

## WHI MANUSCRIPT PROPOSAL GUIDELINES

To be considered for Publications and Presentation (P&P) Committee calls, which usually occur on the second and fourth Thursday of each month, manuscript proposals must be submitted by the fourth or second Friday of the month to the P&P Program Assistant at the WHI Clinical Coordinating Center. Please email proposals to [helpdesk@whi.org](mailto:helpdesk@whi.org).

- The manuscript proposal must be *no more than six pages, not including references or tables*, or it will be returned for immediate revision.
- It must conform to the manuscript template, or it will be returned for immediate revision.
- Non-WHI investigators must be sponsored by a WHI Principal Investigator (PI).
- The proposal *cannot have more than five co-authors*, including the convener, or it will be returned for immediate revision. Exceptions to this rule are noted in the [P&P Committee Policies](#). Other authors are added during the writing group nomination process.
- Multi-cohort papers—WHI requests that it be represented in proportion to the number of cases it contributes to the overall cohort.
- After reviewing the analysis process and guidelines below, please contact the Statistics Unit Manager at the CCC concerning any questions about analysis plans (email [helpdesk@whi.org](mailto:helpdesk@whi.org)).
- If the writing group will be performing their own analysis, they will be expected to download the necessary data from [www.whiops.org](http://www.whiops.org). Prior to this, a WHI Data Distribution Agreement must be signed. Ancillary study investigators must also sign an Ancillary Studies Publication Agreement form, which will be sent to the lead author after the proposal is approved by the committee.
- Prior to submission to the journal, all final manuscripts are reviewed by the P&P.

Please see [Process Schematic](#) for a more thorough explanation of the manuscript process.

## Manuscript Proposal Template

**Title:**

**Proposal authors (List names of up to 5 – strongly recommend inclusion of junior and/or biostatistical investigators):** (please include name, email, clinical center, address, fax, and phone of the lead author)

**Is the lead author new to WHI?**  Yes  No

**Does this proposal stem from your participation in the NHLBI Northwestern Workshop?**

Yes  No

**Sponsoring PI:**

**WHI Ancillary Study (AS), Core Study, and/or BAA Study number(s) (if applicable):**

**Keywords:** (include at least 5):

**Have you checked for overlap with published and in-process WHI manuscripts?**

Yes  No

**If this proposal stems from a discussion within a WHI Scientific Interest Group (SIG), please note which SIG here:**  CVD;  Physical Activity/Body Composition;  Aging: Cognition & Functional Status;  Physical & Built Environments;  Psychosocial & Behavioral Health;  Bone/Fracture & Body Composition;  Obesity & Diabetes;  Genetics, Proteomics & Biomarkers;  Health Services & Comparative Effectiveness;  Cancer;  Nutrition/Energy Balance

**Data Focus:**  OS  CT  both

**Indicate your preference for where the analysis will be performed (Indicate 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> choice):**  CCC  NE RC  SE RC  MW RC  W RC  do your own

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## *SAMPLE PROPOSAL*

*PROVIDED TO ASSIST IN THE DEVELOPMENT OF NEW PROPOSALS*

**Correlates of serum lycopene in older women  
(Example of a MS proposal with all the required elements)**

**INTRODUCTION**

Over the past decade, increasing interest has been focused on the role of antioxidant nutrients in disease prevention. The carotenoid pigments, which number over 500, are well known for their antioxidant properties. Only  $\beta$ -carotene has been studied extensively; the other major carotenoids found in the human body have garnered much less attention. Of this group, lycopene is particularly important because it comprises roughly half the total carotenoid concentration of human serum. Dietary lycopene is primarily derived from tomatoes and tomato products.

Early research found that intraperitoneally injected lycopene improved survival rates of irradiated mice (1). Interest in this nutrient was renewed following the 1989 publication by Di Mascio et al. which reported that lycopene has the greatest ability of all the common carotenoids to quench singlet oxygen, a mechanism by which protection from the damaging effects of reactive oxygen species is thought to occur (2). Recent biologic evidence suggests that lycopene is a more effective inhibitor of human endometrial, mammary, and lung cancer cell proliferation in cell culture than  $\alpha$ - or  $\beta$ -carotene (3). Although there is conflicting evidence, in some observational epidemiologic studies this nutrient has been found to be associated with a decreased risk of prostate cancer (4, 5), cervical intraepithelial neoplasia (6), stomach cancer (7), pancreatic cancer (8), and myocardial infarction (9).

Although research conducted over the past 8 years suggests that lycopene may play an important role in disease prevention, there is little information about predictors of serum lycopene. It is the only major carotenoid found to decrease with age and does not appear to be higher in women than men, as are other carotenoids (10), thus, lycopene status may be particularly important in older women. There are conflicting results regarding the relationship of serum lycopene levels to both cigarette smoking (10-12) and alcohol consumption (10, 13). As lycopene intake among African-American male health professionals was found to be substantially less than among their Caucasian counterparts (4), ethnicity may be an important determinant of serum lycopene. By investigating the factors associated with serum lycopene in a subset of older women, a better understanding of the relationship between this potentially important nutrient and certain disease processes may be gained.

## **OBJECTIVES**

1. To evaluate the relationship of serum lycopene with dietary lycopene intake, foods high in lycopene and other dietary factors as estimated by the baseline FFQ.
2. To assess the relationship of serum lycopene with lifestyle, demographic, and biochemical factors of WHI participants at baseline.

The ethnic diversity of the WHI also offers a unique opportunity to study the determinants of serum lycopene among the various ethnic groups.

## ANALYSIS PLAN

### *Statistical Analysis*

We propose to analyze baseline data from CT participants in the 6% serum subsample whose blood samples have been analyzed. Over 1500 such blood samples have been analyzed to date and include a large percentage of minority participants.

We will describe the intake and serum concentration of lycopene and the demographic characteristics of the study population (Table 1).

The relationship between serum lycopene and other factors will be assessed by Pearson correlation coefficients and multiple linear regression. Pearson correlation coefficients will be presented, adjusted for age and other covariates, if appropriate (Table 2). The results of multiple regression analysis of dietary, biochemical, demographic, and lifestyle factors on serum lycopene will be presented in Table 3. Log transformation of lycopene and other variables will be used if distributions are found to be skewed. For factors that are found to be associated with serum lycopene, e.g. lycopene intake, we will test for modification of the effect by age, ethnicity, and smoking status (current, former, or never). If any of the findings differ by these variables, the results will be stratified by these variables.

### *Pertinent variables*

1. Serum lycopene
2. Lycopene intake
3. Total caloric intake
4.  $\beta$ -carotene intake
5.  $\alpha$ -carotene intake
6. Total carotenoid intake
7. Fruit and vegetable intake
8. Fiber intake
9. Intake of specific foods high in lycopene
10. Vitamin supplement intake/use- multivitamins, vitamin C, vitamin E
11. Serum  $\beta$ -carotene
12. HDL
13. LDL
14. Triglycerides
15. HRT use
16. Age
17. Alcohol consumption
18. Cigarette smoking
19. BMI
20. Physical activity
21. Ethnicity
22. Years of education
23. Income
24. Region of the US
25. Month of blood draw



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