Data:** Prostate Disease is the number one health risk that men face associated with prostate enlargement (Benign Prostatitis Hyperplasia, BPH), prostatitis, (a non-bacterial inflammation of the prostate in greater than 95 percent of cases) and/or prostate cancer. All diseases of the prostate are epidemic individually and collectively. Fifty percent of 50-year old men have evidence of BPH while the signs and symptoms are the number one reason that men visit the doctor, according to McNaughton-Collins. Voiding symptoms common to BPH are also

common to prostatitis. In a clinical trial presented at the other National Institute of Health in 1999, 235 consecutive men with any level of voiding symptoms were evaluated clinically for men less than 50 years old (n= 83) while 88 percent of men 50 years old (n= 152) were noted with the disease according to the NIH Presentation, by Dr. Wheeler in 1999.

PSA (prostate-specific antigen) represents the most dominant male health disease marker associated with BPH, prostatitis, and prostate cancer. Data from Johns Hopkins, associated with the Baltimore Longitudinal Study, notes that men aged 40-60 years with a PSA reading of greater than 0.6-0.7 ng/ml have a three-four fold increased risk for prostate cancer within their subsequent 10 years when the PSA blood test primarily, costs would likely be eliminated by the resolution of prostatitis with the subsequent decrease in PSA. Prostatitis is the number one reason that PSA rises and arguably the prime culprit in why men are asked to undergo a prostate biopsy. Minimizing the impact of prostatitis would promote a quantum shift in health care expenditure to the cost savings side as the majority of the 70-80 percent of the negative biopsies could be avoided. Additionally, as prostatitis is resolved, annoying symptoms that prompt men to visit the doctor may also be eliminated.

A proposed prostate cancer prevention trial (**the ProCap Trial**) comparing a patented, synergistic blend of natural ingredients for the prostate versus a placebo in a randomized, double blind, age-matched study is expected to alter the landscape of disease understanding. Peenuts®, a prostate nutritional formula was chosen for study consideration based on its worldwide patent and effectiveness in reduction of signs and symptoms associated with prostatitis reported through clinical evaluation referencing the recently published research study entitled, **“Is it necessary to cure prostate cancer when it is possible?”** Peenuts® a synergistic blend of vitamins, minerals, herbs and amino acids is associated with anti-inflammatories, immune boosters, antioxidants, and beta sitosterols. Peenuts® has been validated previously to reduce voiding symptoms in a randomized, placebo controlled, double blind study. The study findings were statistically significant. Reasons for enhanced academic excitement is furthered by the published results of the prospective study mentioned above, evaluating the benefit of the Peenuts® formula with diet in men with known prostate cancer. At an average of 38.5 months, prostate cancer is suppressed in 87 percent of the study participants. This is a sentinel finding as it demonstrates that man can now safely live with prostate cancer similarly to living with rheumatoid arthritis, diabetes or hypertension. The overall effect on the health care budget could be monumental as 50-60 percent of men with prostate cancer have cancer characteristics (Gleason Score) similar to the men studied in this prospective trial.

The ability of nutritional ingredients to have an impact in the evolution of prostate cancer is well chronicled in the literature through the Alpha-tocopherol, Beta-carotene (ATBC-Finnish Study) and through the work of Larry Clark, Ph.D. at the University of Arizona who evaluated the benefit of Selenium on prostate cancer. Specifically, Vitamin E (50 IU) daily was noted to decrease the incidence of prostate cancer by 34 percent while Selenium (200 mcg) was noted to decrease the incidence of prostate cancer by 66 percent, respectively. Notwithstanding the

premature termination of an NCI (National Cancer Institute) study intended to evaluate the benefit

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of the aforementioned Selenium and Vitamin E in prostate cancer prevention, the Peenuts® formula works by reducing inflammation in the prostate. This data has enabled patents to be issued internationally in recognition of formula excellence.

To study further, it is felt that based on the fact that Peenuts® formula can suppress and/or stabilize all cases of prostate cancer in the prospective study, it may be possible for this formula to prevent prostate cancer. The mechanism of action with the Peenuts® formula is believed to be associated with the resolution of non-bacterial prostatitis through a decrease in cellular oxidative stress. Beyond an expected decrease in anxiety as the PSA decreases, inflammation is decreased as noted by a comparative analysis of the expressed prostatic secretion with a predictable decrease in white blood cells as well as an improvement in voiding symptoms; the expected number of doctor visits is expected to drop.

While the health care budget is strained due in part to the diagnosis and treatment of prostate cancer, the ability to prevent prostate cancer gives men and improved opportunity to extend their quality of life while saving the health care system hundreds of millions of dollars, if not, billions. Beyond the expected prevention of prostate cancer (the ultimate goal of the study), the number of biopsies requested is expected to drop precipitously with an anticipated decrease in PSA level with the Peenuts® formula when compared to placebo. Presently, in excess of 2.2 billion dollars are spent yearly on prostate biopsy with the majority of procedures performed based on an elevation of PSA only. Despite our best efforts, only 20-30 percent of biopsies yield a cancer, suggesting our current model for biopsy consideration qualifies men excessively and inappropriately. None of this is surprising when it is noted that PSA elevation is more commonly associated with inflammation than prostate cancer.

**A paradigm shift to an improved health care model for men has been proposed. This study is about ... more than altering a disease course... it is about altering or eliminating the number one health risk for every adult male while ensuring a healthy, more productive society. The only remaining challenge is to locate the financial commitment to fund the study. Finding a person(s) or organization to embrace this noble project remains difficult despite anticipated outcome that promises to tame an epidemic and foster wellness for all men.**

**Cancers Answer, LLC**

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